UNITED STATES
DEPARTMENT OF AGRICULTURE

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

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INSPECTION MEETING.)

Holiday Inn Capitol
550 C Street, S.W.
Washington, D.C.

Tuesday,
June 5, 2001

The meeting in the above-entitled matter was convened, pursuant to notice, at 8:35 a.m.

ATTENDEES:

Gladys Bayse
Sandra Eskin
Carol Tucker Foreman
Michael Govro
Martin Holmes
Lee C. Jan
Alice Johnson
Collette Schultz Kaster
Daniel LaFontaine
Elsa Murano
John Neal

P R O C E E D I N G S

(8:35 a.m.)

MR. GIOGLIO: Good morning. Welcome to the spring 2001 meeting of the National Advisory Committee for Meat and Poultry Inspection. My name is Charles Gioglio from FSIS, Director of the Meat and Poultry Advisory Committee staff.

We'll just touch on a few administrative things before we kick off the meeting. I have my staff here, Moshe Dreyfuss and Lorraine Canon. Sonya West is out at the registration table along with a number of other FSIS folks. We're here to help you if you have any questions or anything that we can help you with please let one of us know.

We also have a telephone out at the registration desk for incoming calls. You may want to make a note of that number. It's (202) 475-4000 and the extension is 7188. I'll repeat that if you need, (202) 479-4000, extension 7188. If you get any calls during the meeting we'll take the messages out there and post them for you or one of the staff will track you down and bring you your messages.

With that, I'd like to turn the meeting over to Ms. Margaret Glavin, Associate Administrator of FSIS. She will be Chairing the meeting this morning.

With that, Maggie.

MS. GLAVIN: Thank you, Charlie.

First of all, I'd like to welcome you on behalf of USDA and FSIS. There's some new faces this time which is lovely. So in a few minutes I'm going to ask you to introduce yourselves, but I'd like to extend a special welcome to our new members. We really appreciate your willingness to serve on this committee and participate in this very important process.

It's very important to us as an agency to receive advice from a good cross-section of stakeholders. This committee certainly has a good cross-section of stakeholders.

The last committee made very valuable contributions to the Department on issues such as listeria monocytogenes action plan and recommendations about ratite and squab inspection. It's because of these types of accomplishments that I look forward to your hard work and contributions.

The issues you'll be presented with today include our emergency strategy on eggs and egg products inspection, the industry petition to amend the HACCP regulations and Federal, state and local government relations.

In a few minutes I'll have each of you introduce yourself, but before that I'd like to introduce our special person here, Mr. John Hogan, who is the Acting Deputy Undersecretary for Food Safety.

John?

MR. HOGAN: Thank you, Ms. Glavin.

I will add my welcome to that of Ms. Glavin and I'm sorry I haven't had a chance to meet all of you individually but I hope that will be corrected perhaps before this meeting is over.

I also want to congratulate you on your appointment. This is an important committee. It's one that the Secretary and all of USDA consider important. It's one of the two principle committees that serve the FSIS agency.

This is the 30th anniversary year of the creation of the National Advisory Committee on Meat and Poultry. Congress established this in 1971, as you know, and it's been doing yeoman's service ever since.

Both enactments require the Secretary of Agriculture to consult with the Advisory Committee before issuing product standards and labeling changes and other related matters. The committee has served as a valuable asset in addressing issues referred to among those that Ms. Glavin just mentioned in the last appointed committee.

Ensuring the safety of meat products has set forth the enactments mentioned above, that is the Meat Inspection Bill and the Poultry Inspection Act, rather, is an important responsibility, one that Secretary Venemon, the Food Safety Inspection Service and its employees, take very seriously.

The mission of food safety is very important, not only to all citizens of the United States but to the millions of people around the world who consume the meat and poultry products produced here in this country.

From my observations of the Department the food safety priorities are given close attention by the Food Safety Inspection Service and by this committee as it has in the past. I am sure that you are aware, as the Agency is, that for all policies, especially the new ones, to be successfully implemented and effective they must have input and cooperation from all links in the food safety chain that are affected by those policies.

A hazard analysis and critical control point system adopted in 1996 is a case in point. It was a major undertaking by the Department of Agriculture to address the serious problem of food-borne illness in the United States associated with meat and poultry products. That system clarifies the respective roles of government and industry in the food safety mission of the Agency.

More recent innovation of that system, the HACCP-based inspection models project otherwise referred to as HIMP, has been tested and redesigned by the Courts and is being implemented on a voluntary basis in several poultry and meat plants today. Government, industry, scientists and consumers can and do come together as noted to solve

problems and promote solutions to food safety issues.

Recently a study by the Control Disease Center in Atlanta, Georgia appears to support the fact that the HACCP system is having a very positive effect on the number and severity of certain food-borne illnesses. The numbers remain higher than the Food Safety Inspection Service would like to see them and perhaps that is where you and your committee can help this Agency do a better job with your advice and suggestions.

Through meetings such as this we can all come and ensure that USDA's food safety policymaking process continues to be transparent giving industry and the public opportunity to provide input and be fully involved. The Secretary, I and the FSIS Agency look forward to receiving the recommendations and advice of this committee as you address the issues set forth in today's agenda. Thank you very much.

MS. GLAVIN: Okay. Thank you, Mr. Hogan.

