UNITED STATES
DEPARTMENT OF AGRICULTURE

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

Pages: 1 through 235

Place: Washington, D.C.

Date: October 31, 2000

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, N.W., Suite 600
Washington, D.C. 20005-4018
(202) 628-4888
hrc@concentric.net

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MEETING	)

Ballrooms B and C
Loew's L'Enfant Plaza
480 L'Enfant Plaza
Washington, D.C.

Tuesday,
October 31, 2000

The hearing in the above-entitled matter was convened, pursuant to notice, at 8:42 a.m.

APPEARANCES:

Attendees:

THOMAS J. BILLY, Chairman
CHERYL GREEN, Coordinator
YOLANDA LUCAS
SHEILA NOVAK
MICHAEL MAMMINGA
CAROLINE SMITH DEWAAL
DALE MORSE
TERRY BURKHARDT
DONNA RICHARDSON
JAMES DENTON
CHERYL HALL
LEE C. JAN
ROSEMARY MUCKLOW
NANCY DONLEY

GARY WEBER
COLLETTE SCHULTZ KASTER
ALICE JOHNSON
MAGDI ABADIR
KATHLEEN HANNIGAN
JUDITH RIGGINS
RONALD HICKS

APPEARANCES: (cont'd.)

Attendees:

CATHERINE WOTEKI
CAREN WILCOX
KAREN HULEBAK
MICHAEL GRASSO
CAROL TUCKER FOREMAN
CHARLES GIOGLIO
YVONNE DAVIS
JANE ROBENS
JEANNIE AXTELL
PATRICIA STOLFA
DANNY LAZENBY
JERRY GILLESPIE
JAMES LINDSAY
CAROL MOSCA
MARK MINA
FELICIA NESTER
DALE BOYLE
STAN EMLING

P R O C E E D I N G S

(8:42 a.m.)

MS. GREEN: We're about to start the meeting. I would like to take this opportunity to welcome everyone to the National Advisory Committee on Meat and Poultry Inspection meeting.

My name is Cheryl Green, and I'm coordinator of this meeting. Yolanda Lucas, sitting at the table, is assisting me. There are several agency personnel out at the registration desk, Lois Thomas, Mary Lou Brown and Judy Hall. If you have any questions or concerns, you can just go outside the door and talk to them.

The phone line to the registration desk is, and you may want to make note of this, (202) 646-4423. This number is for incoming calls only. If someone calls you, your message will be posted on the board right outside the door. Public phones are located right down the hallway, along with the restrooms.

The public is invited to make comments at the end of each day. We do ask that you sign the registration book outside the door and also sign the public comment sheet.

We would like for the committee to speak into the microphones so the transcriber can catch every word that you say, and at this time I would like to turn this meeting over to our chair, Mr. Thomas Billy, administrator of the Food Safety and Inspection Service. Mr. Billy chairs the committee, and Dr. Catherine Woteki, Undersecretary of Agriculture for Food Safety, will address the committee on current food safety issues.

Thank you.

MR. BILLY: Okay. Thank you very much. It's good to see all of the committee members again. Welcome to Washington. It's a great time of the year to be here. We've had spectacular weather, although we intend to keep you pretty busy, so I don't know if you'll have much of a chance to enjoy it.

I also would like to welcome all of the rest of you that are attending this meeting. This is a meeting of the National Advisory Committee on Meat and Poultry Inspection. This committee was established back in 1971, and it's required by both the Meat Act and the Poultry Products Inspection Acts. This committee advises the

Secretary of Agriculture with regard to important issues involving federal and state programs related to meat and poultry inspection, as well as other issues related to products, product labeling, product standards and so forth.

This committee is designed to serve as a forum for discussion of issues, important issues that are currently being addressed by the agency or the administration, and we look forward to once again getting advice from this committee on several important issues that we have jointly identified.

I think that this is an important opportunity as well because while a lot of progress has been made in terms of the initial phases of HACCP and pathogen reduction implementation under the pathogen reduction and HACCP regulation that was finalized back in 1996, there's still room for improvement. At least two of the three issue areas that we've asked the committee to consider are directly related to the next steps that we need to take in terms of further improving the value of HACCP and pathogen reduction efforts to consumers.

Specifically, the subcommittees have been asked to

look at three issues. They're in the agenda, but just to highlight them at the beginning of this meeting, the first relates to sharing recall information with state and other federal government agencies. There are several issues related to this that we want to lay out and then have the committee consider them and make their observations and recommendations.

The second issue area is what we have dubbed HACCP Phase II. Some people like that name. Others don't. The concern is that this isn't a totally new approach to what we know of or what we consider to be HACCP. Instead it's a refinement and improvement, and it's important that that be clearly communicated, but there are several issues there.

The agency is in the middle of a process to identify what it thinks needs to be focused on over the next two to three years, and through bringing this issue to this committee, as well as our plans for a public meeting, we want to have a good interchange in terms of the input from all interested parties.

And then finally, another issue related to HACCP, but also important on its own account, is the residue

control concerns in a HACCP environment. By that we mean given the changes that have been made in terms of HACCP and the role of the industry, we are now beginning the process of reconsidering how residues, pesticide residues, drug residues, all other types of residues of that type, ought to be addressed in a HACCP environment or a HACCP framework.

We will charge each of the three subcommittees under this full committee with the challenge of addressing these issues after full briefings during the day today.

This meeting is open to the public. The public is invited to provide comment. We will have a comment period later today, and if you're interested in commenting you should notify the desk outside of this room.

To kick things off, what we'd like to do is now turn the microphone over to Dr. Catherine Woteki. She is the Undersecretary for Food Safety in the Department of Agriculture, and she will address current food safety issues, as well as the status of the President's food safety initiatives, so with that I'd like to invite Dr. Woteki to take the microphone and kick off our discussions today.

MS. WOTEKI: Thank you very much, Mr. Billy. I'd

like to add my words of welcome as well to the committee and to all of those of you who are here as observers.

This is probably -- well, it is -- the last meeting that this committee is going to be meeting as it is currently constituted. As you know, the committee charter is up for renewal, as well as a review of the membership and appointments of some of the members of this committee. Some of you will be reappointed and there will be some refreshment of the membership with some new members, so all of that is currently in process, and Mr. Billy is going to talk about this committee renewal immediately after my remarks.

I did want to take the opportunity on behalf of the Secretary, Dan Glickman, to extend to all of you his thanks and appreciation for the work that you have done on this committee over the last two years. The recommendations of this committee to the Secretary have been very important as he's thought about the agenda of work in food safety.

They've been very important to me also, so I have very much appreciated the opportunity to participate in the meetings of this committee, and I have also very much

appreciated your written recommendations as they have been crafted by you in such a very thoughtful way in your work as members of this committee.

Your advice and recommendations then have been important to the Secretary, to myself, as well as to the agency, and I think many of the initiatives that FSIS has undertaken over the last couple of years do reflect the discussions and the recommendations of this committee.

One example of the work that you have done that I think is really going to set a good example for the future is the work that you did on developing the concept paper for the interstate shipment of state inspected product. I hasten to note that while it may not have been passed into law, the committee established a very good process that can be used again in the future for legislative initiative, and in fact that process is being used right now by the committee as you're examining the whole question of amenable species, so that is a topic that is on the agenda later on for discussion by the committee.

I'd like to point out also that as you developed in working with FSIS in the development of the concept paper

on interstate shipment, you helped to identify a number of very important issues of concern, and the concept paper changed over time to reflect those issues of concern.

One of the examples that I frequently point to when I talk to other groups about the type of advice that we get from this committee, as well as from the Micro Committee, is to point out that this committee was very insistent that salmonella testing remain a responsibility of FSIS in order to insure consistency across the country and that the bill as it was drafted by the Administration did reflect that recommendation from this committee.

Now, as you're approaching a renewal on the part of the membership of the committee, I want all of you to understand that there will be no dearth of issues for that new renewed committee to take up in coming weeks and months. As Tom Billy said in his opening remarks, there is a considerable amount of room for improvement, and that's clearly a role that is an important one to consider, for the new committee to consider. What are those rooms for improvement?

The agenda for today's meeting reflects the fact

that the industry and the agency achieved a very significant milestone just this year with the completion of the implementation phase of HACCP. This process, from my perspective, has been very successful, and I refer to three measures of success, the three things that I've been watching over the last three years, as industry and the agency have moved forward in that implementation.

The first measure has been pathogen reduction, and the data coming from the salmonella performance tests with respect to prevalence of pathogen in products is one measure of pathogen reduction. It's been, as you know, in the range of 25 to 50 percent, depending on the product.

A second measure of pathogen reduction are the data that the Centers for Disease Control have been collecting on food borne illnesses, and CDC has attributed some of the declines in food borne illness to the implementation of HACCP.

The second measure of success that I've been following has been industry compliance, and we've seen at each stage of implementation of HACCP the large, small and very small plants over the last three years, that there has

been a very, very high level of industry compliance, well over 90 percent in each of those three stages.

The third measure of success that I've been following has been the effect of HACCP implementation on the structure of the industry, and there has been an enormous amount of concern about concentration in agriculture and in the food industry, and in this case there was also an enormous amount of concern about HACCP implementation and its effects particularly on the small and the very small plants.

I was very pleased to see that there were very, very few closings that were attributable to HACCP implementation, so the overall effect on the structure of the industry has been so minute as to be not really something worth comment.

Both I think the industry and the Food Safety and Inspection Service deserve considerable credit for this success, and despite having reached this very significant milestone of HACCP implementation clearly the job isn't done. HACCP was never intended to be static, and FSIS certainly realizes that there are many aspects of HACCP that

require review, evaluation, improvement and refinement. The Secretary and the agency will need help from this committee as FSIS considers the next steps for HACCP, and, as Tom commented, that is being talked about under the name HACCP Phase II.

In addition, HACCP implementation did not extend into all aspects of plant operations, and there clearly remains a considerable agenda of work to be done to extend HACCP to the slaughter line with the approach that the agency has taken of experimentation through the models project.

FSIS is working towards mandatory HACCP for egg products as well as another indicator of further work to be done, so there's a very large agenda of topics for which we will be seeking advice from this committee, as well as from the National Advisory Committee on Microbiological Criteria for Foods.

Now, I'd also like to note that there have been some very significant challenges to HACCP implementation and to its extension into slaughter operations. I'm referring to the legal challenges presented to the agency's

enforcement of the salmonella performance standard and to the models project, and today's agenda is actually designed to provide you with some briefings on both of these topics.

I'd like to say that I really can't close without mentioning the activities of the President's Council on Food Safety. At the last couple of meetings of this committee, I've provided you with updates and fairly substantive discussions of what was underway within the Council, particularly as it related to the work on strategic planning. Unfortunately, I don't really have much to report this morning on this topic other than to say that the strategic plan is under review.

As you will recall, there were three parts or there are three parts to the strategic plan. One is a five-year plan of work that includes and cuts across all of the federal agencies with responsibilities in food safety and considerably focuses as well on strengthening those working relationships with states.

The second part of the plan deals with organizational structures for food safety within the federal government, and the third part of the plan focuses on need

for legislative change. These last two areas are the ones that are clearly very controversial. As a result, the process of approval hasn't moved as rapidly as I might have hoped when I spoke with you last, but I remain very optimistic that there will be a report that will be issued in the next several months.

As always, I look forward to the discussions of this committee. There will be several presentations that are going to provide you with more background, in addition to the written materials that you've received for review, and I also want to give you in advance my apologies. I'm going to have to leave at noon time today. There are several members of the European Parliament who are in town with which I will be meeting this afternoon to talk about food safety, but I'll be able to return late this afternoon to rejoin the meeting.

Once again, my thanks for all of the hard work that this committee has done over the last two years, and I would at this point return the speaker's responsibility over to Tom Billy, who's going to do a brief review on the meeting agenda and then also, as I had indicated earlier,

talk about the committee renewal and where that stands.

MR. BILLY: Are there any questions from the committee regarding Cathy's comments or any other questions you'd like to ask Cathy while she's here?

Yes, Rosemary?

MS. MUCKLOW: Do you have any data or how can you back up the statement that there were very few closings attributed to HACCP? Could you tell us how you came to that conclusion?

MS. WOTEKI: Certainly, Rosemary. As HACCP implementation began, one of the things that I asked the agency to do was to collect information on plants that were closing and particularly for the small and the very small plants, so there was a system set up to maintain data on the reasons that plant owners gave for closing, so there is a very good set of data to substantiate it.

MS. MUCKLOW: Is that data available?

MS. WOTEKI: Uh-huh.

MS. MUCKLOW: Could we be provided with it?

MS. WOTEKI: Certainly.

MS. MUCKLOW: Thank you.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: Thank you. Caroline Smith DeWaal, Center for Science in the Public Interest. Thank you for your remarks this morning, Dr. Woteki.

I'm excited that we're talking about HACCP Phase II, but I'm still stuck back at HACCP Phase I and particularly the fact that a year ago almost exactly I criticized the Department for the fact that we still don't have salmonella testing going on for the turkey industry.

We're approaching the time of year again when a lot of turkeys are being produced and a lot of consumers will be buying and eating turkeys as part of their holiday festivities. Where is the Department of that?

You know, at the time that the HACCP rule was implemented we were promised that there were a few species that you didn't have salmonella criteria or salmonella performance standards and testing in place, but you promised that would be done quickly. It was really quite -- you just needed the baseline data. That's all been done. We've had baseline data for a couple of years. Why no standards? Why no testing in the turkey industry?

MS. WOTEKI: Caroline, as I had indicated, there are certainly some areas of HACCP implementation where there's more work that needs to be done, and you've pointed out one case in point.

Tom, do you want to add this to the agenda, or do you want to make a comment about the status of implementation right now?

MR. BILLY: First, perhaps I could call on Judy Riggins to provide us more specific information in terms of where we stand on any rule making in this area.

MS. RIGGINS: My current knowledge is that we are working to develop the construct for the salmonella performance standard. Dan Englejohn's group is working on that. It is in the queue. It is something that we are actively putting resources to.

I can find out, you know, a better reading of when we might be moving toward an actual written document, but I know that we are working with Kay Watson at the Office of Science and Public Health to establish the basis for the -- to actually lay out the framework, you know in the document, so I will find out the status of the ongoing work and give

you a report later on this afternoon.

MR. BILLY: Okay. Are there other questions or comments? Katie?

MS. HANNIGAN: With the upcoming Presidential election, regardless of who wins that do you anticipate the President's Council, their agenda, their itinerary, will change significantly, or do you think it will stay on course regardless of who is elected?

MS. WOTEKI: Well, I think it's worthwhile to point out that the President's Council is established by Executive Order, so the President's Council itself will remain in effect until that Executive Order is changed, so our anticipation is that there will be a President's Council.

With respect to the work that has gone on so far, I think in particular the strategic plan, that process, because of the involvement, the enormous public involvement and the very active participation of the states, that there are within the strategic plan the directions that need to be taken to strengthen the food safety system regardless of who the new President will be and what the new Administration

will be, so I think that the strategic plan is going to live on, and certainly very large parts of it are going to continue to provide an agenda for the food safety agencies at the federal and the state levels.

MR. BILLY: And I'd like to add to that and use an example. Sitting from my perspective as administrator of one of the regulatory agencies, I found that Council invaluable in terms of opening the door for a process that allowed us to develop an integrated egg safety plan for a product category where jurisdiction is divided up among a number of agencies.

As a result of that Council and the process that it represents, I think we were able to come up with a very innovative and I believe we'll find a very effective strategy for dealing with the food safety issues related to shell eggs and egg products, so I'm sure that example and other examples will be considered by a new Administration in terms of the value that can be derived from having such a Council to integrate the food safety activities of the federal government.

MS. WOTEKI: Another footnote to that is the

agenda for today's meeting reflects a number of the ideas and important concepts that are in the strategic plan. The sharing of information with state and other federal government agencies is very important to how agencies can work together at the federal level, as well as exchanging information with states when there are outbreaks of food borne disease. That's part of the strategic plan.

Also, the closer coordination of development of research priorities with the research agencies is also an integral part of the strategic plan. The first of the goals relates to the scientific basis for food safety, as well as risk assessment, and the Joint Institute for Food Safety Research is part of the work of the Council, so your agenda reflects already key aspects of what is in the strategic plan and has for a while.

MS. WILCOX: I'd just like to point out also that --

MS. WOTEKI: Identify yourself.

MS. WILCOX: Caren Wilcox, Deputy Undersecretary. That food safety has really become a worldwide discussion and effort, and regardless of the election here our

President discusses food safety at the G-8 every year now.

It's not possible to sort of go back in terms of discussions, certainly not internationally, so I think that, you know, there's a constant discussion of building food safety systems at a national level, and we're communicating with other governments constantly about their efforts that they're interested in.

We're going to do that today at lunch, so this is an issue that has grown in interest worldwide, and it will continue that way.

MR. BILLY: Okay. Well, thank you. Thank you very much.

I would now like to call everyone's attention to the agenda. It has some comments on the agenda. First off, we've attempted to follow the same basic format that we've used in the committee for the past several meetings, so in that sense it ought to look familiar to you. However, we've also made an attempt to bring more focus to the key issues for discussion and to limit the agenda so that we're not loading too much on the committee.

It's more important, we believe, and you have

certainly stressed this desire, to have ample time to discuss the key issues that you've been asked to focus on, to have the information in advance and then to be able to play your valuable role of giving advice to the Secretary in these important areas.

If you look specifically at the agenda, after this opening period we will have briefings as usual to provide updates in terms of the National Advisory Committee on Microbiological Criteria for Foods. We also are providing at this time an update on the antimicrobial resistance task force. This is an interagency task force in the federal government.

Then we're going to provide an update on the dioxin working group, which is another important food safety issue that is coming to the fore once again, and then finally we're going to start into the more specific issue discussions and focus on the HACCP based inspection models project, then the recall information sharing area and then HACCP Phase II.

To finish up today, we will then shift and provide some additional briefings, some of which were requested by

the committee, particularly provide you some important information about the new Joint Institute for Food Safety Research and then focus on an important research area that is the research going on with regard to Campylobachter jejuni.

At the end of the day we will open the mike for public comment, and once again if the public is interested in providing comment you are encouraged to notify the desk outside the room.

Then this evening, as always, we keep the committee's nose to the grindstone. We will have three subcommittee meetings, one on each of the three areas, and if you have any question about which subcommittee you're part of you can look in your briefing book. I believe it's under Tab 4.

FEMALE VOICE: Three.

MR. BILLY: Tab 3?

FEMALE VOICE: Tab 3.

MR. BILLY: Tab 3. Again, you're welcome to if you finish your work early in one of the subcommittees, you're encouraged to if you still have the energy to go over

to one of the subcommittees and provide input as well.

Looking to tomorrow then, we will focus on hearing reports out of the subcommittees. This is an important part of our process because the subcommittees meet simultaneously so it is important that the full committee have an opportunity to hear the results or recommendations of the subcommittee work and to have that full committee discussion on each of these items and focus in particular on the recommendations that are developed by the subcommittee for endorsement by the full committee.

We then will follow up with a couple more briefings. One agenda item that's been on our agenda for the past couple of meetings, this is extending the USDA's inspection program to the non-amenable and exotic species, and there are some new developments in this area that are a result of our Appropriations Act that was just signed by the President, and then another briefing in terms of our approach to the area of other consumer protections. What that refers to is the non-food safety consumer protection activities that are part of the meat and poultry Acts and are part of our inspection activities.

Then we'll have another opportunity for public comment and input and then wrap up this meeting of the Advisory Committee.

Are there any questions regarding the agenda? Yes, Lee?

MR. JAN: Mr. Billy, if I remember from last meeting we asked that FDA be invited to talk about their position on the nitrite/nitrate issue and non-amenable species, particularly if their views or how their views have changed following the Toxicology Committee report.

MR. BILLY: Yes.

MR. JAN: I wonder if there's a reason why they're not on the agenda?

MR. BILLY: Well, we actually have made an arrangement for that, and during Robert Post's briefing Dr. George Pauley from the Food and Drug Administration will present FDA's current thinking on the area of nitrite and nitrate as it relates to non-amenable species.

MR. JAN: Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: I'd just like to say, and I think

several people may echo the thought, these are better digs than you've taken us to before. We like it a lot.

MR. BILLY: I don't see anything dangerous above your head, so that is an improvement. All I can say is they must have lowered their prices. Thank you.

Any other comments? Okay.

Let me talk very briefly about committee renewal, where that stands. The committee's charter expires on March 21, 2001, so we are currently at the stage of submitting the charter to the Department for review and renewal or approval. This is a formal process that occurs with committees of this type. The charter is currently in review at the Department, and we expect that that will be completed on a timely basis to renew the committee before it expires.

In a similar manner, we started this past summer to request nominees for the committee, as well as to determine which of you currently on the committee are interested in serving another term. We got a lot of interest in this committee. Many, many people submitted their names or others submitted their names on their behalf.

We've completed the process of identifying a potential roster for the renewed committee. That, too, has been sent forward to the Department, and our expectation is that the new members of the committee will be known sometime in the new year, obviously prior to the expiration date.

So that process is underway. It's complicated a little in the context that there is a Presidential election this year and there will be a change of Administration, but this is such an important committee to the agency and the Department that I expect that we will see this move forward and be completed on a timely basis.

Are there any questions about the renewal process? No? Okay.

Then I'd like to move on, and the last item under Opening Session is an update on the Supreme Beef case. To provide you this update, we have invited Sheila Novak. She is the staff attorney in the Office of General Counsel at the Department that has been extensively involved in this case, and she will provide you an update in terms of the status of the case at this time.

Sheila?

MS. NOVAK: Good morning, everyone. As I'm sure you are all aware, in early September USDA filed a notice of appeal with the Court of Appeals for the Fifth Circuit. We also filed at that time a motion requesting that the appeal be heard on an expedited basis.

On September 27, Supreme filed a petition for Chapter 11 bankruptcy in the Eastern District of Texas. On the same date, they also filed a document which they called Appellee's Suggestion of Bankruptcy with the Court of Appeals for the Fifth Circuit.

The following day the Court of Appeals entered a stay of the proceeding. Under the bankruptcy laws, this is done pretty automatically. There are provisions for an automatic stay of any judicial, administrative or other proceeding against a debtor, and the stays are designed to maintain a financial status quo of the debtor pending the bankruptcy petition.

Actions involving exercise of police or regulatory power are excepted as a matter of law from the automatic stay provisions, so we don't believe that this is the type of action that should have been subjected to an automatic

stay.

The following day, on September 29, Supreme ceased operations at both its Ladonia, Texas, slaughter establishment and its Dallas, Texas, processing plant, so the status of the case as it stands right now is that the stay has been entered, and it will continue to be stayed until the government files a motion requesting that the stay be lifted and there is a decision on that motion. We're discussing at the current time, you know, our future strategy in this case with our colleagues at the Department of Justice.

Are there any questions?

MR. BILLY: Rosemary?

MS. MUCKLOW: I was curious. When the decision was announced, and I don't remember the exact date, from the District Court, and I think it was in May or maybe June, the Secretary spoke about the need to move very quickly on the case, yet the government took a full four months and on the very last day of the four months filed an appeal.

I didn't quite understand the extreme expressions of concern by the government and then this long delay before

the government filed its appeal and then followed the appeal with a request for an expedited hearing.

Maybe you could explain the four months and how that all happened.

MS. NOVAK: Yes. Well, there is a process that we have to go through in any case to request an appeal. It has to happen at the Department level, and it has to happen at the Department of Justice level.

As you can well imagine, there was a lot of discussion about this particular case and so that worked its way through the process, and we did file the notice of appeal. The Justice Department does not believe that filing on the last day would in any way impact the motion for expedited appeal.

MR. BILLY: Cathy, would you like to add to this?

MS. WOTEKI: Well, I think Sheila really did a very good job in explaining what the situation was. Certainly the Secretary's expression of his level of concern did reflect our position throughout, and, as Sheila indicated, though, it is not a simple process to reach and put together an appeal, and we very carefully constructed

that so I think you did a good job in responding.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: Caroline Smith DeWaal, CSPI. Tom, perhaps you might be the person best suited to answer this. What is the status of the sampling program for salmonella in the Northern District of Texas or the district where the District Court ruling came out?

MR. BILLY: Okay. The status is the same as the status anywhere else in the United States. We are continuing to take samples, sample sets from plants throughout the country, and are encouraging, you know, the industry to comply with the performance standards as they're contained in the regulation.

The process that we are following has been amended somewhat in that our current policy is that once a plant has failed its second salmonella sample set that triggers an in-depth review by the agency. This committee has been briefed on in-depth reviews and what they're about and the format for them.

We think that's an important step and a shift in our approach in that it allows both us and the plant to look

very thoroughly at any problems that might exist in the HACCP plan and the critical control points and critical limits and the other issues that may be contributing to why we are seeing those outcomes in terms of the sampling of the salmonella.

This policy has been in effect now for some months, and we think it will provide a basis to allow plants to make appropriate decisions that will bring different results hopefully in terms of a third sample set that is inevitable once there's a second sample set failure. I think that's a change that we made, but, nonetheless, what I said at the outset. We continue to collect samples throughout the country and are following the regulation as it's written.

MS. SMITH DEWAAL: Just a follow up, if you don't mind. You used a word that concerns me, and that is we're encouraging plants --

MR. BILLY: Uh-huh.

MS. SMITH DEWAAL: -- to comply with the regulation. I mean, there were allegations, and I don't know if the Department published anything on this, but that

Supreme Beef failed the fourth set of salmonella tests after -- while it was still operating. I don't know whether it was before or after the District Court decision. That to me indicates a real continuing gap in food safety protections.

Are gaps like that occurring today? Is that a one in a -- you know, was that a one time situation, or do we have an ongoing problem with the salmonella performance standard not being fully enforced and plants repeatedly failing sampling sets?

MR. BILLY: The current picture is that there are three plants nationwide to date that have failed three salmonella sample sets. In only one of those three instances did a plant fail a fourth sample set after the plant had made necessary and appropriate changes to their HACCP plan and control measures. The other two plants passed the fourth set without any problem whatsoever, and I'm sure that's attributable to the adjustments and changes that they made to their operations.

So we do not have any gap, and, you know, as we continue to take samples with the policy change I described earlier I think that we'll see less of an opportunity or

likelihood that we'll see that kind of situation reoccur. I think we have a better strategy and approach at this time.

Nancy, and then Rosemary?

MS. DONLEY: Thank you. Nancy Donley from STOP, Safe Tables Our Priority.

Kind of following on Caroline's question, can you tell us how many other plants within this district are currently undergoing salmonella sampling sets? Are there any?

MR. BILLY: We can pull out that information. I don't have that, but, as I said, we're continuing to sample plants using a random strategy, and I'm sure there are some plants in that area that are subject to the sampling regime, but we can pull that information --

MS. DONLEY: I'd be interested in knowing that.

MR. BILLY: -- together and provide it to the committee.