Now what I'd like to do is ask each of you to introduce yourselves and tell us a little bit about what you are bringing to this committee, your point of view, what you are interested in. You're going to be working together over the next two years and this is an opportunity to kind of jump start the beginning of those relationships.

Also, as a housekeeping matter, it's essential

that you talk into a mike. The acoustics would be terrible without the mikes. It's also necessary that when you speak you start by saying your name for the recorder. The danger if you do not is that something Dan LaFontaine says that you absolutely disagree with violently will be attributed to you.

(Laughter.)

So if you want not to have that happen you have to say your name as you start.

So, if I could, I'd like to start at this end of the table with one of our new members and ask you to introduce yourself and tell us a little bit about yourself.

MS. LEACH: Good morning. I'm Irene Leach and in my work role I am a faculty member in consumer studies at Virginia Tech teaching both graduate and undergraduate students. I am President of the Virginia Citizens Consumer Council, a consumer advocacy in education organization that's active in Virginia and currently President of the Consumer Federation of America.

I have a history of growing up on an Angus beef and Yorkshire hog farm in Central Virginia. Today I help run that farm. We have a Farm Manager who's there on a daily basis, but I am actively involved in that operation.

MS. GLAVIN: Thank you very much.

Marty?

MR. HOLMES: My name's Marty Holmes. I work for the North American Meat Processors Association and have for the last three and a half years. Prior to that I was with Southwest Meat Association in Texas, which was representing a five state regional state trade -- regional trade association.

Been working with the meat industry since 1987. From '87 to '91 I was actually in meat processing for a food conglomeration company out of Houston, Texas. Thank you. I look forward to working with the group.

MS. GLAVIN: Thank you.

MR. LaFONTAINE: I'm Dan LaFontaine. I'm with the South Carolina Meat and Poultry Inspection Department. I have been with that department for eight years. I'm, along with a few others, one of the oldtimers on this committee. This has been fortunate to be reappointed for the third, and final, time.

Prior to my going with the South Carolina program, state program, I had a 26 year career in food safety with the US Army Veterinary Service. Thank you.

MS. GLAVIN: Thank you.

MR. GOVRO: I'm Michael Govro with the Oregon Department of Agriculture. Been there since 1976. I spent many years as a field inspector and Oregon does not have a meat and poultry inspection program but we -- in my agency

we do inspect retail-exempt operations and have considerable experience with HACCP through the seafood HACCP inspection.

MS. GLAVIN: All right. Thank you.

MS. MORENO: Howdy! I'm Elsa Moreno. I'm at Texas A&M University. I'm a Food Microbiologist by training. Have been down at Texas A&M for about six years. I'm also the Director of the Center for Food Safety there.

Prior to that I was at Iowa State University. I'm a researcher first and foremost as well as an educator and have been engaging in not only research but a lot of training of industry and also overseas with some government officials in other countries regarding HACCP and also good agriculture practices, which is not germane to this committee perhaps but maybe it is. Thank you.

MS. GLAVIN: No. I think there's a real connect.

MS. MORENO: Yeah. I think so, too, yeah.

MS. GLAVIN: John?

MR. NEAL: My name is John Neal. I'm with Coursey Smoked Meats in the little town of St. Joe, Arkansas. I'm a member of the Southwest Meat Association and we've been in business -- it's my wife's family business which we basically inherited and were pushed into but we love it.

We've been USDA inspected for over 25 years. We ship statewide. We have a small retail area but we do a big business for a little business and we are currently into the

exporting of our product overseas. I'm looking to bring in some higher-level education for small plants as well as industry that are suited toward the personnel that are involved in those situations. Thank you.

MS. GLAVIN: What do you produce, Mr. Neal?

MR. NEAL: We produce cured and smoked meat, hickory smoked meat.

MS. GLAVIN: Oh, thank you.

MR. NEAL: We're very exclusive on that, just nothing else.

MS. GLAVIN: Thank you.

MS. Kaster: My name's Collette Schultz Kaster. I'm with a company called Premium Standard Farms. Premium Standard Farms is a very large vertically integrated farm to table pork operation. We are the second largest producer of pigs in the country and we are in the top 10 for processing operations.

We have operations in Missouri and North Carolina. We're also owned by Contee Group, who is a large also feeder of cattle, you know, it's a large poultry operation. So I guess it would be fair to say that I represent a larger segment of the meat industry.

I have been with the company for seven years. I do our food safety and quality assurance programs as well as our R&D programs. This is my second stint on the committee

and I'm looking forward to meeting the new members and interacting with the group that was here before. Thank you.

MS. GLAVIN: Thank you.

MR. JAN: Good morning. I'm Lee Jan. I'm the Director of the Texas Meat and Poultry Inspection Program, which is located in the Texas Department of Health. This is my second go on this committee.

I'm also, in addition to meat and poultry inspection, I've also been in the Air Force Reserve for 26 years in public health, military public health. I've got nine years experience in private veterinary practice.

So I've got experience on the government side and the private industry side.

MS. GLAVIN: Thank you.

MS. LOGUE: Good morning. My name is Catherine Logue. I am from North Dakota State University. I'm an Assistant Professor in the Department of Vet and Microsciences. My specialty is in food micro and particularly meat microbiology, slaughterline and slaughterline technology.

I also teach food safety, food-borne pathogens and food micro. We have at NDSU the first minor degree in food safety in the country.

MS. GLAVIN: Okay. There's something for Mr. Neal, who's looking for higher education in the small

industry, yeah. You two will have to get together.

MR. LINK: I'm Charles Link. I'm Director of Regulatory Affairs for Rocco Incorporated. Rocco is a vertically integrated turkey and broiler producer in Harrisonberg, Virginia. I don't know where we rank on that, so we're not number two for sure but we try to hold our own.

I've been in this business for 21 years, which means I probably started when I was 10.

(Laughter.)

This is my first meeting and I'm glad to be here and I hope to participate or add some light somewhere, anyway.

MS. GLAVIN: Thank you.

MS. BAYSE: Good morning. I'm Gladys Bayse from Spellman College in Atlanta. I'm a professor of chemistry there. I just finished year 27 in terms of academic years. I'm new on the committee, as well.

My students and I over the years have done some research on the benzene arsenid additives used in poultry and swine so perhaps I can bring something from that background. I'm delighted to be on the committee.

MR. MAMMINGA: I'm Mike Mamminga. I'm with the Iowa Department of Agriculture and Land Stewardship. I am Bureau Chief of the Meat and Poultry Inspection Program. I put on white pants, a white shirt and black bow tie 30 years

ago, a couple of weeks ago.

We have had cooperative agreements with the USDA, the FSIS, since the Acts were passed and it was possible to do so.

I am interested in the relationship between the state programs and FSIS and I'm interested in how we apply these rules and regulations to all sizes of plants and to do our jobs, to produce safe food and prove that we have produced safe food. I enjoy the start of my second term.

Thank you, Maggie.

MS. GLAVIN: Thank you.

MS. JOHNSON: Alice Johnson with the National Food Processors. I appreciate the opportunity to serve for my second term of the committee.

I have worked seven years with trade associations dealing with meat and poultry and food. Prior to that I worked for 10 years for the Food Safety Inspection Services in IIA and the Circuit Supervisor.

MR. MORSE: Good morning. I'm Dale Morse, a Physician-Epidemiologist with the New York State Department of Health.

I grew up on an apple and dairy farm in Western New York and attended Cornell University College of Agriculture. I trained as an internist also at the Centers for Disease Control and have spent the past 20 years

investigating failures in the food safety system at times involving outbreaks with noroic virus in clams, salmonella enteritidis associated with shell eggs; E.coli with hamburgers, listeria and other pathogens.

I'm a member of the State Epidemiologist Food Safety Committee, FORCG, and the National Center for Infectious Disease, CDC's Board of Scientific Counselors and have grants, NIH grants, in Eastern and Central Europe. This is my third time returning so I'm one of the oldtimers. Thank you.

MS. GLAVIN: Thank you.

Sandra?

MS. ESKIN: Yes?

MS. GLAVIN: I thought that was you standing over there but I'm so nearsighted I was afraid to say something. So could you introduce yourself?

MS. ESKIN: First, I'm sorry I'm late but I'm a local resident, which means I got stuck in rush hour traffic.

My name is Sandra Eskin. I'm an attorney and public policy consultant again here in the D.C. area and I cover a range of issues dealing with consumer protection for public interest groups.

Primarily I've done work for about 10 years now for AARP on a whole range of food safety issues, both

dealing with FSIS and FDA as well as general food labeling and drug labeling. This is my first time on the committee.

MS. GLAVIN: Okay. Thank you.

I will just mention, two members who have not made it to the meeting although we expect them, Nancy Donley is from the organization Stop, Safe Tables are a Priority, a consumer organization that represents victims of food-borne illness, and Carol Foreman, who I spoke to last evening and she said that she would be here later this morning. So they will both be here and if you will remind me I'll get them to do the introduction when they come in.

One thing that a number of you mentioned, you know, being in a second term or a third term and I thought I would just say a little bit about that in case some of the -- some of you may not be aware of this, in our charter for this committee the terms run for two years and an individual can serve no more than three consecutive terms.

So when the two year term is up we try to get about a third new members so that at any time we have people who've been here, who have a working relationship, who are engaged in the issues and some new people. You know, that's -- the Charter does not require us to do that one third turnover but we try to hit that roughly so that there's a regular turnover and there's also some consistency.

So we have a very full agenda for the next two

days. There's always a tension between all of the things we want to get before you and get your advice on and trying to leave a sufficient time so that we really do have a dialogue and a discussion and not just presentations.

We will -- what I'd like to do is just go over the agenda. I'll be talking about two different kinds of presentations, briefings and issues. We've used that terminology.

Briefings will be relatively short presentations on something that is very relevant to the moment. It is not something we will be asking to explore at this time in depth, but something that we think you need to know about. There certainly will be time for some questions and answers, but not for extended discussion. Some of these may become topics for discussions at future meetings.

The second kind of presentation will be issue presentations and there will be three of these. These are the issues that we have asked you to focus on over the next two days and give us your thoughts on. So you will see that this evening we have divided you into three issue groups and we'll ask you to work this evening and to return tomorrow to give us the benefit of your deliberations on those three issues. So when you see briefings and issues that's the distinction we're making.

So we're going to start off today with a briefing

on ratite and squab inspection. As you know, our appropriations bill this year requires us to provide mandatory inspection for ratites and squabs. We had a very short turnaround time to get that into place.