MS. DONLEY: Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: I think it was a year ago this week that we were presented with the in-depth review concept.

MR. BILLY: Uh-huh.

MS. MUCKLOW: One of the concerns that I expressed at that time was that you would be likely taking enforcement action, and it would not be appropriate to take enforcement action on documents that were all stamped with the word Draft.

Do we now have final documents describing the in-depth review process that are published documents now that it's a year later?

MR. BILLY: Yes. I'm going to defer to Judy Riggins in a moment, but the fact is, Rosemary, that we don't take regulatory action based on a protocol. We take regulatory action based on a failure to comply with regulations.

We did, as you said, about a year ago present a draft protocol for these in-depth reviews. At the same time, we indicated that we wanted to carry out a number of additional in-depth reviews in a variety of plants to get more experience with the protocol and make sure that it was working effectively to achieve its intended purpose.

With that, let me defer to Judy to give us an

update on the status of the in-depth review process.

MS. RIGGINS: Based on the experience that we've had over the last year, we have updated and currently have in a second draft, or I guess it's actually a third draft --

MS. MUCKLOW: I'm sorry. I can't hear you.

MS. RIGGINS: A third draft, which incorporates information that we have learned as a result of the in-depth reviews that we've conducted.

We can make that document available as soon as we get it through clearance in the agency, but keep in mind that we have said that the in-depth review document itself is going to be one that we will revise as we learn about better ways to conduct the in-depth reviews. We are learning from our experience.

We have not had any enforcement actions that were the result of in-depth reviews. What we have done is in those instances where the in-depth review report has been provided to a company and we've issued a letter asking them to please review the in-depth report and to come back to us within 30 days, and we've had very good experiences thus far. We've sat down with the companies, had phone

conferences and discussed the issues that were in the in-depth review, clarifying any questions that they might have.

That is the way that we've conducted, to my knowledge, all of the in-depth review follow ups.

MS. MUCKLOW: So can I be clear? You've now got a third draft, but it's not publicly available. When will it be publicly available?

MS. RIGGINS: We can make it available as soon as we get clearance. I believe it's in Tom's queue at this point, but it is a living document. I hate that word, but it's a living document. We are updating it and sharing with -- and will be sharing with you what we've learned in that document as we acquire that knowledge.

Keep in mind that this is not the final -- it won't be the final final because as we learn more we will update the document. That was the purpose of having something in writing was to improve it over time.

MR. BILLY: That's fine. One other point. We are talking about HACCP Phase II, and as part of that process, which we'll talk more about shortly, it is our intent to

hold a public meeting probably sometime in December on this subject area, and it is our intent to use -- make available and use -- that public meeting as an opportunity for public discussion regarding the current version of the in-depth review, as well as a lot of other tools and strategies that we're trying to develop currently to identify our approach as we move forward.

I think we're on the same course that we indicated earlier, and there will be further opportunity for input on this particular tool that we have available.

MS. MUCKLOW: Could I just --

MR. BILLY: Yes?

MS. MUCKLOW: -- make one final comment? Dr. Woteki referred earlier to why is concentrating occurring and is any of it attributable to HACCP implementation. One of the reasons that concentration in the meat and poultry industry is occurring is because of regulatory uncertainty. Regulatory uncertainty occurs when people don't know what to expect.

People want to know what the rules are so that they can meet and comply with the rules, but it is

constantly a moving target and something that is nebulous and without firm, clear understanding. It is very concerning, particularly to very small plants, and we have a lot of small plants. Those are the people that were most concerned about concentration because concentration occurs when the plant continues, but is owned by somebody larger who has just bought them up because they couldn't face that regulatory uncertainty any longer.

When several FSIS officials, most of them with degrees and who come from Washington or Omaha or whatever, arrive on your doorstep to conduct an in-depth review it scares the bejeebers out of people, and that is the atmosphere of regulatory uncertainty with those people. Why should I have to do this? You know, let's sell out to one of the big guys and let them take the ticket for this.

I would encourage you most strongly to be very forthright and clear with the working documents that you're working from. If you've got people out there conducting your review on a certain protocol I think it's very appropriate and important that the inspected industry know that expectation so that they know what to expect and have

to beat.

MR. BILLY: Okay. Just one brief comment, and then I want to call on Caroline.

Rosemary, I don't think there's anything nebulous at all about our HACCP and pathogen reduction rule.

MS. MUCKLOW: I'm talking about in-depth reviews.

MR. BILLY: I understand what you're talking about. What the review is is a process to determine compliance with that regulation. A plant that has established the HACCP plan and other procedures to address the requirements in that regulation has nothing to fear in terms of in-depth review.

When plants get into problems, and most often now we're doing in-depth reviews because of failures of the HACCP system, we think it's appropriate that we establish a protocol for ourselves. I certainly agree with you that it is important that we inform everyone of the procedures that we're following. As I already indicated, it is our intent to continue to do that as we have already done here at this committee and in other venues.

I think this is an important area. It is an

important tool that we will continue to us as we move forward, and we intend to follow the strategy that I indicated earlier.

Caroline?

MS. SMITH DEWAAL: Thank you, Tom. Caroline Smith DeWaal, CSPI.

I am just struck by the fact that this in-depth review following on the second round of test failures is a little bit like hand holding by the government. You're walking into a plant. They've had a failure. You're looking around. You're saying well, maybe you could do this better or that better. In a way I thought the whole effort towards HACCP was to move away from that hand holding.

The one thing I would ask is that the third set of salmonella tests not be delayed as a result of this in-depth verification review. We, as in the public, were under protected by this agency in the Supreme Beef situation when the plant had failed two tests, rounds of tests. They failed them badly, and they were still selling meat to the school lunch program.

The public expects better protection than that, so

I think, you know, the agency drafted a regulation that allows three strikes and you're out, and that system is I think extraordinarily lenient to the industry and the companies that are failing that test, so I think, you know, the agency can do the in-depth verification. That's probably a good regulatory choice, but it shouldn't delay by one day the commencement of the third set of tests.

Another question. When you said there was one plant that had failed four sets, and I mentioned that we had heard that Supreme may have failed the fourth round of tests, perhaps you could just tell me if that plant is currently operating?

MR. BILLY: Yes. That was in fact the Supreme processing plant in Dallas, Texas, that failed the fourth sample set.

MS. SMITH DEWAAL: Okay. Thank you.

MR. BILLY: I'm going to move on to the next part of the agenda. I'd like to thank Sheila for her update.

The next item on the agenda focuses on a number of important areas that interface with the Food Safety and Inspection Service in various ways. There are three update

subject areas. Dr. Karen Hulebak, our senior scientist, will be providing these updates. We're going to allocate about a half hour, so that's ten minutes per topic. I'm working hard this time to keep us on schedule.

At this time it's my pleasure to turn the mike over to Karen.

MS. HULEBAK: Thank you, Mr. Billy, and good morning to all of you. My first topic for the 30 minutes I've been allocated and that I will try to surprise you by taking less of is an update from the National Advisory Committee on Microbiological Criteria for Foods.

My first order of business is to introduce to you the new permanent executive secretary for the Micro Advisory Committee sitting to my right, Dr. Carol Mosca. Carol came on board about three months ago. That's about right. She has a Ph.D. in Toxicology and Pharmacology from George Washington University. She comes to FSIS after six years directing the program of study in toxicology and risk assessment at the National Academy of Sciences, so she brings to this committee expertise in risk assessment, which is a subject that is coming increasingly to the attention of

the Micro Advisory Committee.

Of course, through her extensive experience in directing that program at the Academy she brings intensive and extensive experience managing committees of very high powered experts, so we're very, very pleased to have her here. Prior to being at the National Academy of Sciences, she was for some years directing programs in toxicology and risk assessment in the private sector.

Now, since the last time this committee met, the National Advisory Committee on Micro Criteria for Foods has not had a meeting. We had planned a meeting for the summertime that was canceled as a result of the fact that one of the major subjects for discussion at that meeting, which was the risk assessment being conducted by FDA on listeria in conjunction with FSIS, wasn't quite ready as it happened for discussion at the Advisory Committee. Because that was to be a major focus of that meeting's discussion, we decided to delay the meeting.

The other event that has been -- we've been working through on the Micro Committee is the rechartering of that committee. That committee's charter expired at the

end of September, and the committee's charter, a new charter, has been developed and signed.

We are also well underway in the process of reappointing the Micro Advisory Committee, and that process is -- we are now dealing with language that has been put in the agricultural appropriations bill, now law -- well, yes, now law; just now law -- that is causing us to have a look at how we are proceeding with reappointing that committee

The language in our appropriations law now causes us to look at the membership of the Micro Committee as it compares with other federal advisory committees at FDA and EPA and other federal agencies and so we are looking at the slate that we had under development in view of this language that's in our appropriations.

We had planned to have a next meeting late this fall, and we're considering whether we could possibly meet that target. It seems, frankly, unlikely at this point.

Are there any questions on the Micro Advisory Committee? Otherwise I'll move to the two more substantive update news items for you.

MR. BILLY: Rosemary?

MS. MUCKLOW: Yes. Is it fair to say -- this is Rosemary Mucklow. Is it fair to say that you're probably not going to have a meeting of that committee until next year now?

MS. HULEBAK: It seems very unlikely.

MS. MUCKLOW: Yes. Okay.

MR. BILLY: I think it's more than fair. It's a definite.

MS. HANNIGAN: And hopefully, Karen, they pick up where they left off as far as the things that this committee sent to them.

MS. HULEBAK: That committee has a number of things on its agenda, some of which have been forwarded by this committee. There are, of course, the listeria issue that FDA needs to bring to the committee and questions related to that that we need to bring to the committee will be in the queue as well.

MS. MUCKLOW: Rosemary Mucklow again. When did the committee actually last meet?

MS. HULEBAK: It met in December.

MS. MUCKLOW: December of 1999?

MS. HULEBAK: 1999, correct.

MS. MUCKLOW: How frequently is it supposed to meet?

MS. HULEBAK: Well, it meets I believe the charter says at least twice.

MS. MUCKLOW: A year.

MS. HULEBAK: Uh-huh.

MS. MUCKLOW: So it may go through the year 2000 without meeting at all then?

MS. HULEBAK: I don't know if that's fiscal year or calendar year. I mean, it will have met one time in that fiscal year.

MR. BILLY: Okay.

MS. HULEBAK: Okay. Next I think on the agenda is an update on the task force on which I have served for the last year and a half as the member for the Department, a task force co-chaired by three Public Health Service agencies, the Food and Drug Administration, the Centers for Disease Control and the National Institutes of Health.

The task force is developing an action plan to combat antimicrobial resistance. The task force is made up

of eight or nine different agencies ranging from those that I mentioned through Health Finance and Services Administration of the Public Health Service, the Department of Defense.

This task force is looking at the issue of antimicrobial resistance in a way that's been unusual for large, high profile task forces in this country or internationally. It has looked at the issue of antimicrobial resistance across the board. It's recognized that antimicrobial resistance is a problem to which many sectors of society contribute, and it recognizes that the practice of human medicine, the practice of human medicine by physicians and the behavior of patients in use, misuse and abuse of antibiotics plays a role in development of resistance to microbes that infect human beings.

It also recognizes that the animal production sector of the economy also has a role to play in the development of resistance and in the combating of the development of resistance. The action plan acknowledges those multiple factors in development of resistance and lays out I believe there are close to 90 action items that are

designed through coordinated federal action and in some cases state action, coordinated action, to tackle all these numerous factors that contribute to development of resistance.

Now, clearly a key factor in the success of this action plan is going to be funding of a number of these activities, but we've developed I think a very comprehensive action plan that is in its final stages of approval. Our hope, the task force's hope, is to have that plan be final before the end of the calendar year. I think we are well on our way to doing that. We're at the stage of final review and approval by all of the agencies and departments that have contributed to developing this plan.

The plan, by the way, has focused on only one aspect of this problem, domestic issues. We recognize that this is clearly a global issue. Everybody contributes. Everybody has a part to play in answering these problems. The task force's plan is to undertake a second activity in the coming year to address global issues having to do with resistance.

Now, any questions on that point? Yes?

MR. BILLY: Caroline?

MS. SMITH DEWAAL: Caroline Smith DeWaal. Thank you for that update, Karen.

That's very exciting. It's exciting that all the agencies are getting together and grappling with that problem at that scale because there are both important human use implications, but also a huge percent of antibiotics are actually used in the animal production sector, and we need to analyze ways to assure that that use doesn't result in increased risk to the public from antibiotic resistant bacteria.

Can you give us any information on the flora quinoline, the change in flora quinoline uses that was suggested in the *Washington Post* on Friday? Apparently there is a Federal Register notice that FDA is reversing its position on the use of flora quinolines in I believe it was poultry. Can you fill in any of the gaps on this? It is a very exciting development.

You know, CSPI for one thought that the original approval was wrong, given the importance of that particular antibiotic to the human population; that it's approval for

animal use was incorrect, so it's exciting to see that they're changing their mind, but can you fill in any of the gaps on that?

MR. BILLY: Yes. I think Dr. Woteki would like to take a shot at that.

MS. WOTEKI: Yes. I have some information that was actually provided by the Center for Veterinary Medicine at FDA, so I'll provide you very briefly with that information.

What FDA is proposing to do is to withdraw the approval of the new animal drug applications that were issued in 1995 and 1996 for the use of flora quinolines in poultry. According to the FDA regulations, the process that they have used is to issue a notice of opportunity for a hearing on that proposal.

They are basing their decision on three determinations. The first is that the use of flora quinolines in poultry causes the development of flora quinoline resistant Campylobachter, which is a pathogen to humans, but it causes the development of that resistance in Campylobachter in poultry.

The second point is that this flora quinoline resistant Campylobachter are then transferred to humans and are a significant cause of the development of flora quinoline resistant Campylobachter infections in humans.

The third basis for the action is that flora quinoline resistant Campylobachter infections are a hazard to human health, so that's essentially the basis of the decision and the process that FDA is following under its regulations.

MR. BILLY: Okay. Do you want to add anything to that?

MS. HULEBAK: I'll just add that the actions that Dr. Woteki have described have been ones that are essentially part of what FDA has called the framework document that is referenced in the action plan and essentially rated and encouraged by the action plan.

MR. BILLY: Okay. Katie, and then Cheryl?

MS. HANNIGAN: I have a question about your you said 90 bullet points or thereabouts.

MS. HULEBAK: Uh-huh.

MS. HANNIGAN: I'm wondering if the committee has

ranked them with near term and long term initiatives, et cetera, and if the action plan is like one year completion, two year completion. Just maybe a little bit more there if you could.

MS. HULEBAK: The task force has identified approximately a dozen high priority action items and has for all of the 80 to 90 action items identified whether activity is ongoing, whether it is likely to be undertaken within one to two years or within three to five years.

It also identifies which agencies or departments coordinate that activity or ought to coordinate that activity and which agencies in addition are collaborators with the coordinators.

MR. BILLY: Okay. Cheryl?

MS. HALL: Cheryl Hall. This sounds like a very detailed and comprehensive study that's been done on Campylobachter and the resistance to flora quinolines. Could you tell me when it was completed?

MS. HULEBAK: This was all part of the FDA's Center for Veterinary Medicine review process, and I would refer you to them for further details about the background

documentation that they had used in the development of that decision.

MS. HALL: And have all the scientific reviews on this been done? Do you know?

MS. HULEBAK: Pardon?

MS. HALL: Have all the scientific reviews on this information been done? In other words, is this a detailed study that has been completed?

MS. HULEBAK: Well, their decision is actually based on a variety of different types of scientific information, studies that are published in the literature, a risk assessment that was conducted, as well as information that has been forthcoming from the NARMS system, which is a monitoring system for antimicrobial resistance that is conducted under the auspices of several USDA agencies, including FSIS, as well as the Food and Drug Administration.

So there are various types of scientific information, much of it reviewed in the scientific literature through the published studies, the risk assessment, which has also been made available, as well as data from the NARMS system that has gone into the decision.

MS. HALL: It was my understanding that these had not been completed, so that's why I asked the question.

MR. BILLY: I think the answer is they would have had to have been completed to take this action, but we can give you a contact point at the Center for Veterinary Medicine where you can get much more specific information on that.

MS. HALL: Thank you.

MR. BILLY: Yes. Rosemary?

MS. MUCKLOW: I don't want to interrupt any continuing discussion on flora quinolines. I thought it might be helpful, especially since I'm on the subcommittee to review this this evening, to get some clarification from you or from Karen about another drug that we're dealing with in the meat industry called phenobutezone.

We're very pleased to cooperate and work with the agency as it does a pilot project on phenobutezone, which is a drug approved for horses, dogs and people, but not for bovine animals. We're looking for it in bovine animals, and, unfortunately, we've found some of it, or the agency has. It's a very complicated program for testing because

the FDA lab does the testing for the bute, and your lab does the testing for other residues.

I learned this last couple of weeks that it's what is called extra labeled, as I understand it, and the veterinarian may prescribe for a food producing animal the use of phenobutezone.

My question for Karen and for the agency is that if a bovine animal has been treated with phenobutezone for which there is no withdrawal time, does that animal become red tagged in some way that it should never enter the food supply? Is that what needs to happen on the livestock end to make sure that that animal never comes through as a food producing animal?

If so, what are you doing with the Food and Drug Administration that has the jurisdiction over the live animal end to make sure that such an animal, once treated with phenobutezone for whatever reason, is not eligible to enter the food supply?

MR. BILLY: Yes. Rosemary, I appreciate your question and your interest in that area, but what I'd like to suggest is that we hold that question until we get to the

residue discussion, and then we can have an appropriate person here that can address your question very specifically.

MS. MUCKLOW: Okay. Will we have that chance today before we --

MR. BILLY: Yes. It's between 1:45 and 2:30.

MS. MUCKLOW: Okay. As long as they will come on with that information, I'll be happy to hold the thought.

MR. BILLY: They'll come on with whatever information we have. We'll do our best.

MS. MUCKLOW: They have the chance to go get it before they get here.

MR. BILLY: I understand, but you'll probably think of several more questions in the interim.

MS. MUCKLOW: That's entirely possible.

MR. BILLY: Alice?

MS. JOHNSON: I want to address two issues, one with Karen.

The action plan document that you were talking about, will that be made public within the next few months in time for some of the hearings that this information will

be considered?

MS. WOTEKI: Yes. We hope that it will be made public very soon; within the next couple of months at least.

MR. BILLY: That refers to that final clearance process.

MS. WOTEKI: Right. It's in the very last stages before it becomes public.

MR. BILLY: It will become public when that process is finished.

MS. JOHNSON: So the recommendations and actions from that committee can be taken as part of the notice and comment from CDM.

It's also my understanding, and this was as of Friday, that the risk assessment that CDM has done has not been publicly released at this point, that it's still internal.

MS. WOTEKI: As we had indicated, I think it's appropriate to address those questions to CDM.

MR. BILLY: Yes. Okay. Caroline?

MS. SMITH DEWAAL: I'm fine.

MR. BILLY: Okay. Your last item?

MS. HULEBAK: I was at risk there, Ms. Mucklow, of not finishing in 30 minutes.

MS. MUCKLOW: I take full responsibility.

MS. HULEBAK: The last update I have for you concerns the agency's and the Department's activities in the area of dioxin.

As the Environmental Protection Agency has moved forward to bring to closure its nearly decade long reassessment of dioxin as an environmental contaminant and as a contaminant in the food supply, we have organized within the Department of Agriculture a cross Department working group to track the issue and to keep ourselves updated and develop actions that we need to take with respect to this issue. I chair that working group. There is also an interagency working group that is chaired or run by the Office of Science and Technology Policy that we take part in as well.

The status of the reassessment is that it is very shortly, like tomorrow and the next day, to go to the Environmental Protection Agency's science advisory board for a thorough review prior to being made final and released to

the public. As such, the reassessment is still a draft, and the scientific considerations and conclusions that are presented in that report are a draft.

We recognize that dioxin is -- it may be a contaminant of foods. It may be a contaminant of the foods that we regulate. We have been interested historically in the possible presence of dioxin in meat and poultry and meat and poultry products, and, as you probably know, in the mid 1990s in conjunction with the Environmental Protection Agency we carried out a survey of beef, poultry and pork for dioxin.

We had been planning to repeat that look at possible dioxin contamination in those products shortly, and in fact we are continuing to talk about shortly undertaking another look at dioxin in those products. We will be coordinating our plans to carry out that testing with the Food and Drug Administration and also with EPA.

Are there any questions? That really sort of brings it up to date with where we are.

MS. SMITH DEWAAL: I'm Caroline Smith DeWaal. I just want to encourage you to do that survey.

With the recent information out on the dioxin issues and the possible health effects, CSPI has recently issued an alert saying, you know, the major way to avoid dioxin in your diet is to avoid eating meat and poultry products. The best data that we have available that we can then give to our members and to the public at large to give them appropriate dietary advice would be -- really this type of a survey could be instrumental in getting better and good dietary recommendations out to the public.

Dioxin is a very serious, potentially serious health risk, and it really -- consumers who want to watch their diets in that way want this kind of information, so I would encourage you to do that survey and to publish it as soon as possible so we have the most up-to-date information.

MR. BILLY: Yes. I'd like to ask that Karen also mentioned the work that we're initiating with the National Academy of Sciences and also if you can make any comment with regard to overall trends in terms of dioxin in foods?

MS. HULEBAK: I apologize. There was one other news note that I neglected to mention, and that is that we have been working through the interagency working group with

the Office of Science and Technology Policy to develop a study that the Institute of Medicine and one or two boards of the National Research Council would carry out looking at dioxin as a potential contaminant of foods within the broader context of sound nutrition and good food public health policy.

There are a broad range of questions that are clearly raised here; how individuals can think about their diets and think about the possibility of their exposure and the need to consider making sound judgements. These are very sweeping questions, and we feel that the Institute of Medicine and the National Academies are well equipped to consider those questions. We are in discussion with them right now about what would make a good, useful and a sensible study.

I can also say that the reassessment has made very clear and the data are available to anyone who's looked at them that as a result certainly within the United States of environmental regulations through the Environmental Protection Agency dioxin emissions to the environment as a result of human activities -- municipal waste incineration,

various utility plant stack gases and so forth. Emissions have fallen tremendously over the last 20 years, and there is evidence that dioxin levels in foods have fallen over the last 40 or 50 years.

There is corresponding evidence that body burdens of all of us -- we are all of us exposed to dioxin largely through food. That's not really a subject of controversy, but our body burdens are continuing to fall as a result of the continuing decline in dioxin emissions to the environment and, therefore, into food. So the news is good. The trends are good, and there is every indication that they will continue in that decline.

One thing we have to recognize is that dioxin as an issue of a contaminant, a food supply contaminant, is not just a U.S. issue. It is again a global issue, and that's one that we have limited direct control over, but it is a global issue. In order to continue those trends globally, that will be a challenge.

MR. BILLY: Okay. Thank you. Okay. Thank you very much, Karen.

I'm going to move on now. The next item on the

agenda is the redesigned HACCP based inspection models project. Our presenter will be Mike Grasso. Mike plays a very key role in terms of this very important project that the agency has underway.

Mike?

MR. GRASSO: Good morning, everybody. What I'd like to do this morning is give you an update exactly where we are with the project. We'll probably have to discuss it maybe two times, the original design of the project and the most current redesign of the project due to the U.S. Court of Appeals decision.

If you would turn to Tab 5, I believe, in your book? We've put some information together in this tab for you and some results from the original design of the HIMP. For everybody's information, the original design of the HIMP had inspection personnel in two positions. One was an oversight position where the inspector moves up and down the slaughter line and a verification position where the inspection personnel perform various tasks such as caucus reinspection activities.

What we have provided for you in this handout is

RTI, Research Triangle Institute, has gone back into the plants that originally conducted baseline, seven of those plants, to compare how they've done in the change from the original HIMP. So there were seven plants in which RTI went back into, and they collected 14,000 samples on other consumer protection.

If you go to Attachment 1, it's the accomplishments of the HACCP based inspection model, so this is comparing the baseline of these seven plants with the RTI data from these seven plants, and it's headed Traditional Slaughter Inspection Versus HACCP Based Inspection. Does everybody have that section?

MS. MUCKLOW: Give us what the page looks like, Mike. Okay. Dr. Jan is helping me get to the right page.

MR. GRASSO: Do we have it? Everybody have it? Okay.

Basically what this chart shows you is the seven categories of defects, the two food safety categories and the five OCPs. The first column is for these seven plants what the results for these seven plants were in baseline. The next column is the number of defects that RTI found when

they went back into the plant and looked at samples from the same plants.

As you can see, for Food Safety 1 there was a 100 percent decrease, for Food Safety 2 a 92 percent decrease, OCP 1 a 45 percent decrease, OCP 2 a 43 percent decrease, OCP 3 13 percent, OCP 4 we had an increase of 26 percent, and OCP 5 there was a decrease of 60 percent, so just to make sure that you understand, seven plants. RTI collected baseline data when FSIS inspection personnel were doing the activities on line. When the plant changed and they performed the sorting, RTI came back in and collected samples again, and this is the results of those seven plants.

Now if you just go to the next page, this is kind of like a confirmation. Attachment 2 is this one here, okay?

MR. BILLY: What's the title of it?

MR. GRASSO: It's FSIS Inspection Results Measuring HIMP Plant Performance Against the Pilot Performance Standards.

What I'd like you to do is, Lennie, I have a more

recent one than this that gives me one more month, and I'd like to hand that out at this time.

MR. BILLY: While that's being passed out, if we could go back to the first chart just so I'm clear and the committee is clear, this table where it compares traditional slaughter inspection results to HACCP based inspection model project results in young chickens?

The column title Traditional Slaughter Inspection Percent Defects, these are the defects that were found after the plant and our inspectors on line in the traditional role that they play carried out their various functions.

MR. GRASSO: Correct.

MR. BILLY: So for seven plants, this is an indication of what results were obtained by RTI through that process, and I think we shared that data earlier with the committee.

Now, the second column in this table, the HIMP Percent Defects, this is with the original design of HIMP where we had an oversight inspector and a verification inspector carrying out the functions that were designed to assure that the sorting done by the plant was effective in

meeting both the food safety and the other consumer protection defects

The results here then show the impact of this design change and different approach in terms of the plant's role and our inspectors' role commensurate with what the plant was doing. Is that correct? Is that what we're --

MR. GRASSO: Correct.

MR. BILLY: One other thing you didn't mention that I thought was important is just above this table in the Accomplishments handout salmonella data is addressed, and the last sentence there that points out that under this redesigned inspection approach under HIMP in fact the salmonella prevalence was better with the redesign than it was under traditional inspection.

We saw an improvement there as well, so it's not just that these other conditions were met, but that we actually through sampling and analysis determined that we saw further improvement in the salmonella prevalence as well.

Caroline, do you have a question about this?

MS. SMITH DEWAAL: I do. Thanks, Tom.