Fortunately, this committee had spent several meetings working on the inspection of species that are not required -- that have not been required to be inspected. So we had some real good background which really served us in good stead since we got pushed into this very quickly, as it turned out.

Following that briefing Joe Levitt, who is a Director of the Center for Food Safety and Applied Nutrition at FDA, will give us an overview and update on food safety activities at FDA. So he'll be joining us later this morning and told me he would try to stay around for part of the meeting.

Following Joe's update we'll discuss our first issue and that is our emerging strategy for egg and egg products inspection. We are in the process of making our approach consistent with the Agency's current science-based food safety regulatory approach to meat and poultry products and we look forward to receiving your input.

Then before breaking for lunch we will brief you on our current thinking for new technologies. One of the staff is here to do that, several of the staff.

We'll follow lunch with a second issue and that is FSIS' current thinking on the industry's petition to amend the 1996 HACCP regulations. We'll then move straight into the third and final issue which is Federal, state and local government relations.

As part of our farm to table strategy we need to continue to develop and improve our working relationships with jurisdictions at the Federal, state and local levels. Your input will be extremely helpful.

As you no doubt noticed as we went around with introductions, we have a number of state program people here from different parts of different states but the state input to this committee is one of its most vital.

We'll finish today's presentations with two additional briefings, the HACCP-based inspection models project and FSIS Next Steps. Then we'll close out the day with public comments. We have a large audience. My goodness! The last time I looked over there there was no one there --

(Laughter.)

-- and now it's filled up.

For those interested in providing public comments it would be very helpful if you would notify either Charles Gioglio or Sonya West, who I think is still at the front desk, so that we can work out times.

The three subcommittees will meet this evening from 7:00 to 9:00. Dale Morse is leading the subcommittee on emerging egg and egg product strategy. Mike Mamminga will head the subcommittee discussing the industry's petition to change the HACCP regs and Dan LaFontaine will lead the third subcommittee, who will discuss Federal, state and local government relations.

We'll get started tomorrow again at 8:30 and each subcommittee will provide a briefing on their discussions and recommendations from the evening session and then we'll break for lunch.

After lunch we have planned three more briefings, one from the National Advisory Committee for Microbiological Criterias in Foods. We have traditionally had that committee report to this committee on their activities. A second briefing on applied epidemiology and a third one on our field correlation strategy. Then we'll discuss any remaining issues and plans for the next meeting and wrap up again with public comments.

So in order to get things started -- well, first of all, let me ask you are there questions or issues with respect to the agenda?

(No response.)

Okay. Then what I would -- what I will do now is turn over to Dr. Arshad Hussain, who will address the

Agency's recently implemented regulations concerning the inspection of ratites and squabs.

Dr. Hussain?

DR. HUSSAIN: Thank you.

(Pause.)

Good morning and welcome to Washington again. This is the first briefing, the easy one, and it's a very brief briefing on ratite and squab inspection.

We were mandated by our budget attachments that we should have an inspection system in place within 180 days, that's about six months. What this mandate really did was it mandated the PPI to incorporate squab and ratite inspection in it. Presently we are -- we were doing a voluntary inspection for both of these species and on April 26, 2001 the inspection became mandatory.

I will just briefly walk you through a couple of things before we go into the meat of it. We had to define ratite and then we had to define the squabs. The ratites were very easy, these are flightless birds of either sex with small, rudimentary wings and medium-tender meat, etcetera. In ratites we have basically the major interest is in ostriches, emus and rheas.

The squab definition is a little bit controversial, was controversial, most will remain controversial, but this is the best we have today. Squab is

a fledgling pigeon of either sex that is tender meated with soft pliable smooth-textured skin, flexible breast bone cartilage and has not flown yet. I think this comes from Webster directly.

We did some research and there are other reading definitions within the squab and pigeon industries and interested parties. The definition is still controversial.

We did publish a Federal Register notice amending the regulation on May 1, 2001 which was a couple of -- three days later than we were supposed to, but we were very fortunate that we were able to do that still on time. Six months is really not much time to do the staff work and get everybody's input in and publish it. Then we published two FSIS notices which covers the ratite and squab inspection procedures.

In the case of both of these birds, so to speak, all rules of PPIA apply. The only thing Congress did is made it from voluntary to mandatory inspection. There were no strings attached. So without any difficulty all the regulations that we have now presently in place apply to both these birds.

We had in place under voluntary inspection a guideline for ratite inspection. That guideline has been adopted as is for the time being. We will continue conducting inspection in Federally inspected plants and

state plants using that guideline.

The squab slaughter inspection is being conducted and was being conducted using the traditional inspection system which is still part of the regulation for the line and inspection activities.

The ratite slaughter inspection guideline is under review. Once we have finished reviewing that guideline we will publish it. The reviewed material will be finalized after consultation with the National -- of the union.

We will work on E.coli and salmonella performance standards as well as the requirements as is under HACCP. We do not have data at this time for both of these birds.

As usual regarding the present regulations and the requirements of BODAC (phonetic) the state inspection will continue as it is. It's just changing over from voluntary to mandatory. There is really no change in there, either.

For interstate and foreign commerce the product must be inspected. This is a major departure from the past. There were no requirements for interstate movement and no requirement for exports and imports.

With the species coming under mandatory inspection all of the rules of PPIA and FMIA apply and all regulations under CFR 9 apply here. So both import and export are under standard Federal inspection.