Let me just try to make sure I understand this chart. Just looking at OCP 2, it says 70 percent had defects under traditional inspection. Does that mean that 70 percent of the meat that's going out has bruises or sores or other processing defects?

MR. GRASSO: Correct.

MS. SMITH DEWAAL: And 39 percent was going out under the HACCP inspection models project?

MR. GRASSO: Uh-huh.

MS. SMITH DEWAAL: This does not reflect the standard. Is that correct? We're not looking at two different standards. We're looking at the actual results achieved under the systems.

MR. GRASSO: The seven plants -- okay. It wouldn't be fair to compare the seven plants to the 16 plants where we developed the performance standards from baseline from 16 plants, so this chart -- we went back specifically to these specific seven plants and what was the 75th percentile position for these seven plants.

MR. BILLY: Let me try to answer it --

MS. SMITH DEWAAL: Okay.

MR. BILLY: -- in a little bit different manner. The first column, which is titled Traditional Slaughter Inspection, these numbers that are in this column represent a standard for the seven plants, not for all 16, because we didn't have data in the second column for all 16 so we compared apples to apples. We tired to make a direct comparison.

The numbers in the first column are our initial thought of what a performance standard should be for these various categories of defects and food safety concerns. We've done that by identifying the 75th percentile; not accepting the overall number or result, but actually tightening the standard, if you will, as represented by these numbers by choosing the 75th percentile in terms of the data results.

The 75th percentile approach is what we're initially working from, but obviously if in fact we continue this project and arrive at a point where we're convinced that this is an improvement then the percentile that we actually end up with if we were to change the regulations would be subject to notice and comment rule making with

input from the public.

So we have picked a benchmark for comparison purposes. One could argue well, it ought to be 50 percent or it ought to be 80 percent or whatever, and I'm sure that debate will occur at some point in the future, but in order to make a comparison that's what we attempted to do here.

MS. SMITH DEWAAL: But I'm still a little lost. Are we comparing the actual achievements of the traditional inspection process in these seven plants with the actual achievement, or are we comparing the standards applicable to the traditional inspection of these plants versus the standard under the new HIMP --

MR. GRASSO: What this chart explains to you is that in these seven plants RTI went in originally under traditional inspection and gathered results on these seven. There were 16, but this, the first column, --

MS. SMITH DEWAAL: I understand.

MR. GRASSO: -- is their results for the seven.

MS. SMITH DEWAAL: I understand that. That's not my question.

MR. GRASSO: So that's the results. That's the

traditional system in these seven plants.

MS. SMITH DEWAAL: So in those seven plants --

MR. GRASSO: This is what was going out the door.

MS. SMITH DEWAAL: Under the traditional --

MR. BILLY: That's not right, Mike. That's not correct.

If you multiply these numbers under the column Traditional Slaughter Inspection by I think 125 percent you'll get the actual numbers of what was going out the door. Is that correct?

MR. GRASSO: This here is the 75th percentile, --

MR. BILLY: Yes.

MR. GRASSO: -- so it's a position for the seven plants. It's probably a position between the fifth and the sixth plant.

MR. BILLY: Here's a way, and let's pick that category that you chose, OCP 2, a way to think about it.

MS. SMITH DEWAAL: Okay.

MR. BILLY: You have seven plants, and for those seven plants each had a set of performance results under the traditional inspection, some percentage that was in as a

result of the way the plant and the inspection system performed.

If you arrange those data from one to seven in terms of the numbers, what this column represents is a number that is at the 75th percentile of the actual numbers that came out of those seven plants for that category. It's the 75th percentile, so some plants may have had numbers below 70 percent. Others had numbers above 70 percent.

We picked the 75th percentile and said all right, for purposes of comparison to the experimental phase we're going to use that number, the 75th percentile, as the point for comparison. We didn't say we're going to compare it to the plant that had the highest number of defects or the lowest number of defects. We chose the plant that was positioned nearest the 75th percentile, and that's true for each of these categories.

The next category we arrayed the same data results, whatever they were, from the best or lowest number of defects to the highest. We found out what the 75th percentile was, and that's the number that's represented in this column, so it's not the actual results, if you will.

They varied by plant in the pilot study. What this number is is what the 75th percentile position would be.

MS. SMITH DEWAAL: Okay. So we're comparing plants, Plant No. X, who achieved the 75th percentile --

MR. BILLY: Right.

MS. SMITH DEWAAL: -- mark under the traditional system, to Plant Z, who achieved that 75th percentile mark in the second system?

MR. BILLY: No. These are the actual results. How would you say it?

MR. GRASSO: The second column is when RTI went back in and we had to change where the plant took on the responsibility. They looked at samples, and they identified defects on the birds. That's the actual results in these seven plants under the original HIMP.

MS. SMITH DEWAAL: So the averaged actual results for these plants?

MR. GRASSO: The 75th percentile.

MR. BILLY: For the right column.

MR. GRASSO: Correct.

MR. BILLY: Okay.

MR. GRASSO: So you're able to compare the two systems, traditional, 75th percentile, versus the HIMP.

MR. BILLY: Okay. Carol Foreman?

MS. TUCKER FOREMAN: Two things, please. Do you have with you what the figures in that first column were for the 16 plants?

MR. GRASSO: Right. That's the next sheet that I've handed out.

The point I was trying to make is that under the original HIMP, okay, for those seven plants you had the results. Then RTI came back in under the original HIMP. You could see the results and compare how they were doing.

This here result right here, this here result is FSIS data in 11 plants since February 1, okay, so this is significant. This is 11 plants for a longer duration of plant where FSIS inspectors have collected close to half a million samples for food safety and close to 200,000 samples for OCPs.

You have the seven categories. The first column is the baseline from the 16 plants where RTI went in and we took the 75th percent. Those are the performance standards

that the HIMP plants operate under. The column on the right is the column, the results, an average over that period of time of what the inspectors are finding in the 11 plants.

MS. TUCKER FOREMAN: Is Column 1 on the sheet you just handed out a reflection of exactly the same data as Column 1 on the sheet in our books?

MR. GRASSO: No. Column 1, because we only had seven plants of RTI data --

MS. TUCKER FOREMAN: No. Are they looking at the same thing?

MR. GRASSO: Absolutely the same.

MS. TUCKER FOREMAN: Okay. Column 1. Because they're not called the same thing.

MR. GRASSO: I understand that. Because we only had -- in the handout in your book, we only had results from seven plants.

MS. TUCKER FOREMAN: Mike?

MR. GRASSO: Yes?

MS. TUCKER FOREMAN: The top of the column doesn't say the same thing. One says Traditional Slaughter Inspection Percentage Defects. The other one says Pilot

Performance Standards Based on Traditional Inspection. It doesn't say the same thing, --

MR. GRASSO: Okay.

MS. TUCKER FOREMAN: -- but I'm asking you is it the same thing --

MR. GRASSO: It is the same thing.

MS. TUCKER FOREMAN: -- except in one case for 11 plants and in the one in our book for seven plants?

MR. GRASSO: Correct.

MS. TUCKER FOREMAN: Is it exactly the same figure?

MR. GRASSO: It's the same thing.

MS. TUCKER FOREMAN: What would the figures be, because this is the traditional. What were the figures when you first went in and looked at all 16 plants?

MR. GRASSO: Right here.

MS. TUCKER FOREMAN: No.

MR. BILLY: No. That's not right.

MS. TUCKER FOREMAN: That's not right. You just told me that was 11 plants.

MR. BILLY: What we need --

MR. GRASSO: Oh, no. Let me finish, Tom. This column here was the performance standards. That's 16 plants.

MR. BILLY: No.

MR. GRASSO: That's 16 plants right now.

MR. BILLY: But I think what you're asking for is the report that we presented at the last public meeting, which is the actual result for all 16 plants under traditional.

MS. TUCKER FOREMAN: Right.

MR. BILLY: We can make that available to the committee. That's the RTI report.

MR. GRASSO: Right, but that's this column, Tom.

MR. BILLY: I understand, but I think she wants the actual data from all 16 plants.

MS. TUCKER FOREMAN: I do.

MR. GRASSO: Okay.

MS. TUCKER FOREMAN: Let me tell you something. Do you know what? I am a reasonably intelligent human being, and we've been looking at these figures for four years now. They are not meaningful to me. I do not know

how you expect them to be meaningful to the Court or the public.

They just don't communicate very effectively to someone looking at them immediately that something good is happening here. I think that's probably the case, but I can't get it from these figures.

MR. GRASSO: Well, let me try to give it to you, if I may. If you would look at this sheet, okay? That first column, Pilot Performance Standards Based on Traditional Inspection, that is the results from the 16 plants baseline results, RTI going in, taking 32,000 samples.

MS. TUCKER FOREMAN: 75th percentile?

MR. GRASSO: 75th percentile. Now, the column on the right is FSIS inspector results where they're performing eight food safety checks per shift per line and two OCP checks per shift per line. That's what that right column is. The Food Safety 1 and 2 represents closer to a half a million samples that FSIS inspectors have performed in these 11 HIMP plants.

Now, you want to see something good? Well, what I

see is that under the traditional system Food Safety 1 was .1, and under what we're seeing by our inspectors it's .0. For Food Safety 2, in baseline it was 1.5, and we're seeing .2. If you go down the line, the right column for the OCPs, I see improvement in every category based upon FSIS inspector results.

Yes, Carol?

MR. BILLY: Okay. Hold on, Carol.

MS. TUCKER FOREMAN: Wait a minute. Wait a minute. I've got a question. The left-hand column on this is 16 plants?

MR. GRASSO: Correct.

MS. TUCKER FOREMAN: The right-hand column is 11 plants?

MR. GRASSO: Right.

MS. TUCKER FOREMAN: How do we know that it doesn't look so good because the five plants that aren't in the right-hand column --

MR. GRASSO: I don't have five yet.

MS. TUCKER FOREMAN: -- were the worst five plants?

MR. GRASSO: I don't have five.

MS. TUCKER FOREMAN: I know, but you're telling me that your baseline is 16 plants. The right-hand is 11 plants.

MR. GRASSO: Right.

MS. TUCKER FOREMAN: How do I know that the right-hand doesn't look so good because the garbage was in that other five plants?

MR. GRASSO: Because we don't have the results yet from the other five.

MS. TUCKER FOREMAN: I know, but how come you didn't give me 11 plants? You gave me seven plants in the book. How come you couldn't give me -- why do I have apples and oranges instead of 11 and 11?

MR. GRASSO: I could do that, too. I thought this here sheet would verify that FSIS results, okay, are showing that the plants are meeting the performance standards based on the baseline.

MR. BILLY: I think one reason that there's a difference is because in this instance the inspectors are measuring the samples against the standards based on all 16

plants. That's what we have the inspectors doing in those plants as compared to RTI going in and independently collecting data, so once we have the complete sample set for all 16 plants and identify the 75th percentile then the inspectors are measuring the HIMP performance against the results for all 16 plants.

We had to have -- otherwise what we would have had to do is the first plant, the inspectors would have measured it against that plant. Then the next one we would measure it against two and so forth. We're not that flexible in terms of how we do it, so we're holding -- in terms of what the inspectors are doing, we're holding them accountable for results against all 16 plants.

Those are for the time being the performance standards that the inspectors are applying --

MS. TUCKER FOREMAN: Okay.

MR. BILLY: -- to the HIMP plants, so that's why there's a difference. I think that as we get more data then, you know, eventually we'll have enough of the data for all 16 plants and that problem will disappear. It's an attempt, I believe, to share --

MR. GRASSO: Right.

MR. BILLY: -- on an ongoing basis as we cumulate results what the results look like in comparison. I think they're described in the text and below as well.

MR. GRASSO: If we went back six or seven months when the first plant started, okay, Plant 1, they had to meet the first column.

MR. BILLY: Yes.

MR. GRASSO: That was the performance standard that that plant had to meet. As each plant came on that's the performance standard they had to meet, and that's the performance standard that they generated as an individual plant and baseline because I can just tell you right now. I mean, OCP 2, which is at the 75th percentile for 1.5, the 16th position was 3.3 so we didn't take that 16th position at 3.3. All the plants have to meet the zero tolerance really, but that was what was generated in baseline.

MS. TUCKER FOREMAN: I have one more question if I may, please.

MR. GRASSO: Okay.

MS. TUCKER FOREMAN: The first column, the

baseline data. I want to go back again. Column 1 on both sheets are the same thing except one refers to 16 plants and one refers to seven plants?

MR. GRASSO: Correct, but that's the results of those seven plants in baseline, and we took the 75th percent for those seven plants.

MS. TUCKER FOREMAN: So that explains why --

MR. GRASSO: The numbers are different.

MS. TUCKER FOREMAN: And why they appear to be higher on the seven plants than they are all the way down the line on the 16 plants?

MR. GRASSO: Correct.

MR. BILLY: Okay. Lee Jan?

MR. JAN: Thank you. Lee Jan, Texas Department of Health.

I have some interest and would like to know if there's any data on the percent of the carcasses that were removed from food supply in the traditional versus the HIMP.

Also, in the pilots that have been conducted what training or qualifications did the plant sorters receive prior to beginning their responsibility?

As we move to the future, is there assurance that the plants of the future that would be in this HIMP, and it may have a new name by them, but in this project. Will there be a requirement or some assurance that the sorters will have at least the same qualifications as the sorters in the project?

MR. GRASSO: Well, I'd like to mention a couple of things. Number one, what we did and are still doing is that we are providing for all the HIMP plants slaughter training in College Station, so most of the HIMP plants, if not all, have sent down three, four, five people to be trained in slaughter inspection, so it's like train the trainer, and then they come back and they do training for the sorters.

I know that the industry as a whole has put together a generic training package that they submitted to the HACCP Alliance for validation so that this type of training program could be provided to all of their sorters.

MR. JAN: Is there an assurance that for the future plants, after they pass the project, that those plants will continue that, or is it just whatever they want to do?

MR. GRASSO: I actually think that the performance standards themselves, if they don't put people on line that are qualified and trained and know how to do the job -- looking at 80 birds per shift, they're not going to meet the performance standards. It's going to happen right away.

MR. BILLY: I think to further answer that, I think that's a subject for a rule making. In other words, we're gaining the experience for observing what's happening. As we build that information, that will be shared in a proposed rule and that question will be addressed, and then the public will have an opportunity to advise us on what the best approach is.

MR. JAN: Okay.

MR. BILLY: I think it remains to be seen, and I think that's a possibility, but I don't want to pre-judge it. I think we need to be open to that possibility.

MR. JAN: What about the other part? Is the data on the carcasses removed from the food supply in the traditional versus HIMP? Is there data on that?

MR. GRASSO: You're talking about condemned birds?

MR. JAN: Right.

MR. GRASSO: Right. RTI, in their baseline presentation of the six plants, presented --

MR. BILLY: Sixteen.

MR. GRASSO: Sixteen plants. -- birds that were condemned and the reason for condemnation, and they'll do the same thing again when we get to the 16 plants.

MR. JAN: How does that compare? I mean, I don't see data on that issue.

MR. BILLY: There's data that was in the full report, and we'll provide that to the committee. There's a lot of data in their overall report, and it includes data on that and the criteria, the reasons and so forth, a bunch of pie charts and stuff that were provided earlier, but we'll share it again.

Nancy?

MS. DONLEY: Thank you. Nancy Donley from STOP. I'm just really happy that Lee brought up the comment about the training because that's been a concern of STOP's from the beginning that we feel that it's crucial for this to -- that there be a mandatory training requirement, and particularly now that we just had this recent BSE situation

arise in France. The public is very much interested in what's happening with the sorting process.

My question, my real question here, is do the HIMP results then become a new performance standard for the HIMP plant? I ask that question because we have maintained from the beginning of this pilot study that we could only support the project if at the end of the day the results were better; not the same as, but that there was a significant increase in the safety of the food that indeed comes out of it.

So I guess my question is predicated on the fact that fine, we see some really interesting looking numbers here now that have come out when you compare the plants, but is that performance standard going to remain at the 70 percent -- I'll just use that one as a for instance -- or is it going to drop down to the new -- what was the one I was even looking at here? Sorry. I was looking at OCP 2, 70 percent. Will it now be dropped to 39 percent and that becomes the new performance standard that those plants must achieve?

MR. GRASSO: Well, I think just to add on to what

Tom said is that our game plan is to move forward with rule making, and our initial idea with the performance standards would be to maybe start at the 75th percentile and look at performance standards over maybe a ten year period of time.

We're continuously raising the bar as far as the performance standards are concerned, so now we're at maybe the -- for the 16 plants we're at the 12 position, and maybe after a couple of years you go to the ten position, okay, then the eight position and the six position, so as the plants are able to gear up and to meet the performance standards, continuous improvement. I believe it would be a starting point.

MS. DONLEY: It's just --

MR. BILLY: I want to say a specific thing and then a general thing. The specific thing is that's a possibility. In other words, the process and the rule making process. The agency would make some tentative decision about what the performance standard should be based on all the data and then that would be contained in a proposed rule subject to notice and comment from the public, and that process in the end would sort out what that

standard ought to be, whether it's the one that you identified or something else.

I think one of the -- and this relates to my general comment. Normally both this agency and other regulatory agencies don't have this kind of a transparent process through every step of a pilot study and rule making.

The agency made a commitment when we started on this pilot project that we were going to -- we set some general ground rules, but we would continuously share with the public all of the information and data as we moved along. We knew this was a very important issue area and that it would be valuable to provide that information.

Given that, while it's very appropriate to have all kinds of questions and important for us to share all the data and explain it, in the end I have to ask the committee and everyone else to be a little patient because usually the firs time you see all this is at a proposed rule making. Now you're living the pilot with us and getting the results, and we're trying to figure out how to share the data in the most meaningful way we can on an interim basis.

Whether we're doing it well or not that's fair

enough to comment. If anyone has ideas about a better way, we're open to that as well. Just remember that this was an open process where we're going step by step as we committed to do when we began this project and so I think that that perspective is important as we move forward.

MS. DONLEY: Can I just follow on to that?

MR. BILLY: Sure.

MS. DONLEY: Thank you.

MR. BILLY: Absolutely.

MS. DONLEY: I look at this and recognize that this is kind of like a balance sheet, if you will. It's a single accounting in time, a single period in time when you get these results like this.

MR. BILLY: Right.

MS. DONLEY: I think when you see such number changes and significant changes like this that if we really want to rachet up the food safety measure we have to say okay, we know you can achieve this. You have achieved this. Therefore, we are going to make this the standard.

After the spotlight is turned off, after all of these baselines have been done, we don't want that number to

go back from 39.8 up to 70, so that's why I wanted to change those performance standards, and I think we'll have a significant boon to food safety.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: Thank you, Tom. Caroline Smith DeWaal.

I just want to say that I think there are communication issues around this that are difficult to get over, but one of the important points that I took home from the meeting you held back I think it was February 28 or something because it was the leap year day on the HACCP inspection models project is that -- actually, it wasn't that meeting. It was another one. I have the date wrong.

At that meeting, you said that one of the important things is that these new categories are all lower, and I think there's maybe one or two exceptions, but they are all lower than the standards currently being implemented under the traditional inspection model --

MR. GRASSO: That's correct.

MS. SMITH DEWAAL: -- so that these -- and that fact I don't think has come out in this discussion so that

this column that includes the performance standards applicable to the HIMP plants are already actually a dramatic improvement in many cases over the standards being applied in all the other plants around the country today under traditional inspection. I think that's an important communication point that you need to get out when you talk about this.

Now, these two columns, and I guess one more question on it, I think. Just to follow up on that one point, that is good news for the public, the fact that these HIMP plants are actually being required to comply with tougher standards than all the other plants operating today is good news and I think helps. I think Nancy's vision is an excellent one for the future, but I think that this point helps to make this inspection models project much more acceptable to the public because these standards are tougher.

Now, in Column 2, though, we're comparing the RTI collected data in Column 1?

MR. GRASSO: On this here one?

MS. SMITH DEWAAL: The new one that you just

handed out.

MR. GRASSO: No. That's FSIS inspector results.

MS. SMITH DEWAAL: But is that the RTI data or not?

MR. GRASSO: No.

MS. SMITH DEWAAL: None of this is? Okay. One of the other real positive things out of the inspection models project is the fact that you do have the RTI, the Research Triangle Institute, that is verifying and actually documenting the achievements of the agency and of the HACCP inspection models, and that verification on the agency is very important as you move through this process, so I do think you need to --

MR. GRASSO: Right.

MS. SMITH DEWAAL: -- communicate the fact that these are in most cases, and there is one exception and I think it's something around OCP 3 or something around feathers maybe, --

MR. GRASSO: Right.

MS. SMITH DEWAAL: -- but this is a very big improvement for the industry overall, and what we want is to

get the entire industry to these standards whether they're being traditionally inspected or inspected under the new --

MR. GRASSO: Maybe it would have been better if the seven plant data that I would have shown you, that first column I should have just put the baseline results there and then showed you RTI results.

MR. BILLY: Or added a third column.

MR. GRASSO: Or a third column.

MS. SMITH DEWAAL: Yes.

MR. BILLY: That would be more --

MR. GRASSO: What I tried to do is both show you RTI, that we're seeing improvement, and then our own inspectors and that we're seeing improvement.

MS. SMITH DEWAAL: What this other column shows us is that in fact you have some of not the best plants in this seven plant series, but some of the not so good plants --

MR. GRASSO: Correct.

MS. SMITH DEWAAL: -- are mixed in as well. There is some data that the government accountability project has on one of the plants, and I'm hoping she's going to bring that up this afternoon because I think there are some

significant questions.

It's one of the plants included in this initial list of seven, but overall it's very important to note that these standards are in most cases much tougher than the ones being applied to the rest of the industry today.

MR. GRASSO: You're talking about at the last meeting that we did we provided you with the finished product standards and we did a comparison.

MS. SMITH DEWAAL: Yes.

MR. GRASSO: I could get that over here this afternoon again.

MR. BILLY: Okay. I have three more people on this point, and then I'd like to have the presentation finish so we can break. I know there are some of you just waiting to break, so maybe this will accelerate the completion of this.

Rosemary, Alice and then Jim?

MS. MUCKLOW: Tom, I appreciate very much the transparent process that the agency has tried to go through on presenting the HIMP data. I think it is admirable. I wish you were as transparent on some of the other things you

do, but that's another story.

I would suggest that maybe one of the more important words on this document is the word Draft up in the top left-hand column, and I would suggest that you enlarge that word and that you put it in bold because this is preliminary data. This is not a finished project. It is very much a work in process. I think that we try to think of this as something that is completed, and it is not.

I would like to be assured that when we see the final document on this the right-hand column will reflect 16 plants, and again the next time you come out with this you might want to note that it is a draft document, and 11 plants' data is all that you had at the time you went to press with this.

It's a lot of work. I think you've simplified it well. I think you need a couple more footnotes and a heavy Draft up in the left-hand side, and we'd all understand it a lot better.

Thank you. It is a good process.

MR. BILLY: Alice?

MS. JOHNSON: I want to talk a little bit -- Alice

Johnson, National Turkey Federation.

In May, as Mike referenced, I talked a little bit about some of the training efforts that the meat and poultry industry that had volunteered for the HIMP project were undergoing, and at that point we had submitted to the International HACCP Alliance proposed curriculum for their review.

The International HACCP Alliance is based out of Texas A&M. It has on its membership industry, academic. AVMA is a member. They submitted the outline, the curriculum outline, through their training committee, which is made up of several veterinarians and educators across the country, and they approved it with some minor revisions, of course, and have put it on their website now.

It was the intent of this is meat and poultry working together to try to come up with some sort of we want a standard curriculum so that not just anybody can say oh, I can teach you how to do HIMP in two minutes and it be okay. It would follow pretty much what most of the industry did as far as the HACCP courses with an approved third party curriculum.

When a company or an individual wants to do training in order to be approved through the Alliance, they have to send their training materials to the committee. The committee reviews it and does a comparison between the outline as written and what the materials are. In that way, Dr. Jan, we hope we're getting a lot of uniformity in what's being taught.

The courses include certifying a lead instructor so that there is one person who has gone through additional training and is deemed appropriate for a trainer and lead instructor by the Alliance for HACCP implementation. FSIS has done a really good job in trying to provide training, but you can't send -- a lot of companies are training 60 people, and you can't send 60 people to Texas for the training course so they send a couple of people that later become their lead or their supervisory training people.

All of the plants up to this point have veterinarians, and it is the recommendation of the meat and poultry working group that worked through this that a veterinarian have a part in the training and do follow up.

One important issue with the HACCP Alliance is

that all training has to be recertified every three years, and that way they're assuring that if there are issues that need to be addressed or changes made that it is incorporated into the document. I think the industry now and others, at least three companies that have their programs, work through this approval, and it's hoped that some of the consultants can come in similar to what happened with HACCP.

If HIMP goes forward and is mandated, there's going to be a lot of plants that are going to need training quickly, and hopefully the work that's been done can ease that burden financially on getting the training materials together and also provide the uniformity in the recognition of a third party. It's not just an industry program.

We did a comparison, and most of what you see in this outline came from the FSIS inspector training short of the admin stuff that the inspectors go through with travel vouchers, non-compliance. I think you'll find that in most cases companies are devoting more time to the pathology issue than probably what USDA is doing because of a lot of the other requirements.

There is a follow up correlation and there's

testing, and the sorters actually receive a certificate saying they've gone through this training, and they are looking at the updating process.

I do have some handouts. I don't know if it's appropriate to hand them out to the committee. It's off the HACCP web page and just talks about the fees for registration of the program and the training committee that the Alliance has put together.

MR. BILLY: Why don't you do it at the break?

MS. JOHNSON: Okay.

MR. BILLY: That will be in about two minutes.

MS. JOHNSON: All right.

MR. BILLY: Jim?

MR. DENTON: Thank you, Tom. Jim Denton with the Poultry Center at the University of Arkansas. I would like to take this opportunity to thank you for the approach that you have taken in sharing the information with regard to the HACCP inspection models project.

Speaking to that issue from the scientific research basis that I do the work in, what we've seen this morning is the natural curiosity that comes attendant with

any well-designed project. We get a little excited and a little encouraged about this. We have that natural curiosity of wanting to take a sneak peak at the data and see where this thing is actually leading us.

What we're sharing is the fun part of the scientific process because when we begin to see results like this that are encouraging that causes us to get a little bit more excited about it, but what we've really identified is the danger that is attendant to going too soon before you've actually completed the project.

I anticipate that it's going to follow along the trend lines that we see right now, but I think that we do have to complete the project, conduct the analysis, interpret the data. Then we have a lot more sound basis by which we can make the decisions with regard to the next step.

MR. BILLY: Okay. What I'd like to do now is have a break for 15 minutes.

MR. GRASSO: Tom, can I have one minute? One minute. I can do it in one minute.

MR. BILLY: All right.

MR. GRASSO: One minute. You need to know that we had to redesign the project, okay.

MR. BILLY: I was going to come back to that.

MR. GRASSO: After the break?

MR. BILLY: Yes.

MR. GRASSO: Okay. Done deal. All right.

MR. BILLY: All right. A 15 minute break.

(Whereupon, a short recess was taken.)

MR. BILLY: Okay. We're going to get started again.

I wanted to remind everyone, in particular the committee, that this is a briefing. This isn't one of the three issues that we're going to address. I think we learned some important information that will help us in terms of future briefings and sharing information with the public.

What I'd like to do is have Mike now very briefly just inform us to complete his briefing on the status of the project, including the issue that was raised by the Court case and the decision in the Court.

Mike?

MR. GRASSO: Thank you. I've handed out a colorized chart, so maybe it will be a little bit easier to understand it.

As it relates to the Court case, I'll just give you a quick update. We originally won in the District Court. The AFGE appealed to the U.S. Court of Appeals. The U.S. Court of Appeals ruled in favor of the AFGE, and the AFGE filed for an injunction to stop the project.

We have as of the 20th of this month filed our final documents, and now it's in Judge Lambert's hands in the District Court to render a decision. When that decision will occur is anybody's guess. Maybe two or three months. We'll see what happens.

How we redesigned the project is we put together a flow chart for you of a poultry slaughter line, and, as you can see, we have identified a CI, and that's a carcass inspector. That carcass inspector now is at a permanent location after the final wash and before the chiller.

The carcass inspector is there permanently making the critical determination on each carcass whether it's adulterated or not, so at this location the plant has

already done all of their sorting, all of the washing and trimming of the carcasses, and we have an inspector at that location making that determination.

As you'll see on the chart, we have a VI or verification inspector, and this inspector performs all of the direct bird reinspections, the 80 and the 20 per shift per line for food safety and OCP defects. They actually look at plant records. They also take micro samples, so they're doing all of that verification activity.

In addition, we have an SI, and that's the IIC or the SVMO that's looking over the entire inspection process within the plant, so those are the three layers that we have under the redesign.

I've also attached for your information, and I know we're on a time crunch right now, but on the swine side I've attached the antemortem activities where there was no change that we look at 100 percent of the animals. Then taking it to the postmortem activity, the next sheet, swine is a little bit different than the broilers where we have the carcass, the head and the viscera, and we could have up to three inspectors at those three locations, so you can see

the carcass inspectors and where they're located.

We have the same activity for the VI, verification inspector, and also for the system inspector, which is the IIC.

Yes?

MR. BILLY: Here's my concern. We're running behind. We're about a half hour behind. This is a briefing. My question to the committee is would it be sufficient to have Mike and the other people involved around to answer questions after we break for lunch because this is only a briefing. It's not one of the issues we're going to be addressing.

I don't want to deny anyone the opportunity to comment. I just want to try to manage this time so that we get through the day in the manner that the committee is urged to do so. I'm just trying to get a sense. With that, I'll leave it to Nancy.

MS. DONLEY: Can I respond to your -- I understand, except that I think that this topic is something that is so of such a critical nature to everybody that I know I have some plans during the lunch break, and I'd like

to hear from the other committee members as well as far as -- and perhaps they may have some of the same questions I do on this.

I'll keep my questions really brief. I promise. I found with the initial handouts your three comparisons very helpful on the poultry where you had the traditional, current HIMP and then redesigned HIMP. That was very helpful, and I would ask that we get that same information on the market hogs as well. You just provided the new redesigned HIMP model, but my material at least did not include any of the current HIMP and/or traditional, so if we could have that I would find that very, very helpful.

Then just one clarification if I could with the poultry, and that is that on the current HIMP you've got I just want to verify that this prechill verification location was designated as a CCP before, and it's not indicated so on the redesigned HIMP. Am I reading that correctly, or has --

MR. GRASSO: It's the same. Verification activities, okay, occur before the carcass inspector, and all of the plant's activity occur before those two inspection activities, verification and carcass inspection.

MR. BILLY: But that doesn't answer her question.

MR. GRASSO: It's before.

MR. BILLY: Is there still a CCP --

MR. GRASSO: Yes.

MR. BILLY: -- at the same point --

MR. GRASSO: Yes.

MR. BILLY: -- in the plant?

MR. GRASSO: Yes.

MS. DONLEY: Those verification checks are CCPs.

MR. GRASSO: That's right.

MR. BILLY: Yes. So maybe that needs to be added to the chart to make them comparable, I guess. That would help.

Nancy, do you have other questions?

MS. DONLEY: I just want to understand, making sure I understand these flow charts correctly, that under traditional with the redesigned HIMP, whereas under traditional inspection you had two lines feeding in with the sorting area there and the inspection, and then they went through after the carcass, after the separation and then the trimming and then the prechill, the two lines. By the time

it gets to the chiller, the two lines have converged in and gone in, so you had four people, if you will, at the point of looking at each individual carcass.

On the redesigned HIMP where you've got the on-line inspector at the pre-chiller stage, you've got one inspector now that is looking at double volume of what two inspectors had previously been looking at. Am I understanding this correctly?

MR. GRASSO: It all depends upon the line speed in the plant. With the inspectors performing the inspection activities upstream it was based on approximately 35 birds per inspector, so if the plant was running 70 birds a minute there would have been two inspectors there.

MR. BILLY: I don't think that fully addresses your question. The premise of your question is that they're looking at the same thing and they're not because --

MS. DONLEY: Right.

MR. BILLY: -- under the redesign what they're looking at are carcasses that have been sorted, and all the various conditions that are observed have been removed by the plant so it's not the same thing whereas in traditional

inspection we're seeing that right after the birds are rehung and all of that is there for us to identify, and then either we remove or the plant addresses, depending on what the defect is, so it's not. It's really quite a different role with the redesign and what the inspector is able to spot because all the sorting has taken place.

Katie, and then Alice, and then we're going to stop.

MS. HANNIGAN: My only comment would be as a committee member I prefer if the briefing stay to exactly their time frame because my concern is tonight when we're trying to do these individual meetings if we haven't discussed the issues at length we're going to struggle all evening. I mean, the conversation has been excellent, but I think we've got to stay with the issues.

MR. BILLY: Okay. Thanks.

Alice?

MS. JOHNSON: I have to follow that? Alice Johnson, National Turkey Federation.

In Nancy's comment about the verification being a CCP, the verification is done by the agency, correct?

MR. GRASSO: Correct.

MS. JOHNSON: And the plant puts their CCP wherever they feel appropriate within their process, and so a CCP -- most plants are going to put them before the carcass inspector or wherever they deem appropriate, but the verify is the agency, and it's up to the plant where they put a CCP, but everybody is going to be sure that it's done before it goes through the verification step you can bet. I just wanted to clarify that.

MR. BILLY: Okay. Great. Okay. Thanks a lot.

Okay. Now I'd like to move on to one of the three issues, which is sharing recall information with state and other federal government agencies. This is under Tab 8 in your book, and we have Charlie Gioglio to give us a presentation on this important issue and lay out the questions that we'd like you to address.

Charlie?

MR. GIOGLIO: Okay. Thank you, Mr. Billy. Back I guess it was on September 19, the agency issued a proposed rule that would add a new section, I guess it's Section 390.9, under our administrative regulations which would add

a section amending the -- excuse me. To add a part about sharing recalled distribution information, meaning the actual customer lists, with the state programs and other federal agencies.

The comment period for that rule is open until November 20. The Section 390.9 is, as I said, under the Freedom of Information section, and I'm going to go on and describe it in some detail, but I'd like to go back and give some background on recalls and how recalls are administered by FSIS.

When a firm initiates/conducts a recall of meat and poultry products, FSIS expects that that firm contact usually orally, first by telephone, and then a follow up in writing, all of the consignees or customers of their particular products. In that instruction, we all expect that they provide instructions of what those consignees should do with the product, how those particular possibly they were distributors or others, someplace in the distribution chain, how then those consignees should contact their subconsignees and provide instructions of what then they should do with the product and so forth.

When a recall is initiated, FSIS, we have our compliance officers go to the plants and then to the subconsignees, okay, or the consignees of the plant and collect the distribution information. That information then or the customer lists are used by our compliance officers when they go out to perform recall effectiveness checks. They'll visit X number of distributors, retail stores and the like to see then if the firm has in fact carried out its agreement with us and their responsibility in providing correct information, removing the product from the shelves and so forth.

That distribution information is considered confidential commercial information. As such, we then do not disclose the information to the general public. We use it for the purposes as I described of performing the recall effectiveness checks. The information is not discloseable under the FOIA.

Over time, states and other programs, other agencies, have requested from FSIS that we provide them with those lists of distribution information, and FSIS has continued to deny those requests based, as I've described

earlier, on the fact that the information is considered commercial confidential.

The rule, if it would be finalized in its current form, would allow FSIS then to share that distribution information with states or other federal agencies, provided that the agency that's requesting the information would in writing establish its authority to maintain the confidentiality of the information and also provide a written commitment not to disclose such information without the written permission from the submitter or, in this case, the recalling firm or their subconsignees and distributors and so forth or written confirmation from FSIS that the information is no longer to be held in confidential status.

If the requestor of the information was another federal agency and it was requested of them that they disclose the information publicly, then the other federal agency should refer that request to FSIS. In addition, the FSIS administrator or his designee would need to designate that the disclosure of such information was in the interest of the public health.

I guess the last provision is that the disclosure

of this recall information, the distribution lists, would not in any way change the status of trade secret information or any other Freedom of Information requirements or protections under that Act.

What we would like then, and we'll have some time hopefully for some questions here. What we would like then the committee to discuss and give us recommendations on is, first of all, I guess generally the merits of the proposed rule as written, how best also could this regulatory change be implemented in cooperation with state agencies and other federal agencies, can the committee identify any particular factors that would either facilitate or impede the implementation of this provision, what are those factors and how can we then overcome them in implementing it.

Basically I guess I would say that our overall effort here is to create or attempt to create a uniform system as best we can among all the agencies that would be involved in a recall. We would also appreciate the committee to discuss and deliberate how we might establish a system of communication between and among FSIS and let's say state programs that would be involved in performing

effectiveness checks and so forth on an individual recall or recalls in general, what mechanisms should we develop, how best we establish those communication links and so forth among the agencies.

I guess I would close to say, and I'll wait to see what questions you might have, but to say FSIS' expectations would be and the reason that we've been I think requested as often as we have by state agencies primarily for the distribution list is that state agencies often have their personnel in the field visiting retail stores and other businesses performing recall audits, effectiveness checks and so forth, and we'd like to establish the mechanism where FSIS then would get the benefit of that data also coming back to the agency to assist us in our effort in judging whether or not the recalls have been effective, the timeliness of such and so forth.

MR. BILLY: Okay. Thanks, Charlie.

Questions? Yes, Alice?

MS. JOHNSON: Charlie, I think that the meat and poultry industry is -- one common goal you share with the agency is if there's product out in the marketplace that is

a threat to public health then everybody wants it removed as quickly as possible.

You talk a lot in the preamble about the distribution list, and that seems to be where the agency is going with the sharing of information, but it's not specifically stated in the regulation. Is there any other information that the agency might deem appropriate that you could think of?

I mean, by not clarifying specifically this type of document is what we're talking about, is that --

MR. GIOGLIO: The way we termed it in the regulation, Alice, was recall distribution data or recall distribution information, I believe. At this point, that is what we are limiting. The scope of this regulation, okay, of this proposed change, would be limited to that.

It would not change -- let me just say to clarify, it wouldn't change the status of the way we distribute the information we presently do at all. In other words, currently when there is a recall we put together our documents, what we call our recall notification reports. That does have specific information on the codes of

products, the general distribution, meaning cities and states where we know the product has been shipped to. That would not change any of that, okay? We will continue to do that, continue to do our present policy on issuing press releases and so forth.

The rule only contemplates at this point the sharing with state or other federal agencies the actual customer lists or, you know, what we term the recall distribution information. If that's a point that we need to go back to clarify in the preamble, we can look at that again to make sure that we're clear there that that's what we're talking about.

MS. JOHNSON: One more question. In the preamble you do mention -- you refer to class recalls.

MR. GIOGLIO: Uh-huh.

MS. JOHNSON: Is it the intent of the actual regulation to limit this type of information sharing to Class I recalls?

MR. GIOGLIO: No. I think it would be -- as I mentioned earlier, it could cut across any class of recalls, Class I, II or III, provided that the administrator of FSIS

has deemed that it's in the interest of public health.

So the way the rule is written now, there could be a case where there is a Class III recall for an issue that is of no public health significance at all where conceivably that information would not be shared.

I would say in general we get the requests then. Really we get the requests on the public health related recalls, and generally the Class I recalls are of the most concern to everyone.

MS. JOHNSON: Thank you.

MR. BILLY: One clarification. Alice mentioned the regulation, and Charlie said the regulation. It is a proposed regulation.

MR. GIOGLIO: Right. A proposed regulation. Exactly.

MR. BILLY: I want to make sure that's clear to everyone.

Go ahead, Gary.

MR. WEBER: Gary Weber with the National Cattlemen's Association.

Just a curiosity. How would you verify who was

requesting to have the list provided to them? For instance, somebody calls up, and I say I'm Gary Weber. I represent the State of New York Public Health Department. How do you go through a process of getting that?

MR. GIOGLIO: Actually, that's part of the mechanism that we're going to need to establish, but actually before we would provide the information to a given requestor, okay, the particular agency that that requestor would be representing would need to provide the written documents to FSIS, okay, one, establishing their authority to protect the information, meaning that they would be operating under similar FOIA law that FSIS is or that the federal government is and that they commit then in writing.

The particular program or the particular agency would commit also in writing that they intend to maintain the confidentiality of that information. In other words, they would be using the information in much the same way then that FSIS uses it, uses it now.

MR. BILLY: And perhaps that might be an area that the subcommittee and the committee then might want to look at.

MR. GIOGLIO: Exactly.

MR. BILLY: One possibility would be to include in the protocol that the state agency or whoever provide a list of names of people that are subject to this arrangement or some mechanism like that.

MS. WOTEKI: My last question is what would be the penalties for somebody violating those provisions in a state? What would happen to somebody who didn't follow that? What would you do? I mean, we can talk about that in the committee, the subcommittee, but I'm just curious.

MR. GIOGLIO: Let me just say this. I don't have any specific answer to you on that. If a given agency would then have violated both their written commitment to FSIS and in fact had violated the Freedom of Information Act, I think that the same provisions that would apply today to a federal agency doing such would apply then in that case to the particular say state agency or the individuals who in essence disclosed that information in violation of the law.

MR. BILLY: I think we can get some clarification, but I don't think it's the provisions under the Freedom of Information Act. Rather, it's the provisions under some

other older Act like the Confidential Business Information Act or some.

As I recall, there are both civil and criminal penalties for the revealing of confidential business information. It applies to us. It would apply under these arrangements. Maybe that's also an area that the committee might want to consider.

Yes, Collette?

MS. SCHULTZ KASTER: Yes. My question is whether or not both FSIS and states would then be performing effectiveness checks, or is the intent to sort of coordinate this effort? I'm a little unclear as to the rationale behind how that would come together.

MR. GIOGLIO: Let me say generally the requests that we've gotten from state programs specifically, and that's both the state Departments of Health and in some cases Departments of Ag if they have meat and poultry inspection programs, depending on the individual state. They have requested the information from us primarily to do effectiveness checks, or in some cases they call them audits and so forth.

Often individual states go to the companies themselves and have been provided this information. That's generally where my office and others in FSIS would refer requestors of the information back to the individual companies that are conducting the recalls.

We would hope that through this effort we would be able to establish a more uniform procedures and protocols, okay, where if states were performing effectiveness checks that we would be -- they would be performing them according to the same protocol that we would, and I think that's going to have to take some working together of FSIS and the state programs to work out those mechanisms and so forth.

We have interest that the information then that the state is collecting would flow back into our system, and I think there's benefits for that both from our programmatic point of view and also for both the public and the companies involved, frankly, in that we will then be able to get a better handle on the effectiveness of the recall and in fact close the recalls out I think more quickly since we have more people performing the same type of work. We feel confident in the information coming in if we're all

following the same type of data collection activities.

MS. SCHULTZ KASTER: But that would be a Stage 2? That's not laid out --

MR. GIOGLIO: That is not.

MS. SCHULTZ KASTER: -- in the current proposal?

MR. GIOGLIO: No. That is not in the proposal.

MS. SCHULTZ KASTER: So as it is right now, that would just be -- that sharing would just be in limbo, and there would still be a duplication of efforts potentially between the two or a lack of uniformity between the two?

MR. GIOGLIO: That's what we're --

MS. SCHULTZ KASTER: A potential lack of uniformity, if you're more comfortable to answer.

MR. GIOGLIO: Well, that's actually one of the questions that we'd like the committee to address and to talk about, how best we deal with that particular situation and what mechanisms should we put in place so that we don't have, one, either the duplication of effort or lack of uniformity and so forth.

I think Question No. 4, you know, when you go through your packet, that that in essence is the heart of

the question that we're trying to get to.

MR. BILLY: One other comment that I would make to supplement what Charlie said is often when we get this interest in the list it's for the most urgent recalls where there's an imminent hazard to health and a desire, a strong desire, on the part of the states to really make sure that the recall is happening within their state.

You know, it's about public health protection, and they're really interested in facilitating the process I guess is the way to say it, so in those instances then this proposal would address that in the manner that it's laid out. You know, your questions still need to be sought through.

Rosemary?

MS. MUCKLOW: From a clarification point of view, I haven't recently looked at the kind of cooperative agreement that you sign up with a state where a state has an inspection program.

My memory tells me that under some circumstances in earlier years there would be a provision where you would do some very specific compliance work sometimes in a state

in order to assist that state with the compliance activities. Is that still part of your cooperative agreement with a state, or has that provision sort of disappeared over time?

Where there is a very clear community of interest and a structure set up with some very clear cooperative agreement there may be occasions where this could be useful, but we are dealing with companies' proprietary information. As Alice said, when there's a problem, a health problem, the product needs to be brought back, but there's a lot of information out there already.

The handing over of proprietary information to people unknown across states can be a very troubling question, so there is a balancing of the interest in getting the product back and using every means to do that and the potential distribution of proprietary information, which can do a company in, and so there is a very significant balance there.

I'd be interested in how the cooperative agreements with states up to now have been able to address such issues.

MS. HANNIGAN: Can I make a comment to Rosemary?

Rosemary, I really disagree with that because although we may be a big business or big industry, I think basically everybody knows whose customers whose are, if you will. That doesn't sound real well, but I just -- I'm in agreement with Mr. Billy.

I guess I really think when we're dealing with Class I recalls I think we probably need to do a better job with these effectiveness checks. Since I won't be part of this committee tonight, whoever is chairing it -- I think, Mike, you are.

MR. MAMMINGA: Yes.

MS. HANNIGAN: If you would so note, but I don't think this customer list is as proprietary as you may think because I think we basically know who everybody is co-packing for and where the product is being distributed.

MR. BILLY: Okay. Do any of the state people want to address Rosemary's question regarding what's in the current agreements and cooperation in this area?

Terry?

MR. BURKHARDT: Yes. I want to comment on a

situation that happened in Wisconsin this summer and also comment on Rosemary's issue.

In Wisconsin this summer, you know, there was a large E.coli 0157 outbreak in Milwaukee, and when something like that happens there is a tremendous amount of press attention. Right at that same time, there was a national recall of a company from Pennsylvania, and it was reported that product was in Wisconsin so immediately the press was jumping on that issue. You know, was this the product that was involved in that outbreak? It was right at the time where it wasn't sure at that point.

USDA was provided with that information, and, you know, at that time it wasn't getting a release to us. The press -- it was almost like the press said well, the product is in Wisconsin. Where is it? USDA was not allowed to say, so that was kind of an unfortunate situation.

As it evolved, though, USDA did share that information with us. It wasn't involved in that particular situation, but we were -- the state was very instrumental in identifying where that product was. We located it. You know, it was detained and so forth. It's very, very

important for that information to be shared with states, and in that particular case, as it turned out, it turned out real well.

As far as the cooperative agreements go, they're written broad enough to encompass something like this, I believe. You know, they talk about particularly in compliance all of the state compliance officers are dual certified, meaning they can do both state or federal work. They can go across state lines. Jurisdiction is broad, so I think that authority certainly could be encompassed in the current agreement. Again, it's really important to get that information to the states.

MR. BILLY: I have next Mike on the list and then Cheryl and then Nancy.

MR. MAMMINGA: Right now, between FDA and FSIS announcements on recalls go to many, many, many offices, and there are absolutely no controls in place now about what any state agency may do in response to the notice of a recall. Isn't that correct?

In other words, if the Iowa Department of Health gets an FDA notice about a recall of ground beef for E.coli

0157:H7, it may have come from some other place. There's nothing to prevent them from sending their people out without any coordination with you or me or anyone else. Perhaps this exercise will give us an opportunity to provide some coordination where there hasn't been any in the past.

I would like to have it a little clearer in my mind going into this. The proposal talks about, and this question was probably brought up right off the bat about customer lists or consignees. Is that the length and breadth of the proprietary information that FSIS might have in its possession, because if I were sitting on some other side of the fence and was concerned not only about each and every one of my customers, as people have eluded to, but perhaps also the amount of product, maybe even the price of product, that could certainly throw a monkey wrench, in my opinion, into this whole deliberation.

Could you share with me some clue as to what the companies provide to you that you might provide to us that we will expect to handle as proprietary information?

MR. GIOGLIO: Sure. For the purposes of recalls and what we are actually targeting here, the type of

information we are speaking about here, is the specific locations that a given company shipped the particular recalled product or products and the amount that they shipped there.

Now, along with that information, depending on the means of the mechanism that the particular company actually gives us that information, there may well be additional information on there, okay, that we don't need for our purposes, okay, for the recall. I mean, there may in fact be price information or other information that we cannot help, but that's the piece of paper that the company chose to share with us. We may have all that.

MR. MAMMINGA: I understand. I just wanted to have that out on the table --

MR. GIOGLIO: Right.

MR. MAMMINGA: -- before we started our deliberations. That was the only purpose, to hear that it might be there if the company provided it to you.

MR. GIOGLIO: Correct. Exactly.

MR. BILLY: Cheryl? Okay. Nancy?

MS. DONLEY: Do you see any way that this proposed

rule can work with the situation where you have a recall going out from a particular retail outlet and then taking it the backwards step of going to the distributor?

I'll give you an example that maybe in Chicago we have Jewel stores, and there's a recall going on at a particular Jewel store. Do you see any way that this particular document could then take it back and examine to the distributor level going the reverse route rather than distributing forward, but retailing backwards?

MR. GIOGLIO: This rules does not contemplate that really at all. It does not address that. I guess what you're actually referring to is what we've termed or what we've called a trace back where we actually attempt to trace back to where particular contaminated product may in fact have come from.

That information is collected by FSIS and let's say from a particular retail store. We do attempt to work backwards by looking at the particular retailer's records, the particular distributor who may have shipped to that retailer, their records and so forth to trace that contamination back. This rule would not -- actually does

not contemplate that. It really just deals with the recall distribution information.

I hope I've answered you.

MS. DONLEY: Yes. Is that something, though, that FSIS does routinely, that in the case where it is identified it tracks back?

MR. GIOGLIO: Yes. In the case where -- let me say this. In the case of a retail recall, okay, generally that's going to be ground beef, beef that was ground at the retail stores. We make every attempt to trace back to the source of the contamination.

You know, I can give you some examples, but there are a fair number of examples where in fact we were able to identify the suspected product, and we wound up verifying that that product was in fact contaminated and had larger recalls due to that.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: Thank you. Caroline Smith DeWaal.

I just wanted to note that this regulation is made essential because of the fact that the federal agencies,

both FDA and FSIS, don't have mandatory recall authority. Frequently the states have to initiate recall actions. It's just critical that they have this type of information in order to do their job.

We also don't have uniform recall authority by all the state governments, so there are lots of gaps in the system in terms of consumer protection because of the lack of mandatory recall authority both at the federal and also in some of the state agencies.

I'm glad to see this regulation. I'm glad to see that it's out for public comment, but it's vital that this information get shared and that food is removed as quickly as possible, given the gaps in the regulatory oversight.

Thanks.

MR. BILLY: Okay. Terry?

MR. BURKHARDT: Question. Terry Burkhardt. Considering how food is distributed in this country and bought and sold several times, would this rule cover it after the original producer has sold it to a distributor and then it's again sold? Would it follow it all the way through?

MR. GIOGLIO: Yes.

MR. BILLY: Nancy?

MS. DONLEY: Just one question. Is there any reason or rule or law that says this has to be done on I'll say, for lack of a better term, a passive system? Is there anything that would prohibit FSIS from automatically disclosing -- distributing this information to states without being asked, but just automatically to designated state and local officials to release this information?

MR. GIOGLIO: There is nothing that would preclude that. I think that's something in, you know, the subcommittee to discuss. What is in fact or what would be the best mechanism to make the information available? That's at least one option --

MS. DONLEY: Okay.

MR. GIOGLIO: -- to do that. There's probably any number of different models that could be followed.

MR. BILLY: Rosemary, a last word, and then I'll ask Mike a question.

MS. MUCKLOW: I'm not sure that the issue of mandatory versus voluntary recall is appropriate here. I

always used to make my favorite statement is when did you ever not get cooperation, but now we have a company that didn't cooperate recently.

I don't know if they ever saw the light to that, but it is unique when a company does not cooperate, and we may have one famous or infamous case now that cooperation, cooperative recalls, are what are really needed to get product off the shelf.

As Alice started this discussion with a question said we all want to get that product back the best way possible, and cooperative recalls are the way to do it.

Thank you.

MR. BILLY: Okay. Mike, you chair the subcommittee. Are you comfortable with the stage that's been set? Are you all set?

MR. MAMMINGA: Sure.

MR. BILLY: All right. Good. All right.

MR. MAMMINGA: If it were easy, everyone would do it. We'll just go at it.

MR. BILLY: Very good. All right. Charlie and others will be available tonight to answer any more

questions that the subcommittee has.

Okay. It's about 12:08. We're scheduled for a one hour lunch, so let's be back about 1:15 at the latest.

We have a little bit of information in terms of where you can eat. There's restaurants here in the hotel, but there's also a food court that we can give you directions to I guess from the lobby.

MS. LUCAS: If you'd like to go to the food court, if you go out of the room here to your left and follow the corridor all the way around to the main lobby and take the second elevator on the right-hand side of the main lobby to the promenade. Once you get on the elevator, there's a P marked for the promenade.

Once you exit the elevator, turn to your right. You'll be in the mall area, and there are several eating places in the mall for you to go to.

MR. BILLY: Okay. Thank you. See you at 1:15.

(Whereupon, at 12:08 p.m. the meeting in the above-entitled matter was recessed, to reconvene at 1:15 p.m. this same day, Tuesday, October 31, 2000.)

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

(1:19 p.m.)

MR. BILLY: I think we'll get started again. I appreciate the committee being back here in a timely manner. We've got many other important issues to address, and I want to get on with the agenda.