We did consult with the states while we were

developing the policy and were developing the regulation and the notices and we were in the process of trying to implement it so all interested parties were brought into the picture. We sent two letters, one to the states, which have equal to inspection system with FSIS and the others who do not. The message still was the same.

What establishment had to do on April 26th thereafter is to apply for inspection under the new regulations from voluntary to mandatory inspection and then it requires that they should have SSOP and HACCP implemented within a specified period of time.

I have with me Dr. Henry Sidrak on the right side of me, who is the principle staff officer of ratite and squab inspection, and Dr. Ragland, who is a senior staff officer with my staff. At this point if you have any questions we'll be more than happy to answer them.

MS. GLAVIN: Thank you.

MR. JAN: This is Lee Jan. I just have one question and I'm sure you may not be the right person to answer it but someone here may.

I just wonder why these birds or species were selected and quail was omitted? It seems to me that at least in the southern parts of the southern states and in any of the restaurants I've gone to you see quail on the menu but you don't see the pigeons or the squabs on the

menu.

So it seems like there's a bigger market for quail and that product has been omitted. I just wonder if there's a reason for that?

MS. GLAVIN: This was not something that the Department put forward as a legislative request. The provisions were put in through the Appropriations Act. So we really don't know, you know, what was driving that or -- the record shows little to no discussion of it. So there's not -- there's not a legislative history to go to.

I think that the appropriations staffs might be able to give you some further information but it was not -- you know, it was not a bill that was brought up and subject to debate and markup, etcetera. It just came in through the Appropriations Act. So I can't really help you on that.

As you know, with this committee we talked a lot about what kinds of criteria ought there be -- ought to be applied to determine whether a species not currently under mandatory inspection should be brought under mandatory inspection. Certainly, one of the ones that I remember from those discussions was the amount of product being produced and sold in this country.

MR. JAN: Thank you.

MS. GLAVIN: Yes?

MS. ESKIN: Sandra Eskin. Did either of these two

species present any unique food safety concerns?

MS. GLAVIN: Let's go to our experts.

(Laughter.)

MR. SIDRAK: Henry Sidrak, FSIS. Nothing really particular about ratites or squabs that presents a unique food safety concern. They are pretty much the same as other poultry.

I think, as Dr. Hussain mentioned, the E.coli -- the generic E.coli, E.coli and the salmonella is already taken into consideration to be developed.

MS. GLAVIN: There are obviously some practical issues with respect to the ratites since those aren't able to be processed in a poultry plant. They are generally processed in a red meat plant, for obvious reasons.

(Laughter.)

Dan?

MR. LaFONTAINE: First of all, an add-on to Sandra's question.

Some who hadn't been involved with the committee or that had been involved with the committee before knew we spent quite a bit of time in the FSIS staff on doing literature research on all of the non-amenable species. If you look at that it's -- although it's weak in some areas it shows the same food-borne pathogens that we look at in poultry or in -- in other poultry species such as salmonella

campylobacter, et cetera.

So the conclusion of this committee was that all of these species that are regularly produced for commerce need to be under inspection. The basis for that was public health.

The question that you may not have an answer to is what, if any, activity by FSIS or Congress is happening as far as the additional species that in principle should go under mandatory inspection? Can anyone from FSIS give me any information on that?

MS. GLAVIN: Well, at this point the Agency is continuing to look at options on various kinds of animals and, you know, using the work of the Advisory Committee. We do not have any legislation either drafted or -- obviously, if it's not drafted we haven't sent it forth to the Hill.

I'm not aware of what -- and I don't know -- I don't see anyone here who could give us a legislative update in terms of what kinds of bills are pending on the Hill, but I can ask that we -- we keep a list of all bills that are introduced that have anything to do with our work. As you know, there are many, many, many bills that are introduced and so -- but it does give you a quick overview.

So maybe we could arrange to have Chris or someone from the legislative staff bring copies of that over, that list. That might shed some light on it. I can't help you.

Sorry.

Do you have any of these species under inspection in your state, Dan?

MR. LaFONTAINE: We have squab. Is that what your question was? Yeah, there -- to the best of my knowledge there are two major squab slaughter and processing plants in the United States. There are others but one in South Carolina and then the other in California.

So we were quite involved with your staff early this year to familiarize them with the -- with the process. Fortunately, I'll add that it was pretty much a non-event for us because they already had an FSIS grant of inspection for poultry. So it was a matter of some minor changes in our case.

MS. GLAVIN: Okay.

Lee? I was going to ask you if any of the other states had experience with these -- with these previously non-amendable species but perhaps you could answer that and ask your question.

MR. JAN: Well, let's try it. Lee Jan.

In Texas we've had ratites under inspection, mandatory inspection, since it was first introduced as a new or a -- a new form of meat. We've also -- squabs, we don't have any producers in Texas. We have quail. We have a big quail producer in Texas.

But we require inspection, mandatory inspection, of all species used for food if they're birds, any bird species. So we don't -- if someone does a bird, even if it's one that's not inspected currently under -- by FSIS it's mandatory under Texas. We also have exotic game and buffalo that is mandatory under Texas.

But my question or initially I guess a comment and then a question, since we have had ratite -- mandatory ratite inspection for some time one of the hazards that we recognized and were concerned about was the use of microchips for identification that was particularly used often early in the industry, the development of the industry, when the birds were very valuable.