The next issue that we've asked one of the subcommittees to address --

MS. MUCKLOW: Just before you get going and before you get everybody in here, I would like you to know that this nice token gift that you've got sitting waiting for us does in no way assuage the anti-family sentiments that I expressed to you before lunch.

I admire you for producing this really fast, but it is really anti-family of this Department and this Administration to hold this meeting away from people's homes and to keep us working into the evening, Mr. Billy. I just want to register my complaint that we are here on Halloween.

I understand we were also here on Mother's Day. It bothers me somewhat less. Halloween and Mother's Day. Better be Yom Kippur and Christmas next year or something.

MR. BILLY: An interesting idea.

MS. MUCKLOW: Thank you very much.

MR. BILLY: Some things are better off not responded to.

MS. MUCKLOW: I understand.

MR. BILLY: This issue that we'd like the committee to consider, and this falls to the subcommittee that Katie chairs, is the subject area of HACCP Phase II.

Now, I'm sure all the committee members have noted that there's no paper in the briefing book. There's nothing to make available. I'm going to explain that and also set the stage for some very brief presentations from four people in the agency that are involved in key aspects of the very formative process of figuring out what this really is, this HACCP Phase II.

I made a comment this morning, and I want to repeat it right now, which is that we have a very strong desire to be transparent and to involve not only this committee, but the public in our processes. This is another good example of that.

It is our intent to develop a Federal Register

notice, to have papers and other things available to share in advance of the public meeting that, as I indicated earlier, is going to be held probably in December. We haven't locked in on a date yet. We're having some problems because of how busy December is and being responsive to some of the concerns that Rosemary raised. I just thought of that, Rosemary.

What we can do is I'll set the stage. We'll share with you some information, and it will in fact demonstrate to you that this is in the very formative stage, but, nonetheless, we think it's valuable to have this committee be aware of where we're headed and to have an opportunity to share your thoughts or ideas with us at this stage.

As all of you are aware, we've gone through the process now of having industry implement HACCP in their plants. That's both the 6,000 federal plants and the 2,500 state plants where there are state programs. While we believe that we had good success in getting HACCP in place, our view is, based on our experience, that there's plenty of room for improvement both in terms of industry and what it's doing, as well as FSIS and the state programs in terms of

what they're doing.

Let me be a little more specific about that. It's taken us a little over three years to get to where we're at in terms of implementing the pathogen reduction and the HACCP rule. It has a lot of provisions. It's got the SSOP, provisions on sanitation. It's got HACCP that was phased in based on plant size as you're aware.

After that now initial three and a half year period, what I think is appropriate for us to do is to now ask two questions. The first question is what can industry do to improve the quality and effectiveness of its HACCP programs?

Now, I recognize, and I think all of you will as well, that there are plants out there that have excellent programs, there probably isn't a lot more that they can do, but as for every one of those plants there are other plants where there's plenty of room for improvement. They don't fully understand HACCP. They may not fully understand the responsibilities. They have the same plan now they had two years ago, and HACCP is supposed to be dynamic. There are things that I believe industry can do to improve the quality

and effectiveness of HACCP for consumers.

In parallel with that and just as important, I believe there's plenty of room for improvement in terms of what FSIS and the state programs are doing carrying out their responsibilities under HACCP. We've heard concerns about inconsistencies within FSIS and the application of the regulation, the recommendations for more training, recommendations for other steps that we can do to improve our effectiveness in carrying out our responsibilities under a HACCP framework.

It's my view, and I hope it's your view as well, that it would be worthwhile to have a process now that HACCP is in place where we will address those two questions and that we would address them together. What we're planning to do is we started various groups within the agency to begin talking about this. You're going to hear in just a minute some of the ideas that the people within the agency have surfaced, and that's just fodder for you in terms of your thinking about that.

What we're planning to do is hopefully come together with a strategy that would set some priorities in

terms of addressing these two questions and that we would be able to announce the strategy sometime around the end of January, the anniversary of HACCP implementation throughout the industry, the idea being then that we would go through a process.

We'd consider all the ideas, and we'd sort through them. We'd set some priorities, and we would then move forward in terms of improving the quality and the effectiveness of HACCP plans in industry and improve the effectiveness of what we're doing at the federal and state level to make sure that HACCP is working as well as it can for consumers.

Recognizing the possibility that we needed to do something with this, we've started several groups that are addressing different aspects of this. What I've asked are for four five-minute presentations, and I'd like them to be done in sequence. If you have any questions, note them down, and we'll ask the questions after we're finished because one presentation might answer the question and it hasn't been given yet.

First, I'm going to ask Ron Hicks to talk about a

retreat or a go away that the senior executive management of the agency had a little over a month ago, I guess a couple months ago now, to explore these questions and describe to you how we approached it and, more importantly, some of the ideas that came out of that process.

Ron, would you go ahead?

MR. HICKS: Good afternoon. We took all of our senior managers from headquarters and the field out to Baltimore a few months ago, and we went there for a couple different reasons. It was the first joint -- I guess first corporate meeting of our senior manager leadership where we started to dialogue on HACCP next steps or HACCP II and what we thought it was.

We went there to develop themes and issues associated with those themes to try and set some priorities and to start to do some responsibility charting to make sure that we had the right people taking responsibility for the right issues through their completion.

We had a couple different outcomes in mind when we went there. First was to create a blueprint for implementing HACCP Phase II or HACCP next steps; also to

discuss communications issues as to how the communications issues impact the work that we do and in fact our work force and discuss ways to improve upon that communication.

The third issue was looking at workplace environment issues, issues that impact our work force so that we can insure that we're getting optimal performance out of our work force while at the same time doing the things that we need to do by our work force. Those are three general outcomes that we had in mind when we went to Baltimore.

The first thing we did was that we broke down into what we called stakeholder groups and asked to list issues from the perspective of different stakeholders, FSIS being one, consumer groups being another, industry and so on, the media, and attempt to try and start to put issues on the board, on the flip charts, on the table, that we felt were most important. We did that based on the question based on all that I know about HACCP, we can achieve better results and implement it more successfully if we, and we all completed that from those various perspectives.

Once we had all of these perspectives on the

board, we then consolidated these into what we called stakeholder themes, and we came up with five different themes. The first theme was structure/resource issues. The second theme was risk based program design/authority issues. The third theme was training and education issues, fourth was workplace environment issues, and the fifth was communication issues.

Since the meeting in Baltimore, one of the things that we've been most encouraged with is that, as Tom has indicated, as subsequent groups met on the same general overall issue of HACCP II or HACCP next steps they came up with some of the very same major themes and major areas that needed to be focused on.

I just want to give you a rundown of what were the primary issues or the priority issues that each of the individual groups came up with under these various themes. Under the theme of risk based program design/authority issues, I guess the first priority that was mentioned there is we need to define what is an adequate hazard analysis and what is an adequate HACCP plan. That was the first thing that was seen as a priority.

I won't give you all the priorities, but I'll give you a flavor of some of the other ones that were under there. What's the role of GMPs in HACCP, the need to clarify the distinction between hazard, risk and intended use, risk based performance standards, insuring that we have adequate tools to enforce HACCP. Those were seen as the top priorities that needed to be addressed and further developed in subsequent meetings from the group that worked under that particular theme.

Under the next theme we had infrastructure/ resource priority issues, and this is FSIS infrastructure. As you all know, we reorganized it three years ago and went from a certain number of regions to a certain number of districts and made some other organizational changes, too, all with the purpose of allowing us to better and best implement HACCP.

Now we feel there's a need to look at some of those decisions again and make sure that we have the proper organizational structure to best make HACCP work, as well as the infrastructure in place to support the managers and employees responsible for making things work.

Some of the key items under that, the first one obviously would be do we have the infrastructure to support the mission. The second priority was to provide work force tools and empowerment. It's very important to make sure that the people that we're asking to do the work are adequately provided tools to do so and are adequately empowered to get the job done.

We need to hold the work force accountable from the top levels to the bottom rung, if you will, and we need to continually evaluate the system. Those were identified as the four key priorities under this particular theme.

Knowing full well that since this is not a final product some of these priorities will be changed, some will be added to, some may be revised based on our follow up discussions and feedback and input that we get from you, but the current thinking at that meeting was that these were the top four priorities under infrastructure and resource priority issues.

The third one involved training and education, and this one absolutely as specifically as I just said it has been raised by each and every group that has taken on the

HACCP II/HACCP next steps challenge. The issues raised under there were supervisors need the resources to deliver training to employees from a time standpoint and from a fiscal standpoint.

Employees need to have the knowledges, skills and abilities to deal with the complexities of the job, so it's very important that we take that issue in a very real way and see what adjustments, changes and improvements need to be made.

Needs of the agency to partner with other agencies and other organizations. The agency needs to invest in outreach to its stakeholders. Those were the key areas that were identified under training and education issues.

The fourth major theme was workplace environment issues. I was part of that group, and it was very interesting to hear some of the things that came out of that as primary issues. Some have been deleted, but some of the primary issues were the need to value our employees and their contributions. That's pretty obvious and speaks for itself, I think.

The need to have more effective management and

supervision. Under this whole area of workplace environment, it was interesting that so much of the responsibility, and probably improperly so, was placed on managers and supervisors to make sure that the workplace environment is the one that it needs to be.

Accountability is clearly defined and expectations and roles are clearly defined and quality of the work life. It's very important that if you ask people to do bigger jobs, tougher jobs, stronger jobs that we continue to consider the quality of work life in terms of taking care of our employees as well. That was a very nice group to be part of because they are issues that are very near and dear to our hearts in there.

The last one, the last major thing, was communications issues. The number one priority under that was the need to clarify rules, roles and procedures regarding HACCP. A couple of the other issues identified was the need to expand formal and informal opportunities for input and feedback. I think we do a good job of that, but there's recognition that we can do better.

Enhance the development and proactively provide

information to the media and other stakeholders, strengthen and expand partnerships through improved communications and to review and strengthen our communications infrastructure.

Those were the five key areas that we identified. Those were the issues and the thinking at that time that were identified as issues under those themes. We have a follow up meeting next week of our senior managers on the 8th and the 9th here locally where we're going to further develop these themes and these issues, and we'll see what happens at that point.

Thank you.

MR. BILLY: Okay. The next meeting that was held again in this formative stage was held by Dr. Mark Mina of the district managers and other officials from our field operations area.

Similarly, we posed the same questions to our field folks looking at it from their perspective, so now you're heard sort of some of the headquarters people. Now we're kind of looking at it more from the field perspective. There are a lot of common areas, also some unique ideas that they came up with.

Mark?

MR. MINA: Okay. Thanks Tom. As Tom indicated, we met the first week in October, and we devoted two full days to address the issue of HACCP Phase II. Of paramount importance was for us to strengthen the foundation that we built over the past three years.

We continued to work on continuous improvement and make continuous improvement in this process because we cannot afford to back slide. I think we need to make every effort, collectively and cooperatively, to succeed in that effort. That's how we started our meeting.

As Tom said, there are areas of overlap between what Ron talked about and the district managers talked about. One of the issues -- we divided the issues in about three major categories. One of them is organizational structure that focused particularly on the field operation organization and whether that supports HACCP the way we're structured today or we need to take a second look at that and maybe refine it and adjust it.

One of the things that the district managers talked about is to make sure that we have not only the right

number of people, but the people that have the appropriate skills. I think as many of you know, we are working on upgrading the skills and knowledge of our work force not only at the in plant level, but also at the district level, because it's extremely important to provide that scientific and technical support in addition to the supervision and management of the system.

One of the issues that is extremely important for us to follow through on and we're working hard to accomplish it is to free time for the veterinarians that are in our plant to get engaged, fully engaged, in HACCP evaluation. As you know, today most of our veterinarians are kind of tied up with the slaughter operation and maybe don't have the time to devote and properly use their skills and knowledge and their education.

We have not as an agency capitalized on that knowledge and skill, and so we are in the process of figuring ways to kind of free the veterinarians' time so they can spend time on evaluating HACCP and actually work maybe with the producing community in other areas like residues and other appropriate areas. That's also a

recommendation that was made by the task force of the future, so we're following through on that.

Another area that the district managers talked about in terms of the organizational structure is for us to look at the circuit supervisor position and the in plant inspector in charge and their subordinates and see if we can make some changes in that area that would benefit us in implementing -- in strengthening HACCP.

The second major area, and you're going to hear a lot more about that obviously, is training and education. We trained all our inspectors, and they've all been through that eight days of HACCP training. That I think served us well in the first phase of HACCP implementation. There is a lot of areas that we need to train and I want to emphasize educate -- more importantly educate -- our inspectors and teach them what is the scientific basis for all the decisions that we make.

In addition to the regulatory basis for those decisions, they also need to understand why we're doing what we're doing, so training and education received a lot of attention from the district managers. They made a lot of

suggestions on how we do that.

The third area, and this is also a very important area, is FSIS/industry relations and how do we improve that not only in terms of sharing information, but also in terms of how we deal with each other professionally and conduct it in a businesslike manner.

Now, in terms of sharing information, they made several suggestions about inviting industry to district manager meetings and circuit supervisor meetings, also maybe creating a chat room and put case studies on the internet and have a discussion about actual case studies because we have three years of experience in HACCP. We know what works well and what doesn't work for us and have a discussion about what worked and what did not work. Also maybe develop some CDs and share those.

We also are seriously considering face-to-face training sessions. You know, that's probably easier said than done because of the large work force that's geographically dispersed throughout the country, so we have plans to do some face-to-face training plus using the technology that we have today to transmit that information

and, more importantly, share that with industry so we'll all be hearing the same thing on what's required and how we're going to accomplish it.

Basically those are the three areas. There are several subtopics that I'm not going to get into. I'll turn this back to Tom.

MR. BILLY: Now, our plan at the meeting coming up next week is to have several representatives of the field, the district managers, participate now with the executives that met in Baltimore, so we're starting to blend this together to come up with more comprehensive themes, if you will, of the areas that we as an agency need to focus on, as well as any ideas we have for industry in terms of what they need to do.

Another area that will contribute to this is the area headed up by Yvonne Davis, which is our work force of the future task force. This has been underway for over a year, and it's focused on identifying the make up of our work force that we need to carry out our roles in the future based on a HACCP environment.

Yvonne has also had her task force look at this

area and come up with some recommendations. Now, in this instance her task force is made up of people at all levels of the agency, so now we're moving away from management to people at the inspector level, the technician level, all throughout the agency and different parts of it. I'll let Yvonne explain some of the ideas that they came up with.

MS. DAVIS: Thank you, Tom. Well, as Tom said, our steering committee does represent a good cross section of the agency. We have about 35 individuals that come together periodically to talk about work force issues.

Our most recent meeting was at the end of September, and we also focused on the same themes, wanting to come up with a set of recommendations that would be useful from a work force perspective in helping the agency improve the effectiveness of its HACCP program, improve the work place environment and communication and also to deal with some of the cultural change that this group felt was needed to further the agency's mission.

In terms of the first theme that we looked at was HACCP and looking at it from the standpoint of beyond basics. Where do we need to go now with HACCP now that it's

implemented, has been in place and is operating? They had a number of recommendations in this regard.

Two major issues that they focused on were that HACCP plans need to be improved to make the system work as effectively as possible, and they said that one way to do that would be to establish FSIS teams to look in depth at HACCP plan design and do correlation with industry and inspection.

They talked about developing guidance materials on realized case studies for technical assistance to industry. At Dr. Mina's supervisory conferences that he held this year there were sessions on case studies that were very effective in communicating how to evaluate if HACCP systems are working and carried out as they are intended. This group felt we needed to do more of that work using case studies and working with industry.

Also, have an industry/FSIS meeting on best practices. Industry could use it as a forum to highlight and recognize good plans and again use the format of a case study.

In terms of the second issue, which is FSIS needs

to improve the effectiveness of inspection under HACCP, the group thought that we needed a training needs assessment. You're going to hear a lot of recommendations about training and education. I think you heard it from the district managers, from the executives, and you're hearing it from the work force as well.

Specifically, this group felt that we needed to refocus and retrain on hazard analysis, scientific validity, enforcement, regulations, data interpretation, critical thinking and applied computer skills.

We also need to change the supervisory mind set in terms of accountability, training, improved camaraderie, more teamwork, rewarding good practices and providing good supervisory models. I think we have a lot of very effective supervisors. We have some that need to do more work.

They are also dealing with a new system and all the change that's going on in the agency, so we need to provide support to them so that they can carry out their responsibilities. Creating resource teams for correlation, answering questions on site assistance for both improving HACCP plans and the effectiveness of inspection.

This group, too, recognized that the VMO, the veterinarian, needs to have time freed up to focus up on systems kinds of analysis, leaving free the supervision that takes place in the large slaughter plants to perhaps a supervisory food inspector. They felt that that was very important.

The second issue or theme that we looked at was workplace environment, and the group was very energized by talking about the environment. A couple of issues that they focused on was the employees often do not feel valued by the agency. Not a surprise. I think that things are happening so quickly in FSIS with all the changes that sometimes you feel kind of lost as an employee in the process.

They thought that maybe it was a time to take a look again at how their performance is appraised, although they did agree that a new performance appraisal system itself may not be the answer. It may be making sure that the current system is carried out in an effective way, that they do get appraised, that they get good, rich feedback on where they need to improve, looking at the award system, making sure that it's recognizing effective performance.

The second issue area under workplace environment was some field employees do not feel they have the information that they need to perform their jobs, and one of the recommendations was to encourage or insure that circuit supervisors and IICs hold quarterly work unit meetings. They felt that that was a really effective way of getting across information from the immediate supervisor. Of course, that supervisor needs to rely on the rest of us in the agency to get the information to them to convey in a meaningful way.

Also, an issue was with 90 percent of the FSIS budget needed for salaries, there's very little discretionary budget available for the agency to provide many of the employee programs it needs to make it an employer of choice. You'll hear that over and over again. FSIS needs to be an employer of choice.

We're having a difficult time recruiting, as many organizations in the public and the private sector are, and so we need to put in place the kinds of employee programs that will help encourage people to come to FSIS and to stay. The way to do this would be to provide convincing evidence

to Congress that we need more discretionary funding to provide these programs.

The third theme, and we want this together, is training, education and communication. The first issue was the agency must recognize training as both a priority and a necessary work force investment. I know you'll be hearing more about that under our next topic.

Under the current system, training funds are the first to be cut. I think everybody understands that, doesn't like it and wants to change it. The group recommended that we dedicate funding for training through a budget line item. This is not the only group to make that recommendation, but they did feel that that was an important way of insuring people get the training that they need, especially in a new system.

Factor in ten percent of inspection work time for training activities and a new work assignment system was another recommendation. Again, we feel that distance learning is very -- is a good vehicle for lots of types of training, but they also felt it was important to look at what the training was, the content of the training, to

determine when distance learning is the most effective or face to face discussions or training are more important to do.

Improve supervisory skills of all managers through training in this communication with their subordinates. Team building, performance appraisal and managing conflict and delegating work. Lastly, provide training in workplace violence prevention, conflict management and change management to all FSIS employees.

The last issue, which I think is an important one, was sharing and obtaining information should be every agency employee's responsibility. I think the group understands that it's difficult to maintain communications on a regular basis with a dispersed work force when things are changing so rapidly and that it is also the employees' responsibility to use the information and the tools that are out there, the vehicles, to keep informed on these changes and how they affect their daily work environment.

The last issue that they addressed was culture change, and we set this one apart from workplace environment because we thought it needed some specific focus. The first

issue was that FSIS needs to shift its culture to insure that employees at all levels are held accountable for their assigned responsibilities and are prepared for their new roles in a dynamic, changing organization.

This one I think does deserve some special attention that the group recognizes that we are all accountable for our own performance. I think this is a change in culture. I think our agency has often times felt that supervisors are responsible for telling us what to do and when to do it and how to do it. I think that today the work force realizes they need to do a lot more for themselves to make sure that they're doing their jobs properly.

Also develop a mechanism to shift employee attitudes towards both industry and their co-workers from kind of a top down command and control finger pointing/fault finding to a more collegial, cooperative and professional relationship.

Lastly, all cultural changes should be accompanied by thoughtful, integrated transition processes. Again, this notion of the need to manage change is very apparent.

Transition planning needs to be an integral component of any major change to insure that the merits of the old system are brought into the new and that management or union field and headquarters employees are all on the same page.

Lastly, recognizing that FSIS has an aging work force, provide an effective succession plan with appropriate use of retention bonuses to make sure that we have the work force that we need to carry out the program, today's program, and the food safety system of the future.

MR. BILLY: Thank you, Yvonne.

The last presentation is going to be given by Jeannie Axtell, although it is Peggy Nunry that has headed up this area, which is our TEC 2001 group focusing on training and education, so we've gone from sort of the very large picture, and now we're narrowing it down. This is a little more specific focus on this very important area of training and education.

Jeannie, five minutes.

MS. AXTELL: Yes, sir. Thank you, everyone. Peggy is here with us today, but has just returned from leave. Rather than put her on the spot, she's here to

answer questions that may come up later just in case I don't give the right answer.

The Training and Education Committee 2001 is what we've called TEC 2001. This has been a separate effort that's been underway for the better part of a year now and has had a dual focus. The first focus of this committee has been to look at what are the KSAs that our employees need, and by KSAs I mean the knowledge, skills and abilities that our employees need to be successful in their jobs.

I think as you heard from the presentations that Ron, Mark and Yvonne have given, the notion of employees understanding the complexities of their jobs and being properly equipped and empowered to carry them out is a very common theme that has transcended all of these various work activities.

The second focus for the TEC 2001 committee has been to explore what our responsibility is as a federal agency to provide for shared training and education opportunities with various stakeholder partners, and by stakeholder partners we mean very broadly speaking industry, consumers, state and local agriculture and public health

officials, our international trading partners, academia and the American public from the standpoint of food safety education.

As one part of the TEC 2001 effort, this past summer a future search conference was held in which these various stakeholder partner groups were brought together to begin to talk about some of these opportunities for shared training and education experiences and through that to begin to discuss some common ground for the future.

This afternoon I'm not going to touch on all aspects of what came out during the future search conference, but simply to highlight those particular thematic areas that were held in common with the themes that have been discussed at these other sessions that have been held in subsequent weeks. I think you will find in the identification of these again there is beginning to be a very broad and common sense of a set of themes that should be undergirding efforts that we're doing in the training and education area and that spread across the agency's initiative.

The broadest one is the issue of partnerships and

collaboration and the whole notion that at all levels of government, industry, academia, with consumers and with all stakeholders we ought to be looking, FSIS ought to be looking, for opportunities for partnerships and collaboration in areas that will facilitate understanding.

There's also beginning to emerge in both private and public sector efforts the concept of the food safety university, and in addressing this very broadly just as a university may have many school and colleges within it that focus on a variety of disciplines, the notion of a food safety university has begun to emerge in a variety of settings as a way of being able to speak to comprehensive food safety education efforts.

The notion that food safety education efforts need to be interdisciplinary, they need to focus on certain core competencies, that there needs to be some discussion of certification associated with it, some concept that learning, that education and training is not a one time endeavor but a lifetime over the course of the lifetime of a career and that there's a sense that there are certain unified, standardized training activities that are important

regardless of what the partnership or the collaborator/ stakeholder effort is.

I think through all of this there's also been a common theme about evaluation; that we really need to learn to develop and to have various evaluation mechanisms that help us to determine if the nature of the investment that is being made in training and education is in fact paying off in terms of the performance of those receiving it and that we have -- that we're focusing on the right things in the training and education delivery and investment that's being made.

Certainly the notion of the use of technology as a means to facilitate training and education is also a common theme across a number of these activities, and technology both from the standpoint of the infrastructure, telecommunications, computer equipment, access to information, all of which can be used to communicate ideas and to facilitate distance learning as appropriate.

I think also the concept of credentialing for food safety workers in both the public and private sector is at least a topic that had begun to surface through these

discussions and other discussions in both public and private sector as an issue for discussion. I don't know that there's necessarily any consensus around the notion of credentialing of accreditation or what it means, a certification, but the concept at least is surfacing for discussion.

I think last, but not least, there have been some innovative ideas that have come to the surface as well; for example, notions that in many respects training and education in particular may be able to be something that is associated with compliance interventions that as there are particular types of enforcement issues or difficulties in the execution of HACCP systems that the notion of education in some way being an appropriate compliance intervention, the notion of that has at least surfaced for discussion.

Again, these ideas are formative. These are just a few of the ideas that surfaced through the future search conference that have broad thematic points in common with a number of the issues that have surfaced in the other endeavors.

MR. BILLY: Okay. Thank you very much. Thank all

of you.

This was designed to give you a sense of the broad perspective that we as an agency have been using to look at this next phase of HACCP. Obviously there are many, many ideas that you just heard.

Our intent here isn't to expect you to talk about each and every one of these different ideas, but rather to give you a sense or a flavor of all the different possibilities and then use the knowledge of this committee, your experience, your knowledge, to see what you think in terms of what you've heard and from your own experiences the points that you think ought to be emphasized or included in this next phase of HACCP.

As I indicated, we're going to be taking representatives from all four of these groups and some others and bringing them all together in a process that will narrow this down and bring some focus to it and some priorities, as well as some setting time frames and who's responsible for what, so you're on the very front end of an important process, but we wanted to take advantage of you being here to get you to think about this and to provide

some input.

Let me open it up now for some comments and questions. Yes, Carol?

MS. TUCKER FOREMAN: Carol Tucker Foreman with Consumer Federation.

Tom, at a meeting a little over a year ago I think you had a presentation similar to this, but current thinking on your challenge to have the strategic plan address how to accomplish a safe food supply.

MR. BILLY: Uh-huh.

MS. TUCKER FOREMAN: Could you draw some lines between what you've been doing here and the challenge that you made in the strategic plan?

MR. BILLY: Sure. That strategic plan is in fact the plan that we've put forward to the department as our plan for 2002 through 2007, but I guess a way of thinking of positioning these two things is that the question we're posing here today and what we're talking about in terms of the next phase of HACCP is what we're going to achieve in the next two or three years working towards that kind of outcome, so that's a way of positioning the two I guess is a

way to say it.

FSIS and the state programs, you know, are like any private sector company or corporation. You need to step back periodically and ask yourselves how things are going, what's working, where is there room for improvement and to go through a process that helps you answer those types of questions.

That's what this is about, but we wanted to include not only ourselves, that is the regulatory agencies at the federal and state level, but also the industry because it's the industry that has the HACCP plan, that executes the HACCP plan, and we think that there needs to be leadership in the industry in terms of addressing how to make HACCP work more effectively for consumers, so we'd like to see this move in parallel.

We've been encouraging industry to think about this and identify strategies that they believe will help all 8,500 plants at the federal and state level to do the best job possible under a HACCP type framework, so that's sort of the relative positioning of it, I think, and again this is in a very formative stage. There will be more opportunity

for input as we start to now really put some specific ideas down on paper.

Caroline?

MS. SMITH DEWAAL: Thank you. Caroline Smith DeWaal.

I'm not hearing the thing that I naturally thought was going to be part of this plan, and that is the issue of updating the performance standards and the use of additional performance standards. I think, you know, every time the Secretary gets out and talks about the HACCP program he talks about the salmonella reductions and so I guess that's one question is where is that? Why isn't that being addressed squarely?

I think the closest I heard to it was Jeannie Axtell on evaluation mechanisms, but so much of this, Tom, seems to be focused on your work force. I understand that's a huge management issue and that's an appropriate -- given some very recent history, there is an appropriate focus there, but I think the vision of the future needs to encompass more than that, and I guess I'm not seeing the gap.

I see a lot of focus on issues of training and, you know, freeing up the vets to do more and better evaluation of HACCP, but I see a good discussion of where we are. I don't see yet the discussion of where you're going.

MR. BILLY: Okay. Ron in fact mentioned that area. It was the risk based program design authority issues. When he made reference to risk based performance standards, that was perhaps a less than clear signal, but we do see that as part of what we're talking about there.

It in fact has been discussed and it is viewed as part of what's on the table in terms of moving forward, so it's both refining the HACCP or reconsidering the existing salmonella standards and, where appropriate, tightening them up as signaled in the preamble to the final rule, as well as the possibility of other performance standards.

You should also think in terms of the work that's been ongoing with regard to E.coli 0157:H7 and the policy that we put out in January of 1999 and the follow on work in terms of sampling and the public meeting that we had earlier. That's about refining HACCP and refining our approach.

The same is true for listeria, the public meeting we had, the current thinking paper that was put out several months ago. That is being subsumed under this overall package, but we're open to other ideas and for you to have discussion about this, so it's not -- you know, at this stage it's making sure that the things that you think are important are part of this, and then we can work from there.

Other questions or comments? Katie?

MS. HANNIGAN: Yvonne, if you would be so kind? One of the second things you mentioned, and I did not get it all wrote down -- I'd like to have it for tonight -- was you talked about refocus, retrain, and you said on the hazard analysis the science behind the HACCP program. Can you just go through that one sentence again? I didn't get it wrote down.

MS. DAVIS: Okay. Hazard analysis, scientific validity. We need more focus on enforcement, regulations, data interpretation, critical thinking and applying computer skills.

MS. HANNIGAN: Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: Tom, thank you. When you discussed this last week in an industry meeting, one of the questions I raised, and I think it needs to be raised again here today, is that the Department's authority with the major shifts that it has made into HACCP and performance standards and other places has been tested in the Courts in the last several years in various Court cases.

I don't have a litany of them, but there are several that instantly come to mind -- the honey baked ham, the Supreme, the HIMP, and I'm sure there are others if I put my active mind to working on it. I just don't think you can begin to really evaluate HACCP II unless you begin to reevaluate the authority because we are dealing with a law that was originally written nearly a hundred years ago, updated fairly substantially about 30 odd years ago, but hasn't been touched much since. Tinkered with a little bit.

Efforts have been made to change it, but I think there needs to be some thought go in this process about the underlying authorities of the Department. I would think that that has to be part of the consideration and discussion. We shouldn't have to meet up on the Hill and

fight out in the trenches over changes to that law.

It would be a lot more appropriate if we could at least find some common ground to work together to try to find the way to make the future better for all of us. I just don't think we can exclude the statutory authority and the way in which the agency has been tested in recent years on that.

MR. BILLY: Thank you, Rosemary.

As I indicated last week and will say again, our approach in the discussions that you've heard and the thinking we're doing is from a fairly pragmatic point of view of we have existing laws, and we're going to figure out how to make HACCP work best for consumers within that framework.

It's obviously up to this committee and others to consider and discuss whether it's necessary or appropriate or desirable to have modification of the laws be part of this process, so I'm not taking any position on that at all. I'm just encouraging you to talk about it, think about it, and that can be an important part of your discussion.

Any other comments? Yes, Nancy?

MS. DONLEY: Nancy Donley. I'd just like to say that I find it very encouraging that instead of just saying okay, it's implemented, we're done and go on another hundred years that it's being revisited and being retooled. I just encourage you to make this an ongoing thing that we have HACCP II ad infinitum and just keep making it better.

MR. BILLY: Thank you.

Jim?

MR. DENTON: Quick comment and then perhaps a question to follow up with Jeannie, I think, or anyone else that wants to jump in. Pardon me. My voice is about to fail me. An unusual situation.

I'm real intrigued to hear the use of the term training and education as much as we have throughout the discussion beginning with Ron and continuing through with everyone else. As you know from comments that I've made before, I feel very strongly about that being a real cornerstone for taking HACCP, if you will, to the next level.

We have grappled with that just a bit there at the University of Arkansas, pulling several departments together

and looking at putting together a multi-disciplinary master's degree program in food safety geared toward providing the type of people that will benefit both the industry and the regulatory community.

I would like to hear a little bit more about this concept of the food safety university. I completely agree with the multi-disciplinary approach. There are a lot of things that enter into this, but the one question that I had was about the certification or credentialing, if you will, with regard to the folks that may be coming out of such a program.

We've even considered putting together a program that would capture a lot of other players in providing the type of education that's necessary utilizing distance education as the framework whereby we do that.

MR. BILLY: Okay.

MS. DAVIS: I'll take that question if I can. Thank you for asking that.

Actually, when we did the future search conference in July, we had Dr. John Mycik from Arkansas there. He was a very valued participant and gave us a lot of good

information about what you all have been doing along with Tyson Foods, and I think that's a commendable effort that you all have done.

The food safety university idea is something that is being discussed among several federal agencies right now, and we are one. FDA is another. EPA is another. This is an idea of collaboration among federal agencies as a starting point and then expanding that out to all of the other interested parties or stakeholders, if you will; the idea that why reinvent the wheel if it's already running someplace else? How can we work with our sister agencies, particularly those who are interested in food safety, for the benefit of everyone?

As Jeannie mentioned in her presentation, the idea of a food safety university would encompass those various particular areas of study that federal agencies and the industries that are involved with those agencies are particularly interested in. With us it would be things like meat processing, manufactured foods, that sort of thing.

But where can we go to find the information or the expertise that we can take advantage of to share with our

employees and to share with all the other people with whom we want to establish this partnership? Again, it's just in its infancy right now. We're really just sort of taking baby steps towards this idea of a university, but it was something that came out very strongly during the future search conference as an idea that everybody bought into. It was one of the ten or 12 main ideas that had a consensus around it at the conference.

We want to look to people like Arkansas, other universities who are interested in doing things with us as well, to help us develop a curriculum that our own employees can take and benefit from and that we can do in conjunction with the industry people.

Does that then answer your question?

MR. BILLY: I guess it's clear that this is sort of a university without walls.

MR. DENTON: Right.

MS. DAVIS: Oh, absolutely.

MR. DENTON: That's the thing that we came up against very quickly. It gets beyond the capabilities of any one particular institution to just do the best job.

MS. DAVIS: Absolutely. Absolutely. We just chose the name university, you know. We could have said anything -- consortium or gaggle or really just about anything we could have thought of, but university because people understand the idea of curriculum development.

One of the things that we're looking at in the training area is curriculum development for the different occupations that we have in FSIS. We alluded to the knowledge, the skills and abilities that our people need to have to be successful.

What they needed a dozen years ago are different from what they need now. We're trying to focus on identifying that, figuring out where everybody is because everybody is different just like when you have people coming in at their freshman year. Everybody is at a different level. How can we fill in those gaps, and how can we make sure that people coming out at the other end have what they need?

MR. BILLY: Thank you.

MR. DENTON: Thank you.

MR. BILLY: Yes. You're welcome.

Katie, are you pretty well set?

MS. HANNIGAN: I'm all set.

MR. BILLY: You're all set?

MS. HANNIGAN: Yes.

MR. BILLY: Okay. Thank you very much. Thanks for the presentations. Again, there will be some people around that can answer questions and whatever.

Okay. I'd like to move on then to the next and final issue area, which is the residue control in the HACCP environment. We need to take about a one minute pause here while new people come to the table.

(Whereupon, a short recess was taken.)

MR. BILLY: This is another very important area for the agency and for industry and for consumers. When we implemented HACCP, one of the things that we indicated is that for the time being during the initial stages of HACCP implementation the agency was going to maintain its residue program as it had been designed subject to yearly modifications and changes in terms of which residues we were focusing on and that kind of thing until such time as we had implemented HACCP, and then we would circle back and look at

a whole series of questions regarding how residue control should be addressed in a HACCP environment.

Pat Stolfa is going to lead the discussion, and she has several colleagues with her. I'm going to turn it over to Pat to lead this part of the discussion.

MS. STOLFA: Thank you very much, Tom, and good afternoon. It's nice to see all of you.

This is not basically going to be a technical discussion. It has considerable relationship to the last topic in that our main objective here is to describe for you a process and to invite you into the process. We don't come to you with a newly designed residue program. We come with an invitation for you to participate in helping us think that through.

I have three people with me who are very technically qualified and so should we need to talk in more detail than I intend I want to introduce them. On my far right is Dr. Dan Lazenby, who is in the Office of Policy, Program Development and Evaluation and takes the lead for us on residue policy development.

Next to him is Judith Niebrief. I have the

benefit of a document which Judy in fact drafted for us, but I can't get you yet since it's not finally cleared, although you ought to see it very shortly because it is the announcement of the public meeting during which we will initiate this dialogue we hope to have regarding how residue control should be handled in the HACCP environment.

We're hoping to hold that meeting on the 11th of December and to publish notice in the Federal Register sufficiently in advance that you get a chance to read it because it not only is a lengthy notice. It also has references which you might choose to look at in advance of the meeting, which might facilitate your participation.

Next to Judy is Dr. Manfred Chadry from the Technical Services Center in Omaha, who handles most of the practical residue questions that arise in the course of our limping along between our old program and the program of the future. Dr. Chadry is a virtual encyclopedia of everything that we have ever said about residue control, so he is extremely helpful to us as we proceed.

At any rate, I want to highlight for you what is in the Federal Register notice so that it won't be a

surprise to you. As I say, what we have asked the subcommittee that we're working with to consider is how we can make sure that as we initiate this process we have the kind of broad based participation that we're looking for and so we haven't asked the subcommittee to design a residue program either. We've simply asked them to help us think through what's the best way to go about this and what kinds of things, what kinds of additional things, should we be doing to make this happen.

It's important I think to understand, first of all, why we need to have this discussion at all. I do have transcripts from the implementation meetings of the fall of 1996 in which indeed everything Mr. Billy said is entirely true and that we said well, you know, here is some thinking on residue control, but we're not prepared to deal with this immediately. We're not prepared to deal with this in the short run.

This is a big, complicated program. It has many diverse constituents that need to come together around the various issues that have always been part of residue control, but the real reason we need to have this discussion

is because there's a discrepancy between the language of Part 417, particularly the hazard analysis and the list of hazards that companies need to consider, and what the agency continues to do in the area of residue control.

You know, what is surprising is that a number of people have really tried to deal with that discrepancy and on their own have tried to proceed with that language and make improvements that are consistent with that language, but I would hasten to add that we have not prepared our field force for that significant change, and we think we need to.

Nor have we let anybody know exactly what our expectations are and so, as I say, we can go back, and I think all of the things that were said by various people, including Dr. Benton, who at the time was the head of Animal Production Food Safety and tended to be the person we called on to give thinking about the future relative to residue control. I think all of those things can still come true, but we haven't started them yet.

There are good reasons for that. It is a complex area. In addition, it has seemed to us unfair to start them

in the middle of implementation; that some companies, the large companies, have implemented for some time, but the rest of the population has not implemented, and we thought that it might be considerably disruptive to put out a plan or put out ideas or ask for ideas that would only be applicable to certain companies or might be applicable to companies at different stages of their HACCP implementation, so we're not uncomfortable with the fact that it's taken us a while to get to it.

Now, as I say, the Federal Register notice, first of all, speaks about the reason for having the meeting, and in order to make that case we have to remind you again of things that we said in the preamble. We have to remind you of how important it is for us to have establishments take control and take responsibility and for us to fulfill our role as holding establishments accountable.

We also have to remember that there are some specific concerns relating to residues that cannot be overlooked. For instance, we know that our testing program and the good record that it demonstrates generally about residue control is very comforting to a number of people,

and we don't want people to think that there's any lessening of control or any lessening of that performance expectation. On the other hand, we think that maybe we could do things in a way that would make things even better.

We have concerns about international trade. Residue issues have tended to be very readily adaptable to international trade controversies over the years, and we don't want any programmatic changes that would lead to a lessening of confidence in our exports. We're a successful exporter, and in, you know, a number of cases much of that success depends on our control program. Over the years we have imposed serious controls on the residue programs in other countries in order for them to be able to export to us, so these are issues about which we're mindful.

We're also mindful of the fact that people are particularly concerned about government controls on those hazards that they can't see and that they don't think they can control themselves. They don't know whether or not it's there, and there isn't much that they think they can do about it.

I mean, you can't cook residues out of a meat or

poultry product. There isn't this feeling of control on the part of the consuming public so that we don't wish to -- as I say, we don't wish to lessen the level of protection that our program offers. We do, however, believe that the implementation of HACCP offers us an opportunity to have a program that's not only different, but better, and that's the premise from which we begin.

We needed to figure out how we were going to ask people to review and think about a program as complex as this and with as many different facets. Over the years, this program has attracted the attention and work of some of the best chemists, microbiologists, toxicologists and others throughout the government, and I believe that it needs to continue to do that, and yet we did not want to have the discussion only with those people so we had to think about how can we get people to participate in this.

We chose for the framework a document which is distant in time, but I believe still relevant and I think continues to make the significant topics accessible to a wide variety of people. We went back to the 1985 reports by the National Academy of Sciences on meat and poultry

inspection. This was the first of the reports that we commissioned.

When we asked the Academy -- at a time when we were trying to make a lot of changes in the agency, we asked the Academy to look at the program and tell us, you know, this is some of our thinking. Is this okay? You know, are we maintaining a level of protection? What kinds of things should we be looking at? What kinds of things do you think we ought to approve?

One of the things they gave attention to was residues, and there is a chapter in that report devoted to a description of an ideal residue program. They sort of gave us a little grade for where we were then, or, you know, they at least talked about where they thought we were, but their report was premised on HACCP implementation. They thought we ought to implement HACCP.

Well, lo and behold. Now we've implemented HACCP, so we think it's appropriate to look back at these features that they brought out in this report and ask a broad spectrum of interested parties to think about what we could do now. We have implemented HACCP. What can we do

differently and what can we do better?

Now, one of the references that you can get in advance of the meeting is, of course, the NAS chapter from which the conceptual framework of this review originated. I just want to run through the kinds of issues that were brought up in the NAS model so that you'll get a flavor. Do we have this? Tab 10?

MS. GREEN: Yes.

MS. STOLFA: What's at Tab 10? Do we have a draft?

MS. GREEN: A sheet of paper.

MS. STOLFA: Oh, but that's the short version, right?

MR. BILLY: But not the NAS page.

MS. STOLFA: No, that's not that.

MR. BILLY: You can go ahead.

MS. STOLFA: We couldn't give you this. We would have given you this if it had been cleared, but we couldn't give you this so what you have in the short paper is a summary.

What I'm looking for is the beginning of -- is the

NAS report and the issues that were part of that report. We just sort of systematically went through this list of issues and said well, maybe we should talk about that again.

In a couple of cases and principally because the subject matter was so technical and actually in subsequent years we have remedied the problem that the NAS pointed to. We think a couple of these are not really relevant, but we think a number of the others are.

I just want to run through these quickly so you can get a flavor of the level of generalization that we anticipate this meeting will be about. This is not a meeting about technical details, although we hope people with a variety of technical backgrounds will participate and in essence put their best ideas forward, but these are the kinds of issues that were features of the NAS model program.

The first one they mentioned was public protection as the primary objective, and we did okay on that in their view. They thought there were ways in which it could be improved, and what we're asking people now is with the implementation of HACCP what additional resources are brought to the table in order to make sure that public

protection remains the primary objective. We don't perceive any deficiencies. We want to think about what other things.

For instance, we believe that the requirement that establishments consider in their hazard analyses whether or not the residues of veterinary drugs or chemicals or environmental contaminants present hazards reasonably likely to occur, in our minds that's a whole new population of people that are thinking about this issue, some of whom will already have controls in place, others of whom may wish to think about the additional controls or to put in their HACCP systems the controls that are already working successfully for them, but that's the notion.

The second general area that they mentioned was a focus on prevention. We believe -- they didn't think we were perfect on focusing on prevention in 1985. It was difficult to focus as much on prevention at that time as it might be possible now. HACCP is, after all, a preventive program and so opportunities for enhancing the focus on prevention may in fact be considerably improved.

The third issue, clear tolerance levels. We don't think that's an issue that we have to put before a group to

discuss. The situation has significantly improved. In addition, we're not the setter of tolerances, so that's more some other people's business, and lots of work has been done on that.

The fourth issue was a sampling scheme adequate for prevention, and they pointed out that we have a sort of monolithic sampling approach; that we could have chosen other sampling approaches which might in fact have helped us uncover some problems that we frequently find ourselves chasing after.

You need to know that in residue control, as in almost anything else, we probably have never had as much money as we could usefully spend, and we probably never will have as much money as we can usefully spend so that making up a better program depends on doing things differently.

You know, we don't intend to reduce the level of commitment. In certain areas we expect it to be enhanced, but it's never been enough, and one way that you might get improvement is some changes in sampling strategies, so we would ask people to think about that. We make some suggestions about that.

MS. HANNIGAN: Can I just ask one question?

MS. STOLFA: Yes, ma'am.

MS. HANNIGAN: I'm sorry to interrupt you, but you've mentioned prevention twice.

MS. STOLFA: Yes.

MS. HANNIGAN: Both Alice and I are sitting here saying are they talking prevention of buying an animal into the slaughter facility that has been treated with some type of a drug?

MS. STOLFA: No.

MS. HANNIGAN: What prevention are they talking about?

MS. STOLFA: No. I think they're talking about prevention of permitting adulterated product to enter distribution channels and that there are opportunities -- one of the adulterating substances or the class of adulterating substances that they're focusing on is chemical residues, drug residues, pesticides, et cetera, but they make a general HACCP based presentation. When you read the whole chapter, you'll understand that.

They talk about risk assessment and the

incorporation of risk assessment into the design of the residue program. We've made some progress in that area. However, there are probably additional opportunities for further incorporating risk assessment into a residue control program, but that's another aspect of a program that people might want to focus on.

They speak about adequate analytical tools and testing capacity, methods and laboratory capacity. We have made great strides in methods development over the years, and I think people who know that area would continue to believe that there's more work that could usefully be done.

Laboratory capacity is another sort of provocative topic. If we're the only recognized residue testers, that's a pretty limited capacity. As I say, we've never had enough money, and we probably never will, so it's time for people to consider how are we going to enhance that laboratory capacity.

What do we need to do in order to make sure that the results we get are from laboratories in which we have confidence and people who are using methods in which we have confidence? If we could have those things, could we not

find a way to use other people's results as part of our residue control activities? We think there's discussion to be had there.

We talked about a training inspection force. This is just another area in which we need some more training. It's not a lot different from other areas that people have talked about.

Close links to regulatory enforcement. Probably HACCP offers us a little better opportunity for that than we had previously, but that's a topic for consideration.

Useful information systems. We have a lot of information systems that have developed over the years relating to residues. They probably deserve a good look, and some other people probably need information to get out of our systems.

Finally, this is why we chose to go this way. Priorities are set through an open process, and we believe that we can improve that; that a broader group of people could become interested in residue control, that they could become part of a priority setting process that would start with a program design process and might be updated, you

know, every two years or something as to what are the priorities that we are most concerned about now.

One of the reasons we went to this framework is because of this recommendation, and we think this is an area where there's ample opportunity for improvement, and so on December 11 we're hoping to have this meeting where we call together anyone who's interested in showing up. We divide the participants into subject areas drawn from this broad outline.

Now, we're not going to have exactly the same questions. I think there probably needs to be one group of people talking about methods development and a different group of people talking about laboratory capacity because both of those are such complex issues, but we'll have maybe eight or ten groups.

We'll try and notify you in advance of what the topic areas are. You can get these references in advance, or they will also be available at the meeting. We'll ask the groups to meet during the course of the day and report back generally at the end of the day as to what their overall thinking is.

We would hope that they would have a variety of ideas, a number of which would not be fully developed, but might be attractive possibilities. We're not telling anybody we only want ideas that can be done in the next six months because we don't believe the program will develop that way.

We need to have a goal toward which we're proceeding. It will be implemented in pieces, and some things can happen in the shorter term. Some things can happen in the longer term, but eventually we know this is where we are going, so that's the kind of meeting we will hope to have on the 11th.

This will all be facilitated and the facilitators will prepare things in advance. About the main thing you need to do is hopefully figure out what part of the process you might be interested in participating in.

As I say, that's my preview of the meeting. I want to do one other thing before I open up the questions. As we go along, what we're going to do is we're not going to stop making the reviews, evaluations and improvements that we need to make in the program as they come up. A few of

those are in the works close to being finalized, and I just need to tell you about those. You have no interest in this, but we'll tell you anyway.

There is an interagency group on residue control that includes us, the Food and Drug Administration, and I think EPA, maybe CDC. I don't know. There are several USDA agencies. It's known as the IRCG. We've made a modest change through which the policy office will take the lead for our agency. Everybody else will be represented. They'll have all their rights. We'll just take the lead to make sure things are coordinated and that we follow through on this.

This group meets every couple of months, I think. Is that right? Or every month. Every couple of months. It switches back and forth between us and FDA. That's of no interest to you, but it's useful to us to get ourselves a little better organized.

We have received from a coalition of industry groups a request to replace our current process that nominally serves as a deterrent to repeat residue violations with a different process, namely one that makes the names of

repeat violators known publicly, and we are in the latter stages of considering that request, so soon we will answer the letter.

We are in the latter stages of making a correction, a sort of policy correction. Over the years the practice grew up in our agency and its predecessors regarding the condemnation of parts or carcasses that were found to have violative residue levels. Unfortunately, the policy that we were implementing was not consistent with the federal Food, Drug and Cosmetic Act, which is the source, the statutory foundation, of this particular activity and so we have a need to change that.

We are in the process of preparing a Federal Register notice which will announce that change and which will give people an opportunity to adjust their practices. We won't announce it today and make it effective tomorrow because we realize that it is an important change.

Let's see. What else are we doing that you care about? We're doing the phenobutezone testing program, which was jointly designed by us and the Food and Drug Administration, has been interrupted because of FDA resource

problems. We don't perform the analysis to determine whether or not phenobutezone is in the -- I guess we're looking at all. We're looking at kidneys, livers and carcasses. Is that right?

MR. LAZENBY: Yes.

MS. STOLFA: Right. FDA does, so if they run out of laboratory resources and they, you know, let us know -- we barely got into the project. They let us know that they had a resource problem, and so we had to interrupt the process. We will pick it up as soon as they tell us their resources got freed up.

MS. MUCKLOW: When was that stopped, Pat?

MR. LAZENBY: Two weeks ago.

MR. BILLY: I think what I'd like to do is stop there. Thanks, Pat, very much.

There is under Tab 10 a series of questions. I just want to remind the subcommittee and the chair of the subcommittee --

MS. TUCKER FOREMAN: I have a question about that before you --

MR. BILLY: Okay. I think Caroline had her flag

up first, and then I'll get to Carol. Okay.

MS. SMITH DEWAAL: Are you ready?

MR. BILLY: Okay.

MS. SMITH DEWAAL: Okay. Caroline Smith DeWaal. I just want to put my thoughts on this issue on the record. I won't be in the subcommittee that's considering it tonight.

This is one of those issues where it just drives me crazy because we've had problems in place with respect to some drugs and important public health effect if their residue is found in the tissue. In others it may not be quite so significant, but the program has really arisen because of the need for the industry to have a level playing field. They can't have cheating in the industry. I have seen this over and over again.

There are lots of hazards in the food supply that consumers want to see better controlled, that consumers have no control over and they can't cook out of the product -- scombroid histamine poisoning in fish, siguitera in fish, many of the shellfish toxins. These are hazards that have much more severe public health implications than the drug

residues, and yet we have no testing, no sampling.

We have no sampling period in the seafood industry, and yet at the same time that we were monitoring that situation, and my numbers may be wrong because they're probably close to ten years old now, but the residue, the drug residue program for meat and poultry, were running something like 80,000 samples a year. We weren't running a single test for microbial contamination of meat and poultry products, but we were running many tens of thousands of samplings for drug residues.

This is a program that if you put it on a list of, you know, what are the major public health problems that we're facing, this would be relatively low on the list. Compared to the resources that we are applying to it, it's just totally out of sync so I think the bottom line here for us, and I understand we're also the organization that criticized the Department when DES was found in some meat products shipped to Switzerland, so there are public health issues, but --

MR. BILLY: Suspected of being --

MS. SMITH DEWAAL: Suspected.

MR. BILLY: Not confirmed.

MS. SMITH DEWAAL: So now that I've vented I will try to be constructive.

First of all, I think the residue issue is one where HACCP could play a pivotal role in redesigning the system, but it's got to be HACCP. This is also a good vehicle to get HACCP on the farm. Record keeping could be very useful for monitoring this, and the testing program as it's currently constructed should be used more as a government verification vehicle, but the farmers themselves should be required to do more, to verify that their carcass, that their animals and the carcasses, are free of illegal drug residues.

I just think this is a program that cries for reinvention. It cries for risk assessment and being put in the context of all the hazards facing the public. The issues around a level playing field should be borne more by the industry than it is by the government, and let's get, you know, a good system of government verification in place, but let's not be the government doing the entire job of verifying that the industry is using the right -- is doing

the right thing.

Thank you.

MS. STOLFA: We'll look for you on December 11. I guess you'll have difficulty deciding which group you want to be in.

MR. BILLY: Carol?

MS. TUCKER FOREMAN: Yes. Carol Tucker Foreman. I'm the chair of the subcommittee this evening. Could you arrange, please, to have somebody bring over that chapter from the NAS report so we have a reference?

MS. STOLFA: Yes. Yes. We can do that. No problem.

MS. TUCKER FOREMAN: Most of us I suspect haven't looked at it for a while.

MS. STOLFA: Yes. No. I'll bring it.

MS. TUCKER FOREMAN: And I'll just hold the rest of mine for tonight.

MS. STOLFA: Okay.

MR. BILLY: Okay. Gary?

MR. WEBER: Just a couple things. I sit here reminiscing. About 14 years ago, one of the first things I

did when I came to Washington, D.C., was dealt with sulfamethazine in swine. We made a lot of progress on that. That's a nice story for a drink sometime to talk about those sorts of things, not to reminisce.