It was -- they were used to try to reduce the thefts but it became a problem or a potential problem for the meat because depending on where that microchip device is planted it tended to migrate. The birds did not have an ear to put the microchip implant as you do in livestock species and the ear comes off and it seems to stay pretty good.

So what we required, we made -- by regulation we required that the producer certify whether or not the birds were microchipped or had been identified with a microchip or if they bought birds that were microchipped and, if so, we want to know the location.

Then we required the plant to find that microchip

before -- and that's where they use a scanner. Now that tended to be some problems but the plants were able to resolve that.

I don't see that requirement unless through HACCP but, you know, whether it's identified, you know, I mean that would be where you'd find it. I guess we'd have to address that, but I see nothing in the regulations that would address specifically microchips. I was just wondering if FSIS has given some thought to that.

DR. HUSSAIN: Identification of animals and flocks of birds have been an issue with us for the last 25 years. I think we worked very hard sometime in the late '80s and early '90s and we have the taskforce and my staff, Dr. Lazenby, headed it. It really did not come to a conclusion because usually you could not convince the cattlemen and others to go along with us on that one.

We are now again active in that area. Computer Sciences Corporation made a presentation to me and my staff last week. They brought with them a package that they are using now in the European Union to track animals for various reasons but to clearly BSE and now the hog diseases.

We did refer them to other folks and we will -- if somebody's interested they can let us know and we will refer them to you. We basically -- this is what we told them that we were looking to get packages that they left with us and

we will be in touch with them.

But at the same time we would refer them to the National Turkey Federation as with Cattlemen's Association AMI and other associations. We gave them their addresses. I think this is -- this is an activity which really depends on the industry to follow. Primarily, not FSIS activity because, as I said, we tried it in late '80s and early '90s. We really did not get anywhere with that.

So that is one package that will be -- these people will be making contacts with you. The European Union is using it very successfully and it's a large package and it was very impressive how they can almost track the animals from birth to the slaughter house. It's very easy to use. It's not very expensive.

So we will work with them and see if we can do anything about it. That's all we have really at this time.

MS. GLAVIN: Okay. What about the issue of when the animal goes to slaughter recovering the chip, the identification, so that it doesn't become part of your food?

DR. HUSSAIN: They had various options. One of the options as a standard option was to have just an ear tag which we definitely use in the case of hogs and other animals. It's not useable in the case of birds.

They will have to develop a standardized or non-standardized species specific product to go along with that.

It could be -- if it's not an ear tag, if it's not an implant in the ear as we use it now in calves and hogs, it could be with a leg band or it could be in the wing band.

The wing bands were used in the early '80s to identify birds. The Swiss used them very successfully in wildlife to monitor the rabies and incidence of other diseases which are zoological or for other purposes communicable to animal species. So they can come up with that.

The key was basically to have the software which is capable of handling all species at all times at all locations. It's almost a little bit better than the Rivers we have which is under Oracle specific part of the stage we can use it together.

But they have several options available and we will definitely -- we have the information if anybody wants it that we will give to provide that information to you and then they will be in touch with you directly. They have a whole whole now in CSE in Herndon, Virginia assigned to their work.

MR. JAN: One thing I would -- this is Lee Jan again -- one thing I would maybe mention here is that I believe this could be identified as a hazard reasonably likely to occur or a hazard not reasonably likely to occur in this address but I think emphasis needs to be made to the

inspection staff that if a plant doesn't address it then the need to ask the question, "Why didn't you address that?" because it is an issue or can be an issue.

The big thing with the ratite -- and the technology I'm sure has improved -- but initially or early on the best place they recommended to use the microchip was in the pippen muscle in the back of the neck and if they did that properly it didn't tend to migrate. But the problem had been when the birds are so valuable coming from the -- coming out of the eggs they were valuable immediately there was a little risk and some birds were killed.

So some people decided that it's easier to use on of the vestigial wings or that area but they couldn't put it very far out because those wings were -- when they run they keep their wings out and so they get damaged, they run into fences and stuff. So they tried to put it closer to the body and that's where the chip would migrate.

It migrates a long way and that was the reason that we required them to scan to find the location of that microchip. That's not 100 percent but at least we had an effort.

But I think if the plants address it in the HACCP plan and our inspection staff and FSIS' inspection staff knows that that is something that needs to be addressed in their HACCP plan and it's not that they ask questions about,

why is that not a hazard? I think that would probably be the best way to address that.

MS. GLAVIN: Thank you. It sounds like something we do need to get into our guidance to our inspectors. That's great.

DR. HUSSAIN: Just for the information, we are developing guidelines for calf implants for residues now.

MS. GLAVIN: Great.

DR. HUSSAIN: To resolve that issue that calf implants do not get into either the animal food or the human food chain. So we are developing guidelines for calves.

MS. GLAVIN: Okay.

Mike?

MR. MAMMINGA: Mike Mamminga. There's an issue here that we haven't really talked about during this presentation and that is, as Maggie said, FSIS didn't ask the Congress to act on ratite and squabs to make them amenable to the Acts. So you might ask yourself, well, why did it happen?

I think it addresses a much broader issue about what is amendable to the Federal Meat and Poultry Inspection Acts which have traditionally been cattle, sheep, swine, goats, equines and domestic poultry until the regulations under the PPIA were amended to include ratites and squab.