One of the things that strikes me about this meeting is it's always imperative when you take an initiative like this on that you build a good foundation under it, and there's an opportunity here.

Having not seen the agenda, I'm assuming you've probably already designed it this way, but it's a great opportunity to talk about how residue tolerances are set and the margins of safety and all those sorts of things, but it's also important to recognize that with our trading partners around the world they're using products which have no tolerances here, and often times those issues flare up when we're importing products and some things is found or somebody makes it an issue and vice versa when we export products, so I think the foundation that you build here at this meeting is important to bring everybody up to the level playing field of understanding of it and then move from there.

Somewhere between all this we do need to recognize that I think the average consumer wants to know that government is engaged in this, that government is monitoring things. I look forward to the dialogue because I'm not sure how companies can be put into a situation where they can really keep up on the developments that occur in toxicology, in pharmacology, in pharmacokinetics and all the other things that have come to bear that government and others can keep track of, so we need to have a hybrid here, maybe not as much government as there is now in it, but certainly not government pulling out of it because that will have, as you've mentioned, international trade ramifications.

I think consumers here will raise a lot of questions, but I know, having sat down with FSIS many years ago and talked about the program and asking questions, why are you expending all the resources to test for this particular compound, and the comment I got back was well, everybody is using it. Well, it was one of the safest compounds out there. No issue at all. I just thought the rationale behind that was flawed.

I know we are very dedicated to zero residue, zero

tolerance, and have an immense amount of resources going out around the country in preventing it, but you really need to help everybody get to the same playing field so they understand what residues are or we're going to end up in another zero tolerance kind of an issue and all the ramifications of that that could come from the result of you expanding people's awareness of what could be there, so with that said I look forward to the meeting, and thanks for putting it on.

MR. BILLY: Rosemary?

MS. MUCKLOW: Thank you. Rosemary Mucklow.

For just over a year, one of my friends here in the audience today and I and other organizations have met to gather as a working group to try to address some of these concerns. We have appreciated that the effort has to span a lot more than Food Safety Inspection Service. It involves multi agencies in multi departments and at different levels of regulatory authority, federal, state, local.

It is a very complex issue, and I would strongly hope that you will use the information that some of the people from your agency were able to learn from this very

comprehensive series of meetings, and they came as our guests to these meetings, to help guide you in this process.

I can't emphasize enough how complicated it all is, and maybe a small vignette will help bring to this committee one of the very complicating issues, and that is that it is a violation of the federal Food, Drug and Cosmetic Act to sell an animal into the food supply that contains violative residues of certain chemical or other biological drugs.

The fact that an animal comes with those violative levels is up to this agency, which has traditionally looked for these drugs in the livestock that are slaughtered. I asked a question this morning about phenobutezone, and I'm interested to hear that the testing for it has been suspended because this is a drug -- oh, lights. God must be on my side. He's just lit up the room for me.

This is a drug for which there is no tolerance in a food producing animal. It should not be used in a food producing animal. It's okay for horses and dogs and people under certain circumstances, but it isn't okay for food producing animals, and yet we are discovering it in food

producing animals.

The industry that I come to this table to represent is the one burdened with that responsibility to find this drug or to work with the agency to find this drug. We, we and the American Meat Institute, have petitioned the agencies, the federal Food and Drug Administration and FSIS, to provide us with these lists of people who have consistently been found in violation of the law for selling livestock with unlawful residues.

We just don't think that should have been one of the world's greatest secrets. We think if we can share that information, which your veterinarians already have, with the industry at large that would help a great deal in resolving this problem. It's very hard to understand why it's something that can't happen fairly quickly, and so we are certainly looking forward to the response to that and the other testing solution which we have submitted in all honesty and fairness to try to help address this problem.

We want to work with you. We don't want to scare people. We believe that this testing scheme is yielding us a safer meat product today than we've ever had before, and

we just do not want to scare consumers into fears about their meat supply, which you have assured us through your testing schemes and others is as safe as we can make it for people today.

There's always room for improvement. We're looking for that, but we would hope and encourage you as you work on this issue with us that you will be mindful of getting consumers reasonable, sensible information describing the real facts of how safe their meat supply is as we face this issue together.

MS. STOLFA: Thanks, Rosemary.

One thing that's in the draft Federal Register notice that I didn't describe for purposes of this meeting is references to the work of the group of which you were a member. I needed to do that in a way that wouldn't breach any confidentiality or anything like that.

MS. MUCKLOW: I'm sorry.

MS. STOLFA: That certainly is one of the groups that our hats are off to that group, which was a coalition of people who felt they had a problem, and they needed to try and figure out something they could do about it. That

occurred even while people are still trying to figure out how 417 relates to residue control, and that is in the Federal Register.

MS. MUCKLOW: We're certainly looking forward to the answer to the requests that we've made. We hope that will come well in advance of the public meeting.

MS. STOLFA: Oh, we certainly are hoping so, too.

MR. BILLY: One more comment, and then we're going to end this discussion.

MS. SCHULTZ KASTER: Just to kind of tie up with what Caroline said, which was allocation of resources -- that's my kind of gross interpretation of what she said. As most of you know, we both raise livestock and slaughter livestock so I guess we're kind of both halves of this argument and so I have some concerns relative a little bit to what Rosemary said.

This list, were we to generate it publicly, would be a pretty small list of people because those of us that are in the business of producing livestock for all the reasons that we all know do not want to produce animals with violative residues. Therefore, when we start talking about

discussions about allocation of resources and here's the time to take HACCP to the farm, I start to get a little bit concerned because I think that runs counter to all the other discussion that we've heard about controlling food safety, where the risks are in the distribution channels and, you know, really trying to get our arms around the problem.

The second part of that is if we're going to marry export into all of this then we might as well sort of throw logic out the window when it comes to food safety risks because those of us that have been down that road with the EU or some of our other exporting partners will attest that there was not a lot of science and risk based analysis to do with the residues that we tried to test for.

MR. BILLY: Okay.

MS. STOLFA: Thanks. I hope you'll be at the December 11 meeting.

MR. BILLY: Okay. I think we're going to stop there. We're running a little behind, so while there's a half hour break listed for the afternoon, I'm going to shorten it to 15 minutes, and then when we get back we're going to have some briefings on food safety research and the

new research institute, so make it brief.

Thank you.

(Whereupon, a short recess was taken.)

MR. BILLY: We now come to what I consider to be another very important part of our agenda for these meetings, which is an opportunity to be briefed on the area of research, food safety research, and the progress that's being made in better understanding some of the issues in the area of food safety. Out of this research and technological development come solutions to many of the problems we're wrestling with.

The first presentation is going to focus on the Joint Institute for Food Safety Research. This institute is an outgrowth of the President's food safety initiative and the work under that initiatives and the Food Safety Council to find a mechanism to better coordinate research across all the federal agencies and universities and so forth with regard to food safety.

Dr. Jerry Gillespie is the executive director. He is located here in Washington. We very much appreciate him sharing time with us to talk about this relatively new

mechanism that we've put in place. Dr. Gillespie started in this new position on June 1 of this year. He previously was the director of the Food, Animal, Health and Management Center at Kansas State University.

Dr. Gillespie?

MR. GILLESPIE: Thank you very much, and I truly appreciate this opportunity to visit with you. I want to begin by telling you that although I had some notion of what it was like in Washington, D.C., I really come as an outsider and have very much appreciated the strong support that I've gotten from FSIS in our efforts to initiate the new institute.

I want to really in my presentation give you a little bit of background in terms of how I view the whole issue of food safety and the whole idea of achieving a safer food supply. I want to do this by virtue of asking the question how we should think about food safety, and then I want to end my presentation with what is the Joint Institute for Food Safety Research and what it is intended to accomplish.

How should we think about food safety? What I

really want to point out is I think, first of all, it is in fact a public health issue that is in itself very complex because it's associated with human suffering resulting from food borne diseases, death on occasions, and we can look at it through the public health window by looking at the etiology of various food borne diseases.

We've talked this afternoon about chemicals, and there are a variety of ways that you can subdivide chemicals. There are different ways of viewing that window -- microbiological, again looking at it from various infectious agents, very important, the emerging infectious agents and the combinations, something I think we know too little about, and the very importance of zoonotic diseases and the etiology of food borne diseases, genetically altered issues, foreign body, the true systems and their relationship to bioterrorism.

Human behavior and practices certainly have a big influence on the issue of food safety and public health, surveillance, treatment and prevention, and, very importantly, the whole issue of professional education as it relates to public health.

Food safety is also, as we have heard today, an economic issue, and it cannot be ignored. I think there's some complexities here that we really must hone in on when we talk about this area, but certainly it increases medical costs to have food borne diseases, loss of productivity, increased cost of food, disruption of the food trade, greater risk to any nation's or region's food security are some of the economic issues, and again there may be others.

Production and preparation practices issues, and I'm going to have to take you through a chart that you have seen a number of times, but I think it's important for us to keep remembering the various sectors that influence the production of the food that makes its way to the consumer.

Increasingly, we are finding the split between domestic and international markets, retail distribution, the link to consumers and finally the consumers. If we think about what's going on in this whole issue of production of food, one thing that we can certainly attest to is that it's changing very rapidly. It certainly does complex our ability to produce safe and wholesome food. It adds uncertainty. It adds complexity. It adds cost in our

efforts to have quality food and safety food. By the way, I have a lot of difficulty separately those two issues, quality and safety.

Increasing the need for research on food management practices across all food producing sectors. I will come back to that issue, but certainly you could almost think of it as a daily chain in which we are using different management practices that really should be assessed from a very deliberate scientific approach.

It certainly is an international issue, and again one of the things I'm struck by is that we now have multi cultural societies around the world, and they again add great complexity to our ability to sustain high quality and safe food.

It's an environmental and wildlife issue, an urbanization and population growth issue. Again, if you think about the challenges that we have in terms of sustaining an adequate food supply and the changes that are going to have to occur in our production systems worldwide, it adds complexity to the whole issue of food safety.

This, by the way, is a photograph shared by a

friend from the Montana fires this summer. I think if we look at the environmental issues, certain changes in the environment affect the ecology of the causes of food borne diseases. Some of our own research have emphasized this relationship.

Wildlife issues. Human intervention into various wildlife ecosystems seems to increase the risk of transmission of food borne diseases, and certainly it has a major effect on biodiversity. That, by the way, is maybe one of the resources that we need for modifying our foods in the future genetically to have a sustainable food supply, so it is not a trivial issue I think in the bigger picture of food production and particularly safe food.

Urbanization worldwide is an issue that also relates to the population growth, and urbanization for different reasons is occurring around the world. It may in fact be the greatest human intervention impacting the environment/wildlife food production and increasing the risk of food borne disease.

So the challenges that are before agencies like FSIS and others in the production system are I think complex

and significant, and certainly if you think about it these issues are definitely interrelated. You push one place. You're going to get an effect at another place in this system. Certainly it is a political issue, and how the body politics responds to these issues impacts food safety.

So I've realigned things a bit to put public health, economic issue and political issue towards the top because they definitely -- these issues predominate, in my judgement, over the ones below, all of which I think are important. If we rearrange it and look at it, the public will really drives the political process and to an extent vice versa.

It is out of this process that we make decisions, policies, practices and regulations that influence the other aspects of food safety. What we would aspire to have is that these decisions be science based. Since science based decisions are dependent upon these four issues -- risk, analysis, risk assessment, risk management and risk communication -- the value of these risk approaches is only as good as the data used in their approach.

So we really need then to have a call for good

science to help guide these decisions. We must have science based solutions that enable production of a sufficient amount of food, but also with the proper variety and safety to meet the world's nutritional needs at an affordable price.

One of the complexities I think we must look at is producers must be able to properly produce food in the face of rising costs, and the food should be affordable to the poorest consumer. This is an issue that we need to look at I think within our nation, but internationally, in terms of how do we sustain food production in this changing environment that we have. That does challenge food quality and safety.

In my judgement, increasingly scientists need to frame questions in a programmatic term that encompasses the complex interrelated issues of food production and their effect upon safety and quality. This doesn't mean that we can't have isolated focus studies, but at the same time we need to have studies that look at the complex issues surrounding food safety.

For example, one of the things that I think

there's great promise is sharing interdisciplinary strengths. One could ask the question will numerical solutions by the epidemiologists help the economists? Again looking back at what the issues are in food safety, we need to have good data in both of these fields if we are to progress in food safety.

That's as a background. I'd like to talk to you briefly about the Joint Institute for Food Safety Research and why I was so pleased to have the opportunity to be its first executive director. I believe strongly in what it's intended to do.

It has been mentioned that it grew out of a Presidential directive, and it is -- really I answer to three different entities, and that is the White House, the United States Department of Agriculture and U.S. Department of Health and Human Services. There are representatives from each of those entities that form the executive research committee.

Now, what are we intended to do? Well, first of all, we are intended to determine the federal food safety research activity and its cause, and we started that process

reaching out to something like 19 different agencies across the federal government to look at what is the research activity and what is the associated cost to determine the proposed and needed food safety research and the projected cost. Again, the FSIS has given us a list of their priorities in terms of things that they need to institute a sounder, more effective regulatory system.

We need to find a way to access the world's scientific knowledge base on food safety; a huge undertaking, but I will show you a model that we are proposing and hopefully will be implementing that makes this somehow possible. The reason we need to do that is that we need to find out where the scientific gaps are.

There was a comment related to the gap in the science as it relates to trade earlier in the afternoon. We can only resolve that if we really know what the science is that people are using around the world and bring those scientists together to really examine it carefully to find out where we really have gaps, where we have disputes and why we have disputes, and that will help us set priorities in food safety research and to bring all the food

shareholders together to assess the food safety research priorities.

My appointment is for two years. We probably won't get it all done, but we will get a start. I do think it's a useful thing to do, and I do believe that it will help us go back and help unravel some of the complexities that we face in the food system as it relates to safety and quality.

I'd just like to show you briefly then our modeling at least, our approach to managing scientific data worldwide. We're going to try to use the model of the web page approach where users and those in need of information can go to a web page, and their inquiry will be processed in a way that will divide the inquiry into federal guidelines, such things as what is the temperature you should cook hamburger or other food related questions for which there are guidelines, federal regulations, food safety science and food safety research.

These inquiries will then be sorted to several different libraries. We're working most intently with the National Agriculture Library that has already made

significant progress in this area, but we will be working with other databases as the repository of information that we will use to sort for managing food safety information. They themselves will be collecting data worldwide, and what we intend then to have is an output process that would sort back to the user.

Now, if we move the general categories over to the left we can do further sorting, and this sorting, by the way, for food safety science and food safety research is in fact the way we have asked the agencies to respond to us, what research are you proposing or would like to have done in detection control, pathogenicity, et cetera, so this is parallel to the inquiry about what research is now being done or needed.

In the area of federal guidelines and federal regulations, again this time we look across the system from germ plasm to consumption and again sorting the question through these windows to the libraries or the data banks. This is then, this being a model and again I've been terribly please with the response that we've had from all of the national libraries in terms of approaching this problem,

and I do think it will help us, first of all, gather the information, but, more importantly, what we'd like as far as the Institute is concerned is help us set priorities and really organize ourselves in a scientific way.

Well, it's been a quick and tough journey, and I thank you for hanging on.

MR. BILLY: Okay. Thank you very much.

There's further information in terms of the Institute under Tab 11 in your book and also a handout that's available to the public.

I don't know if there are any general questions that anyone might have for Jerry? I'm sure he'd entertain those.

MS. MUCKLOW: Where is your office, Jerry?

MR. GILLESPIE: As you walk down the corridor of the hotel and look to your left you'll see a building down the hill. It's called the Waterfront Center. I'm presently on the third floor with a wonderful view. Sometime this week I'll go to the first floor with a lesser view, but first floor space. It's Waterfront Center. It's the only building on 9th Street, S.W.

One of the things that I hope was implicit in what I presented is that we will be making contact with our shareholders.

MR. BILLY: Yes. In the material that's in Tab 11, the handout on the Institute, it includes his address and phone number, fax number and e-mail address, so I'm sure he would encourage any and all of you to get in touch with him if you want more information or for any other reason.

Yes, Rosemary?

MS. MUCKLOW: I told Jerry some years ago that as a little girl in Edinburgh, Scotland, I went to James Gillespie's High School for Girls. James and his brother were snack merchants on the royal mile in Edinburgh. They'd be quite proud of how proud the Gillespies have come.

MR. GILLESPIE: Thank you very much.

MR. BILLY: All right. Any other questions or comments from the committee?

Okay. Thank you very much, Jerry. I appreciate that.

The next item under the briefings in the research area will be a briefing by Dr. James Lindsay and Dr. Jane

Robens from the Agricultural Research Service that focuses on ARS' food safety research with an emphasis on Campylobachter.

Again, we very much appreciate this opportunity where some of the cutting edge research that's underway can be shared with you. It's obviously very relevant to food safety and the role of this committee, so we appreciate the willingness of ARS to share with us this type of information.

Jim?

MR. LINDSAY: Thank you very much, Tom. Yes. We're going to actually present some data that isn't even published to date, so you'll be the first ones to hear it.

What I thought I'd do, what Jane and I would do, is I would just give you a brief introduction to the budget issues, and then Jane would talk about pre-harvest research in Campylobachter, and I would finish with the post-harvest.

This is just a graph showing the trend in the food safety budget. It's quite obvious that, and the agency is very grateful, we've doubled our budget in the last five years from $46 million to slightly over $90 million. We are

truly appreciative of that, and you can see that although this is the 2000 budget we now have a little over 100 projects and certainly slightly over ten percent of the active research scientists with ARS.

If you were to break that down in terms of the four program areas within our program, National Program 108, pathogen control, of which obviously Campylobachter research is a key unit, would be about two-thirds of the budget. As regards to Campylobachter research itself, obviously you can see it's increased dramatically again over the last five years. It now runs, if you take the budget as a whole, around about 6.5 to seven percent of the total budget and about ten percent of the pathogen research budget. It's pretty well plateaued out now.

The majority of that money, you'll see, is actually in pre-harvest. The post-harvest research funding has actually only increased relatively recently, but you can see it's a significant portion, and it's broken up based on those food initiative codes. Again, the majority of it goes into prevention techniques and within the two new categories within our agency into manure and to project research.

MR. BILLY: Jim, there's a couple people that are having a hard time hearing, so maybe you can make some adjustment there --

MR. LINDSAY: Sure.

MR. BILLY: -- that will help. Also, there's a handout that was passed out that's also available out on the table that captures these slides and this information.

MR. LINDSAY: Can everybody hear me now better?

MR. BILLY: Yes.

MR. LINDSAY: Okay. Let me move this up. Okay.

In terms of the locations where the majority of this research is done, as you can see the majority of it is done in two sites, in Athens, Georgia, and in Albany in California. The research in Athens is generally pre-harvest, and in Albany it's post-harvest.

Okay. I'd like to present Jane.

MS. ROBENS: Thank you, Jim.

I'm really pleased to be here and be able to share some of the ARS research with you. Just a minute to go back to the previous slide here, I want to make a comment.

The research at those top locations is where we

really focus on Campylobachter. Those at the bottom six or seven, most of those locations are where we are doing animal manure research, and it gets classified by the pathogens that we're looking for. Campylobachter is one of them, but we're not studying Campylobachter per se.

The research that I'm focusing on here is poultry in Athens, Georgia. That's with Norm Stern. I'm sure most of you in the room have heard Norm talk at one time or another. The second location is the swine research that's carried out at College Station, Texas. Roger Harvey is carrying out that research.

I know most of you are familiar with Campylobachter, but I do want to remind you again that it does present a lot of basic biological challenges. It's difficult to detect. It requires reduced oxygen retention for growth, and it may be overlooked because of overgrowth by salmonella and other bacteria if the samples are not handled properly prior to laboratory recovery and identification.

In particular, samples must be held on ice during transport and holding. It can't be isolated from young

birds prior to three weeks of age, and that, of course, stymied Norm for a number of years, but I think he may be going to get on top of that one. Consequently, the progress in understanding its epidemiology and ecology has been slowed compared to salmonella, and we're now just learning both sources of infection and the mode of transmission in poultry.

Another problem that isn't on there is the co-aggregation of colonies. We find jejuni and coli colonies together, and unless you make a real effort they aren't easily differentiated. Therefore, when we're studying one or the other it's possible that we make a few mistakes, but we're trying hard to get on top of that one.

This is Norm Stern's research here with broilers and with Campylobachter at Athens. There are three different facets of his work I'm going to mention. One is the genetic characterization, and he's working with jejuni. This he's looked at both from U.S. epidemiological studies and also comparisons of commercial breeder flocks with their offspring in the broiler flocks.

Secondly, it's cooperative U.S. epidemiological

studies with four major broiler companies, and the third one is his Icelandic epidemiological study. There he is sampling poultry production sites. He's sampling the birds at slaughter, and relevant human isolates are being sampled by a Canadian study partner to help assess the importance of the Campylobachter from the chickens.

In the U.S. study, there were four large integrated broiler companies located around the U.S. At each of these locations there were two farms, a low production and a high production flock, and they were sampled. All of those farms were sampled over four seasons. The tested sources included feces, water lines and cups, drag swabs, litter, feed hoppers, band swabs, mice and other animal feces, insects, boot swabs, transport crates, carcass rinses, pre-chill and post-chill samples.

The overall incidence of Campylobachter in these studies was lower than in previous similar studies, but the main objective of these studies was to try to determine where the samples of Campylobachter might be coming from that are then found at slaughter. He used molecular methods for this epidemiological testing, used the FLA-A SBR DNA

sequencing wherein they amplify this DNA using PCR. It does have significant discriminatory power to accurately deduce the difference between isolates.

I have two of these slides that are samples of his results. He has a dozen or more and has probably shown them all at some occasion, but these are two from a southern low integrated. That means a low production flock. In this first one, the sequences from the majority of animal production and animal processing samples were identical and, therefore, considered to be of the same clonal origin. This data suggests that final product contamination may originate from feces of the production bird.

As regards the environmental samples such as wild bird samples, they were quite different; as much as 22 percent from both the animal production and processing isolates. He said that this suggests that these samples were not a contributing factor here to contamination of the final product.

This is the same farm in the fall when it was sampled and quite a bit different picture, which I have no explanation for, nor has Norm given me one. The majority of

the animal production samples here were again closely related. However, analysis of all the isolates derived from animal production sources demonstrated up to a four percent difference.

This suggests that multiple clones of Campy may be present within this flock as this is different than the previous one I showed you, while bird feces again demonstrated a 20 percent difference from both animal production and processing isolates.

Okay. I went the wrong way here. His overall results from these four different locations with the high and low producers and so on were that, one, multiple clones of Campylobachter were present within a single flock, and although final product contamination with Campylobachter originates from a variety of sources, some sources are more critical than others, particularly the feces of the production birds.

Now, of course, Norm has also been interested, highly interested, in vertical transmission because this is another way that it may be entering the production flocks. Here he's looked at fresh fecal droppings obtained from a

commercial grower/breeder flock and then also looked at the breeder progeny. He did again molecular subtyping analyses, both ribo typing, SVR LA-AG.

The comparison provided evidence that Campylobachter could be transmitted vertically, that is through the embryonated egg. That may be why the birds are all becoming infected and he's able to pick it up at three weeks or more.

This is the type of result that he shows. This was from an Arkansas flock. This was Isolate 530, and all of the Arkansas broiler isolates were closely related, a 1.4 percent maximum difference; therefore, a likely clonal origin. This means that the broilers got it from their parents.

Now, the third study from Dr. Stern I will mention is the Icelandic epidemiological study. Why go to Iceland for an epidemiology study? Iceland produces 100 percent of its poultry. They don't import poultry. Their fertile eggs do originate in Sweden, however.

The poultry industry of Iceland is generally similar to that of the U.S. the way they are set up and

operate. However, Iceland consumes roughly only 25 percent of the amount of poultry consumed in the U.S. However, the frequency of human Campylobachteriosis in Iceland is several fold higher than in the U.S.

This study is ongoing. They are sampling poultry sites, and they are sampling birds at slaughter. They are obtaining lymph samples from approximately one of every 1,000 carcasses produced from each of two slaughterhouses. They are obtaining isolates of Campylobachter from people domestically exposed to Campy through eating birds. There is no foreign travel associated isolates; at least they're trying very hard to avoid those.

They are performing genetic analyses on these just as they did with the domestic studies. Therefore, they can quantitatively evaluate poultry as a source of human Campylobachter infection.

Now, early results of this study have shown that sequences of human isolates from August, 1999, -- that's a year ago -- were identical to the chicken isolates from an August 9 Flock 1 that they sampled. This strongly suggests that chickens may be a source of Campylobachter infection in

humans in Iceland.

Okay. Now to switch to swine. This is a prevalence of Campylobachter that was found by our ARS College Station laboratory. Roger Harvey was the chief investigator there. There are three little studies that I'm going to mention.

In the first one here, Campylobachter are isolated from the intestinal tract of pigs raised in an integrated swine production system. It was four barrow to finish farms. Samples of fecal contents were collected from nearly 600 pigs weighing 242 pounds at the time of slaughter over a nine month period. The pigs were offspring of Yorkshire Landrase sows and Durrock or Hampshire boars. The Campylobachter were isolated from 70 to 90 percent of the pigs, depending on the farm and the date the samples were collected over this nine month period.

Some results of this Campy isolation were the slaughter plant samples were obtained from 50 pigs per visit. They were originated from the designated farms so that the samples were obtained three times from pigs from each of four farms. We did get some replication. Their

separation of coli and jejuni showed, of course, a wide variation in the percentage of those that were present. Coli was about twice as high as jejuni, and they did find lary, of course, in two pigs.

The numbers of Campylobachter from each isolation ranged from ten to the three to ten to the seventh power in performing units per gram of fecal content. Just for reference, the NARMS 1995 swine survey found about the same percentages of coli versus jejuni in swine.

I've got a couple of slides of results on a neonatal study in swine. Piglets can be colonized as early as 24 hours of age when they are raised on the sow. When positive piglets are weaned and reared together in floor pens, they do remain positive for Campylobachter, but if these 24 hour piglets that are positive for Campylobachter are removed from the sow and raised in wire floored pens, they eventually become negative for Campylobachter. Conversely, their litter mates raised on the sow will remain positive for Campylobachter.

These are some data that show what I was just saying; that the sow reared pigs do retain the

Campylobachter, whereas those that are nursery reared, they go in Trial 1 from 13 of 14 positives to zero of 14. In Trial 2, the Campy positives go in the nursery reared pigs -- they decreased from 12 of 29 to five of 26 on Day 20. Quite a change that's brought about just by growing up in a Campy free environment.

They looked at some factors influencing Campylobachter status. The effects of feed withdrawal and transport were determined in a surgical pig model. Here they had four nine kilogram Yucatan miniature gilts with fecal cannulas that were surgically implanted, but the pigs were naturally infected with Campylobachter jejuni. Then they had a 30 day recovery period and following that feed withdrawal for 48 hours with significantly -- the feed withdrawal significantly increased the Campylobachter jejuni concentration in the fecal contents, and the fecal contents had an increase pH after this feed withdrawal.

Conversely, though, in transportation, which we usually think of creating a problem, when they were trucked around College Station for three to five hours this had no measurable effect on the number of Campylobachter.

Okay. I guess that's it. Thank you. Thank you all. If you have questions, or do you want to give any questions at the end?

MR. BILLY: Thanks, Jane.

MR. LINDSAY: Okay. I'd like to discuss the post-harvest research program starting from east of the United States and moving west.

The post-harvest research program at the eastern regional laboratory is spread over several units. In the microbial food safety unit, which Joan Lachanski is the research leader, this is a new initiative, and it's goal is to determine effects that exposure to food environments have on bacterial stress response, adaptation and virulence. We have a new scientist, Barbara Solla, who has taken up this initiative, and she's working in Peno Fredimico's group.

Now, the specific goals within this are to determine mechanisms of global and specific responses and to understand the biochemical and molecular basis for survival under adverse conditions. There's a variety of different conditions here -- culled heat, osmotic oxygen, acid -- and there's obviously going to be some genomic and proteomic

analysis.

Now, why is this important? It appears that Campylobachter has a different mechanism and stress response than what you normally find with say coli. It doesn't have an RPOS system. We simply don't know how the organism adapts to changes in environment.

Now, one of the things that we do know it does is that it changes its structure, and this may be a function of the lipopolysaccharide in the membrane because Campylobachter is very closely related to Helicobachter pylori, and there is some similarity in the mechanisms of adaptation.

Now, obviously involved in this is the development of methods to detect stressed or injured cells. These are pleomorphic in nature, and what I mean by pleomorphic is that the same organism can have two or three different structures. The normal structure that you might associate with Campylobachter is that spiral rod, but you can also have this globular structure, and then it can go into a viable non-culturable form.

Now, this is very difficult to enumerate, and we

have tried to develop a variety of different medias to try and resuscitate these different stages, but it's proved to be very difficult. FSIS is currently evaluating the Eric Rhine media, and this may be a very useful method. However, it does not discriminate between Campylobachter jejuni and Campylobachter coli.

Jane mentioned aggregation of colonies, and I want to show you some very recent data about this which has caused us to reassess how we do this, how we do our analysis of Campylobachter. One of the things that we have been able to do, and this is the work that Peno Fredimico has done which is not yet published, is we have developed a multiplex PCR for both Campylobachter jejuni and coli, and you can see that it's relatively simple. It's a plus or minus. If you have a 160 base pair band or product plus the 400 it's jejuni. If you have the 400 plus the 894 it's coli.

This was evaluated for some isolates that were taken from the Hatfield processing plant just outside New York, and it was able to differentiate between eight jejuni and 52 isolates of coli. It's much more accurate than the contest, and in talking with Peno about it she believes that

this PCR procedure could be used for speciation from a variety of different samples.

In looking at the isolates, and this was a continuation because of some work that was done by Sam Columbo, who is now retired. Looking at those isolates that were taken from Hatfield, all 60 had very distinctive PFG profiles. This is similar to what Norm has found in that you may have totally different types of organisms within the same environment.

Now, the genetics of Campylobachter is very, very difficult. There appears to be no repeated sequence. The organism has a much higher mutation rate than you normally find with other enterics, and there is certainly some plasma associations with antibiotic resistance and virulence, but these are all very, very new things that we're looking at.

Over 60 strains of Campylobachter in this study were resistant to at least five antibiotics, including those to treat humans. Twenty-five percent of the strains were resistant to one of the three flora quinolines, the three listed there. Three percent of the isolates were resistant to three flora quinolines, and 50 percent were resistant to

suprafluxocin, which is used to treat infections in humans.

Now, each of the 60 isolates were distinct, as I said, suggesting that there are multiple clones present within this processing plant. If you translate that to other plants, this sets up a scenario where you have multiple parts of organisms inhabiting different types of niches, and that in itself starts to complicate matters.

Some other work that's just started within this unit is specifically the effect of competitive flora and temperature on survival, microscopic studies to reveal the specific location and the state of cells, the incidence during stages of processing and the genetic relatedness, some of which I've already mentioned, and methods to limit the number of carcasses or numbers on carcasses exiting the slaughterhouse.

Just to show you actually on a carcass what I was mentioning before, you can see on the left-hand side the typical spiral that you find. In the next slide I'll mention Peno terms the spiral shape of the Campylobachter as being embedded. It is totally different and much harder to remove when you're trying to do processing than the one on

the left where you have this globular or circular type organism.

So in an analysis of the Campylobachter growth on pork skins, it survives better at four degrees than an minus 20 or at 25 under either microaerophilic or aerobic conditions, and that's going to be a very critical issue. Freezing at minus 20 for greater than 48 hours results in a two to three log decrease. Numbers are not greatly altered by the presence of other bacterias, so there seems to be no effect of the formation of biofilms.

As I mentioned, Campylobachter is embedded in pork skin at four degrees C, so the spiral shape seems to attach much stronger than maybe flagera or other membrane proteins involved in this, whereas at higher temperatures under microaerophilic conditions the organism is on the surface of the skin and relatively easy to remove.

Other studies that are planned or in progress, and these are actually studies that have just been approved in Peno Fredimico's proposal that has just finalized its review, is to examine the microbial ecology on pork, including the ribosome sensing in regulating viability and

virulence, develop interventions for controlling pork at different temperatures, but the key in this is obviously doing a four degree C refrigeration temperature, to expand the predictive microbiology and passive modeling program, research to assist industry and regulators, and this will be done in association with the new CRS that has been taken up by Mark Tamplin, who has recently joined us.

For those of you who may not know, Peg Coleman, who works for FSIS, is now on detail with ARS within Mark Tamplin's group for the next year to do or to be intimately involved in this modeling.

To utilize genomics and expression profiling to better characterize and control undesirable strains and obviously to validate the HACCP based inspection model project and the processing plant.

Now, in association with the eastern lab we also have a research facility based at the University of Maryland on the eastern shore, which is Tom Oscoff. He's now doing some work with a member of the faculty, Ian Allen, a new project to develop mathematical models to determine the effect of multiple food formulation variables and

intervention strategies.

Specifically putting this back up again, new projects, development of predictive models for the survival of strains of jejuni on chicken products, develop data to establish modeling methods and use of modeling protocols to examine strain variable. A key issue again, competing organisms, meat formulation and survival kinetics.

This is very appropriate. Tom has been very -- is well known for developing user friendly models for both FSIS and industry relative to organism growth on food products.

In the microbial biophysics biochemistry unit, which is headed by Shuey Tu, we also have a new scientist there, Linda Yu, who worked with us at Hatfield. Her goal is to develop more sensitive, rapid and user friendly detection methods and biocensus for regulatory agencies.

Again, her new projects are the sitopathogenicity assay, which is tissue culture based, and it's based on using the CDT toxin, which is produced by jejuni, but not coli. This is going to be a very difficult method to develop. Relying on tissue cultures can be tenuous at best, but we have high hopes that this may have a real practical

use in determining virulence of key strains that are isolated.

There's also a development of methods using amino magnetic beads and new approaches for extracting and concentrating and isolating the organisms from food. This is key. If you can't concentrate the organisms from the food matrices, it's obviously very difficult to enumerate it.

The group has developed two amino magnetic separation methods. One involved a strip avidin bead and the other one a torso activated bead. To show you some recent data, and again this is not published. This is on the strip avidin. They've been looking at the effective different cutting procedures, incubation times, the number of magnetic beads, innoculin levels, and without pre-enrichment.

This is key. They were able to determine ten to the fourth colony forming units per gram in gram poultry products. That's a start. We'd obviously like to get it much more sensitive than that.

At Athens, we transferred both Rick Monosman and

Mark Loran from Norm Stern's unit to Gene Lyons' unit about a year ago and asked them to develop a new program. Its goal was to lower bacterial contamination incidence on processed poultry by examining the microbial interactions actually within the processing plant, so we have a microbial ecologist working with a Campylobachter geneticist, and this has turned out to be a really good union.

Their goal is to delineate Campylobachter transmissions within the processing plant. As the bird is coming in what is actually within the plant, are there specific niches where certain types of Campylobachter, either be it coli or jejuni or both, that have varying types of structures actually inhabit, to study the population genetics to determine if genetic adaptations benefit from transmission and to determine if environmentally regulated factors contribute to the survival. Again, this is a very new project.

Finally, I want to talk about what's going on within our western lab. This is the food safety and health unit, which is headed by Rob Mandrell. Their program is now shifting from working with poultry to working with produce,

although they still use poultry or chicken skins as a model system.

The goal is understanding how Campylobachter attach and survive in the environment related to food, including soil, water, air, plant, roots, leaves, meat and obviously processing environments. In all of these studies between the different groups or the different centers, Russell, Eastern and Albany, the key individuals are not working in isolation. They talk to each other, and they work as a team in solving problems. Each of them has a separate specialty, and each of them contributes to the common goal in this.

Develop new detection methods for identification, develop attachment models, screen for natural antimicrobials, minimize Campylobachter in processing environments and develop new strategies to minimize contamination during growth and harvesting of poultry and produce.

We were very fortunate in that we were able to transfer in a sense Larry Stanka, who had been a research leader at College Station, to start a whole new biosensor

research program at Albany. He's not the research leader out there, but he's actually heading a whole new group specifically focused in on developing new biosensor technologies. He's been able to produce specific anti Campylobachter antibodies for detection, identification and capture.

There is another scientist out there, Bill Hadden, who has developed mass spectrometry techniques -- this is known as -- for identification, and it could be used for proteomics.

Just to show, this is very recent data, and I mean recent in that it only came out last Friday. This is using a europium labeled monoclone antibody modified with a marker filtration assay which could potentially be used on line. They've been able to achieve a sensitivity of ten colony forming units per mil using either a single or a mixture of monoclonal antibodies and the graph showing on the right-hand side showing different combinations. There's a similarity in all of this. That's the type of sensitivity we're looking for, ten colony forming units per mil.

The work with Bill Hadden, this is using the

matrix assisted laser absorption ionization, also known as MALAITOP (phonetic). What he ostensibly does is that he can take colonies actually out on a plate, pick the colony, put it in organic acid, put it within a laser, bombard it, and the fragmentation patterns, which are shown here, the type of fragmentation patterns can differentiate between the different species. Now, obviously we can't determine the virulence factors, but this is a very rapid way of doing it because this literally takes merely seconds to do, so we are able to classify Campylobachter based on a series of biomarkers.

Some new work that is being done by a young scientist by the name of Bill Miller is the production of fluorescent reported strains to differential fluorescent induction, and what the idea here is to examine Campylobachter jejuni expression.

We can also study attachment of jejuni to poultry skin and to progenies, study the ecology and biology in complex environments and biofilms and may provide a means to measure pathogen reduction, enabling characterization of specific gene products that can be targeted for anti-

adherence strategies performing vivo studies, inoculation studies to determine intra and inter species competition within the gut. That sounds like a whole lot, but this is a huge program involving nine scientists.

Now, Jane mentioned about aggregation, and this is some interesting work that Bill Miller did. He was able to label different strains of Campylobachter different colors and look at them under light. You can see here the two at the top. You've got a light blue and a green one. If you were to look at that actually on a plate it looks like a single colony, but it's actually two different strains.

Now, if you were to try to pick that off, you would never know whether you were actually trying to get a single isolate or whether or not you had a contaminated isolate or two isolates. This becomes key in looking at this because do we want to differentiate between Campylobachter jejuni and Campylobachter coli? Do we really care? Is it important? Is Campylobachter coli as important in terms of food borne illness as Campylobachter jejuni?

There is only one report of Campylobachter coli actually being implicated in Guillian Barre, whereas jejuni

normally is, but that doesn't necessarily imply that the coli is not important as a causation of food borne illness, so you can see that Campylobachter strains aggregate and that more than one colony or one colony could be actually more than one strain.

Now, the fluorescent strains can also be used for attachment studies. Although there are four different studies there, you can see on the top that the Campylobachter is actually adhered so we're able to use these fluorescent marked strains for attachment studies, obviously better culture methods and, as I said, gene expression and study of organisms in complex environments.

I think this is getting close to the end. The interesting thing or an interesting study that they did was to feed fluorescent Campylobachter jejuni to chickens, house them and then take the intestinal tissue and look at them. The interesting thing is that although there were two co-inoculated, there was specific competition for attachment sites within the gut.

It may be that only certain strains of Campylobachter like to adhere to certain or have a

propensity to attach to a chicken gut or a pig gut or a pig skin or a chicken skin, so this is very important information because we need to develop different strategies in each of these cases.

I think that's the end. Thank you very much.

MR. BILLY: Thank you very much. I'd like to thank both Dr. Lindsay and Dr. Robens for their presentations.

I'll speak only for myself. I can't tell you how excited I am about seeing this kind of research being done. We're clearly beginning to benefit from those increases in the budget that you highlighted at the beginning.

What's most important is the understanding that comes from this kind of research will enable us, us being both the industry that's producing the products and the regulatory agency, with our responsibilities to do a better job, a more effective job for consumers. It's really exciting.

Are there questions from the committee? Yes, Jim?

MR. DENTON: I have perhaps two questions for Jane with regard to the work that we reported that Norm is doing.

MR. BILLY: Jane?

MS. WILCOX: Jane?

MR. BILLY: Jane, would you step up here? Come up to the podium.

MR. DENTON: I didn't hear the question.

MS. WILCOX: Well, he's going to ask it right now.

MR. DENTON: Part of the basic challenge or the basic premise for some of the work that you reported on that Norm was doing is that he could not isolate Campylobachter from young birds prior to three weeks of age, and yet later in the report the fecal droppings from both the breeders and progeny were analyzed and found that they were genetically linked with the same strain of Campylobachter, indicating that vertical transmission from breeders through the embryonated egg may be possible.

MS. ROBENS: Yes.

MR. DENTON: Did Norm provide any insight as to why this very unusual situation occurs because of the inability to locate that organism in the first three weeks?

MS. ROBENS: I haven't heard anything specific, but I think all the things that you just heard from Jim

about the specifics of how Campylobachter lives and how it hides and how it changes its colors and so on all probably contribute to that inability to culture it from the very young birds, but I don't have a very specific answer for you.

MR. DENTON: Okay.

MS. ROBENS: We're dealing with an organism that's ever so much more complicated than salmonella.

MR. DENTON: It definitely is a different --

MS. ROBENS: Yes.

MR. DENTON: -- type of organism.

MR. BILLY: Okay. Katie?

MS. HANNIGAN: I'm wondering if this is the only organism you're aware of that a single colony can represent more than one strain?

MR. LINDSAY: We haven't looked at it past this. This was very fortuitous. I mean, the -- colonies was actually only reported to me three weeks go.

MR. BILLY: Jim, would you speak into the microphone?

MR. LINDSAY: Sorry.

MR. BILLY: The reason primarily is we're also recording this.

MR. LINDSAY: We honestly don't know. Bill Miller actually gave this research at a meeting we had in Sonoma three weeks ago, so we would obviously like to look at this in other organisms. You know, most of the people within ARS, most of the scientists, have not seen this information and probably will not see it until the meeting in January.

MS. HANNIGAN: And then the other question I would have for you is do you folks have a theory as to why when hogs are off of feed for 48 hours that the incident rate went up?

MS. ROBENS: I think when they were off feed didn't it -- I think the slide showed they were pulled off of feed for 48 hours.

MS. HANNIGAN: Yes.

MS. ROBENS: Yes.

MS. HANNIGAN: It went up.

MS. ROBENS: No. I do not know. It might have been something to do with the pH of the colon, but this is not just found in hogs. I think that observation has also

been made in cattle and may have been made in poultry as well, but I don't have specifics.

MR. BILLY: Nancy? Okay. Lee?

MR. JAN: Yes. I'd like to ask about the swine process where those that were taken off the sow. On the second project, the Trial 2, five of 26 on Day 20 were still positive. Do you know if those five were five of the first 12 that were positive, or is that five that then become infected and --

MS. ROBENS: No. I understand what you're asking, but I don't know the answer. I can ask Roger Harvey to make it clear if you --

MR. JAN: I was just interested in would that indicate that some have a longer ability to retain or a longer carrier stage than others. That was my --

MS. ROBENS: I'm sure that probably is a major factor, but that line of research has not been carried as far as it might be to show the exact relationship between the infection, which presumably comes from the sow, and the conditions thereafter. They did have to be up on a wire or a mesh floor in order to clear, but as to the specific pigs

I don't know.

MR. JAN: One other question on that line. Do you know if there was any difference if the piglets are allowed to stay with the sow for a period of time and then moved to a screen floor and if they would clear also?

MS. ROBENS: I don't think they did that particular study, but again you could ask Roger Harvey for more details. He did some other studies, which I am not completely on top of. I just picked these three as being representative of the work that he's carrying out.

MR. BILLY: Okay. We very much appreciate the information you've shared with us. It certainly is timely, and we're very excited about these kinds of research results. They're going to contribute significantly to food safety. Thank you very much.

Okay. Now we move on to the final item on our agenda for this afternoon, which is the public comment period. There are three individuals that have indicated their desire to speak.

The first person is Felicia Nester from the Government Accountability Project. She wishes to address

two topics. One is HACCP Phase II, and the other is HIMP. Felicia?

MS. NESTER: My name is Felicia Nester from Government Accountability Project. First I'm going to talk about --

MR. BILLY: Felicia, maybe it would be easier if you went to that podium where folks could see you. Thank you.

MS. NESTER: First I'm going to talk about HIMP. We have two comments on the HIMP program. I passed out a chart before to members of the committee, and now FSIS is getting it.

First I wanted to talk about the statistical comparison that was being discussed this morning and to say that we would like to reiterate our call for an apple to apple comparison. So far, if I'm not mistaken, everything we've seen in terms of comparisons has been the 75th percentile under traditional with the average under HIMP.

What we'd like to see is a comparison of the averages of the traditional and the HIMP and the mediums of traditional and HIMP in both systems using the RTI data

because the RTI supposedly was sent in there specifically so that we could be assured that this data is consistent and objective.

Now I want to move to the chart. This is a chart of OCP 1 failures at one of the HIMP poultry plants for a two month period of time. The concern is this. At the beginning of the project, FSIS said that though they were splitting categorization between food safety and other consumer protections that the public was assured that OCP failures would be prevented by the inspectors in the plant.

What you can see from this chart is that between December 13, 1999, and February 12, 2000, the plant failed the OCP 1 standard on 32 working days, and it either met the standard or was below the standard, did better than the performing standard, on 13 of those days.

Our concern is what happened here? How could this happen under HIMP if the plants were going to be required to maintain control of their process and, in the absence of that, the inspector had the authority to step in and insure that this kind of thing didn't go out to the public?

Our second concern and question is around the end

of this chart, February 11, if I'm not mistaken, the Department released a public statement saying that there was no reason to believe that anything other than safe and wholesome product had been released by this plant, so my question is this. Did the Department not consult its own records before it made that statement, or are we not understanding what the Department's definition of wholesome is?

This is the concern and question. Does this sort of adulteration meet the Department's definition of wholesome, or does this violate the Department's definition of wholesome?

One of the reasons that we've particularly picked the OCP 1 is that at every public meeting on HIMP and at every National Advisory Committee meeting on HIMP, to my recollection, the National Association of Federal Veterinarians expressed concern about the inclusion of air saculitis in the OCP 1 category. There is some information, OIG investigative information and other anecdotal evidence, to suggest that these OCP 1 failures are for the most part, if not exclusively, air saculitis.

MR. BILLY: Okay. Thank you very much.

The next presenter is Dale Boyle, Dr. Dale Boyle, who is with the National Association of Federal Veterinarians.

MS. SCHULTZ KASTER: I have a question first.

MR. BILLY: Sure.

MS. SCHULTZ KASTER: She provided us with these packets, and I appreciate it. I'm not trying to disparage what's in the packet necessarily, but if you remember at the last meeting our esteemed colleague, Katie, provided us with a set of information that I guess we had as a committee a problem with information being presented like that, and that was from a committee member.

Now we have a non-committee member presenting us with information for consideration in a subcommittee, and I guess I would like to know what your thoughts are on that or what the other committee members' thoughts are on that.

MR. BILLY: Yes. I think my guidance to you would be to consider what was presented in terms of HACCP Phase II, and to the extent that you wish to consider other information from your experience or data or information that

was provided from anyone else, that's up to you to factor in. I'm not going to take any position on that.

I think what's important is that at this formative stage we draw from in particular your experience and your knowledge and your concerns about how we move forward in terms of HACCP. There will be opportunity for this type of information to be made available through the common process tied to the public meeting and to be factored into any decisions that the agency ultimately makes about where we focus our energies.

I respect the difficulty it represents in terms of being a lot of information and so I'll consider it as information that's available to you, but it's up to you to decide whether you want to consider it as you carry out your discussions this evening.

Yes?

MS. SCHULTZ KASTER: One other small comment about that.

MR. BILLY: Sure.

MS. SCHULTZ KASTER: I just think we should be consistent because --

MR. BILLY: That's fine.

MS. SCHULTZ KASTER: -- when Katie passed that out, as I recall, that information was scooped back up, and then it was mailed to us. Am I remembering that right? Is that right?

I mean, I could bring gobs of information with me to every committee meeting. I mean, I carry enough home. We need to be consistent in whether or not we're going to allow additional materials besides what you so ably present us with each time.

MR. BILLY: Yes. Fair enough. Perhaps what we need to do as we move forward is to have a more specific policy with regard to that.

I'm very reluctant to say that we shouldn't consider any information. On the other hand, we need to have an approach that's fair to everyone on the committee and the task that you've being given.

Why don't you consider that guidance I gave you for now. I'm not going to ask that you do it any particular way. What we will do is come up with specific guidance for the future in this regard.

MS. SCHULTZ KASTER: Thank you.

MR. BILLY: Okay. Again, the next presenter is Dale Boyle. He's with the National Association of Federal Veterinarians, and he wants to speak specifically on the HIMP project, which is one of the updates that was provided earlier today.

Dale?

MR. BOYLE: The reason I asked to come forward is NAFV, the National Association of Federal Veterinarians, recently endorsed the HACCP inspection models project. We as an organization believe that this methodology represents a substantial improvement which offers both industry a greater opportunity to proceed and also improves the system of inspection oversight.

Basically what we're talking about is a labor intensive system that keeps the inspection force from fully utilizing their capabilities to oversee what's going on in a plant, and bottom line is we really believe that this is the way to go.

Now, you may think, you know, this isn't significant. A year ago I can tell you if I had come up and

made the same announcement, and these are veterinarians in the plant where the new system is. A year ago if I had come forward I'd have been looking for a job the next day. Many veterinarians throughout FSIS did not endorse this. They basically feared it. They saw it as a system that threatened food safety. They saw it as a system that just wasn't going to work.

Last week, and this is anecdotal information. Anecdotal means I have no intention of scientifically defending it. Last week, I was in front of a group -- Bill James was there, and he can attest to this -- of Alabama and Mississippi veterinarians. This was not a group that you would consider friendly a year ago to the HIMP project.

During the past two years, NAFV has criticized and offered suggestions and been very much a part of trying to get the system up and going and working well, and again I want to repeat we now have an unequivocal endorsement of the HIMP process. We tend to play an active role in continued improvement, but we do endorse the project.

MR. BILLY: Okay. Thank you very much, Dr. Boyle.

The final person that has asked to speak is Stan

Emling. He's representing NAMP, and he's going to speak both on the topic of pathogens and residues.

MR. EMLING: Thank you. NAMP stands for the North American Meat Processors Association, for those who are not familiar with that acronym.

I want to commend both the agency and the committee for the forward thinking that they're showing in their interest in the research projects and improving the inspection system for the future.

I think this is one of the first meetings that I've been at where I haven't heard the terms farm to table, so I would like to just refresh you with that comment because it's of very great importance to our members, who are further down the line. They are the downstream processors who take the materials that are raised on the farms, go through the slaughterhouse and come down to us.

I think some of the research projects I've heard about here are terrific, and I think the depth in them is fantastic. I only hope that they come to fruition faster than some of the things I started with when I came down here in 1983 and which I'm just beginning to surface out of the

system.

There were references, you know, to the authority or maybe I should say to the lack of it because some of the things that are important to us as processors -- we're living in the present tense, not the future, and we're still being buffeted by H7 recalls and other kinds of pathogen problems.

As I hear you talk more and more about residues, not knowing where that's going to go, but if it ends up affecting people who are downstream who have no control over it getting into that animal that they may be handling, we're going to have another serious problem because we have no place to go, so I see this being compounded.

I guess what I'm asking you here today is just to consider that maybe we need some authority. Maybe the agency, and I know how difficult it is. We've got state inspection tied up in the Congress, and it's going nowhere because of the politics behind it.

I know that APHIS has animals and FSIS has food safety. We can't seem to combine them, but maybe if we could we could move forward faster, so I'm just asking you

to think about those things and to think about the fact that not doing anything to help the downstream processor avoid more problems with E.coli 0157:H7 and maybe what you're going to do with residues and things, the concentration issue that Dr. Woteki brought up.

Maybe it wasn't affected by going into HACCP, but you're seeing it being affected by the combination of businesses who can't afford the risk, don't have the financial background to be able to withstand recalls, some of which the last one I noted went back to July. I don't think there's much out there, but whatever.

I think you need to take a look at that and help the smaller processors who are not part of the original system get back at the farm, find the answers, do some GMP work back there, do whatever you can to help them, and if you would just consider that we would greatly appreciate it.

Thank you.

MR. BILLY: Okay. Thank you very much, Stanley.

Okay. I'd like to refer you back to the agenda and the evening subcommittee sessions. We have three subcommittees that will be meeting from 7:00 until whenever.

I hope that the subcommittee that Rosemary is on finishes earlier so she doesn't miss out on Trick-or-Treating.

MS. MUCKLOW: I've got my treat. I hope it's a treat and not a trick.

MR. BILLY: I thank the committee in advance for their hard word. I know you're tired now, but hopefully with a little sustenance you'll rejuvenate and be able to deal with these three important issue areas and provide us some good input tomorrow morning for consideration by the whole committee and then eventually by the Secretary.

Any other questions? Okay. In the agenda it lists the meeting rooms. They're all here on the first floor right around the corner.

Okay. Again, thank you all very much. See you in the morning.

(Whereupon, at 4:43 p.m. the hearing in the above-entitled matter was concluded.)

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Nat'l Advisory Committee on Meat and Poultry Inspection
Name of Hearing or Event

N/A
Docket No.

Washington, D.C.
Place of Hearing

October 31, 2000
Date of Hearing

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Lorenzo Jones
Name and Signature of Proofreader

Heritage Reporting Corporation
(202) 628-4888

Heritage Reporting Corporation

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Gabriel Thomas
Name and Signature of Reporter
Heritage Reporting Corporation