That has to do with the fact that mandatory

species are inspected at taxpayer expense. We all pay for that in our taxes. Whereas, voluntary species you have to pay for it.

So with our very consumer-conscious society there is an expectation that all of the flesh that we eat from animals and birds are inspected. If they are not inspected as a mandatory species, that they be subject to some sort of a voluntary inspection program, which FSIS and the state programs often provide for a fee, a fee which may be between $20 or $30 per hour or more.

So for the ratite people and the squab people wanting inspection there was a certain financial consideration here to have their species made mandatory to the Acts and then the inspection is provided for free or at least we all pay for it through our tax dollars.

There are other species or producer groups out there who would like to have their species inspected as mandatory, the buffalo people, the deer people, the people in cervid a long time requested that or wanted it, the same thing for the quail people, oftentimes they request mandatory inspection.

So that goes into the whole issue that we have discussed many times at this committee in the past what should be amenable to the Acts. There are a couple of sides. Food safety is one thing that we're interested in

and the other is the economics of providing another mandatory inspection service at taxpayer expense. Of course, the third issue is the producer groups having to pay for voluntary inspection.

So it's kind of interesting here. It seems to me that the ratite people and the squab people did their homework and went to the Congress and got their business done. It provides the same sort of inspection that cattle and sheep and the rest get and it comes back to us, it will come back to us in FSIS and the state programs, what is our food safety thoughts on the animals that we use for food and whether or not any of them should be voluntary or whether all of them should be mandatory. I think that's kind of an issue here.

MS. GLAVIN: Okay.

Are there further questions of the presenter or comments that people would like to contribute?

(No response.)

Okay. Thank you, Dr. Hussain.

Okay. We are for once -- this never happens on this committee -- ahead of schedule and so I'm going to skip ahead to the issue presentation emerging egg and egg product strategy and have that presentation made.

My proposal is we have the presentation, we take our morning break and then we come back. If -- well, first,

after the presentation if there are any questions, requests for clarification, we can handle those.

This is one that will be going to one of the subcommittees this evening for in-depth discussion. Then we'll take our break and we will hear from Joe Levitt after the break.

So Judy Riggins is going to make the presentation on our emerging egg and egg product strategy.

(Pause.)

MS. RIGGINS: Okay. I think we're ready to roll. Thank you. Thank you. I'm happy to be here with you this morning.

This is the first time that we are bringing an egg issue to the advisory committee. We thought it was important. First of all, you've had experience with meat and poultry HACCP over the last three years and you have experiences and knowledge to share with us and to inform your recommendations to us.

Secondly, most of the state regulators also have responsibility for egg and -- shell eggs and processed eggs. So we thought it was important to share this emerging set of proposals that we hope to publish sometime toward the end of the summer or the beginning of the Fall.

So with that I'm going to first walk through FDA's part of the rulemaking or proposals and then walk through

FSIS'. I need to preface this by saying that we had a very public process that started in 1998 after the publication of the Interagency-SE risk assessment.

We convened several meetings in which we had working groups that were composed of members from the industry, from consumer groups, from the public health community and the states. The states have been very active with us in developing these concepts and then developing them into actual action items.

The egg safety action plan was actually published in December of 1999. After that FDA, CDC, FSIS, AMS, APHIS and the states all started working on the provisions that would ultimately end up in our proposals.

So what I'm going to present to you is our current thinking. Our regs are currently under Department review at this point. What I'm going to propose -- show you is the current thinking.

First let's start with the goals in the egg safety action plan. They were to reduce SE-associated illnesses by 50 percent by 2005 and to eliminate SE egg associated illnesses completely by 2010. I realize that this is an aggressive goal but we are -- you know, we are committed to working toward it.

Then how will we measure success? CDC currently has a number of surveillance systems that they employ and we

will use the information from those surveillance systems to determine our success. The 1998 CDC baseline data will be that which we will begin with, that will be our basis, will decrease in SE cases and outbreaks.

The CDC surveillance systems that we will rely on are the FoodNet, the National Salmonella Surveillance System, the National SE Outbreak Surveillance System and Food-Borne Diseases Outbreak Surveillance System.

The egg safety action plan has two strategies. As we worked through all of the issues we recognized that we wanted to accommodate very small producers as well as large coop organizations. So we developed a strategy that we believe has an equal approach in terms of -- or an equally effective approach in terms of providing a reduction in SE illnesses.

The first strategy has an emphasis on on-farm production. FDA will -- has responsibility on the farm for production animals and they will have responsibility for the rules that will govern on-farm production.

In packing and processing in strategy one is under FSIS' responsibility and then distribution retail surveillance, research and education we share responsibilities among the agencies.

In strategy two there is less rigorous requirements -- there would be less rigorous requirements

for production but there would be a kill step at packing and processing that would provide the same amount of protection and hopefully the same reduction in SE illness.

We hope that over time that there would be a shift from strategy one to strategy two but we recognized that we had to start with the industry as it currently is configured and currently exists. So we wanted to make sure that we had strategies that accommodated both.

We have had, as I said, Federal, state and industry actions that indicate clear progress. There are currently egg quality assurance plans that are employed by a number of the states that have had good results and we are using those as a basis to go forward. Lessons learned, things that were positive from those egg quality assurance plans are being employed and used in this egg strategy.

Secondly, the Food Code. The FDA currently has Food Code requirements that are promulgated by FDA but are actually adopted and implemented by the states. We hope to capitalize on the lessons learned from the Food Code experiences.

A related activity that FDA completed in December of 2000 was to finalize its rule on labeling and refrigeration. The labeling will now subsume FSIS' current requirement for labeling on egg cartons and egg packages. The safe handling instructions will stay to prevent illness

from bacteria keep eggs refrigerated and cook eggs until yolks are firm and cook foods containing eggs thoroughly.

The second part of the final rule is the requirement for refrigeration, that eggs that are received at retail be promptly placed under refrigeration at 45 degrees or lower. This is an extension of the current requirement that FSIS has for 45 degree -- for the refrigeration of eggs in transport. So we're completing the continuum.

The current thinking for on farm provisions would be nationwide consistent standards for the farm, packer, processor and retail. As I said earlier, FDA has responsibility for the farm and for retail and USDA has responsibility for egg packers and processors. Our thinking at this point is that we would implement through the state through contracts.

The on-farm components would include that chicks from SE-monitored breeders be used in all production. That's the APHIS NPIP program that currently is in place. Now there would be biosecurity measures that producers would use negative -- SE-negative feed, that producers would have cleaning and disinfection of houses, rodent and pest control and refrigerated storage of eggs.

With regard to verification that there would be one environmental test per laying cycle and if that

environmental test proves positive then there would be testing of a certain number of eggs based on statistical analysis. If those eggs test positive then they would go to -- they would be diverted to egg breaking and pasteurization.

At retail, FDA would codify certain egg-related provisions of the 1999 model Food Code. It would include options for serving foods containing raw or undercooked eggs, times and temperatures for cooling and holding foods containing raw or undercooked eggs and requirements for substituting pasteurized eggs for raw eggs for at risk consumers.

As I said earlier, surveillance would be that we would work -- we would partner with CDC to determine the human SE infection illnesses, numbers of illnesses. The outbreak detection investigation would be conducted by FDA. FDA would assess the practices and environmental circumstances of the outbreak, product identification and tracking systems and trace-back procedures, as I said, and update preventive controls.

With respect to research, FDA convened in September of 2000, a meeting in Atlanta, to begin to dialogue on research that is needed for SE in eggs. FDA has led the effort to develop a research plan which includes intermural and extramural and cooperative projects.

Then with respect to education, the two agencies along with AMS and APHIS are going to work on campaigns and training for producers, packers and processors, food service, food handlers, for both sensitive populations and the general population.

Then for consumers we believe education is important and we will have developed information for sensitive populations and the general population. We plan to work as a collective group of agencies that will develop the plans, work with the states, to make sure that we are including all of the important information. We'll share this with the public before we actually embark on the education project.

The timeline that we have currently would be that we would propose the rules in 2000. We'd go to final rule and implementation between 2002 and 2004. We would measure our impact in 2005. Then, as I said earlier, our goal is to eliminate SE illnesses by 2010.

Next I'll go to the current thinking on the proposals for FSIS. As you know, earlier this year Secretary Veneman pledged to continue to work to strengthen the Federal food safety programs.

As I said earlier, we identified eggs as an important food safety issue that the agencies needed to work on together. I'll skip this because it's repetitive.

The egg safety proposals at FSIS will be responsible for are founded on three principles. First, that food safety hazards can result in food-borne illnesses that occur in each state of the farm to table continuum and, therefore, each stage also provides us with opportunities for minimizing the effects of those hazards.

Secondly, those in control of each segment of the farm to table continuum their responsibility for identifying and preventing or reducing food safety hazards.

Thirdly, the EPIA, the Egg Product Inspection Act, public health mandate requires that FSIS address food-borne illness hazards within each segment of the egg product chain.

As I talked about earlier, there were two strategies, strategy one and strategy two. Strategy two risk reduction is based on treatments at the processor, designed to eliminate SE from contaminated eggs.

The FSIS strategy also includes provisions for systemic prevention of biological, chemical and physical hazards through the adoption by egg packing facilities and egg product plants of HACCP and targeted efforts to control and reduce harmful bacteria on and in shell eggs and egg products.

It also includes food safety performance standards that provide incentives to egg packing facilities and egg

products plants to improve safety and removal of unnecessary regulatory obstacles to innovation. It also includes efforts to address hazards that arise throughout the food safety continuum from farm to table.

FSIS inspection and our current thinking would be that inspecting products in facilities to verify that statutory requirements are being met and for taking appropriate compliance and enforcement actions when the requirements are not being met. This would be FSIS' responsibility.

We would rely less on after the fact detection of product and process defects and more on verifying the effectiveness of processes and process controls. We would restructure inspection procedures and rely on systems review techniques.

The industry's role. The industry's would be responsible for producing and marketing products that are safe, unadulterated and properly labeled and packaged.

Who would be effected? All egg products plants would be subject to requirements put forth in the proposals. If a shell egg packer sorts eggs from a source that is his or her own the packer would be required -- other than his or her own the packer would be required to comply with the proposed rule no matter the size of his or her flock. However, if a producer/packer with a flock of more than

3,000 layers would also be subject to proposed rules.

There's an exemption in the Egg Products Inspection Act for producers who have 3,000 or fewer layers. In our current thinking, we are -- we want to provide requirements for all those who are producing more than 3,000 and those who are being provided with eggs from other sources. This is who would not be effected. If a shell egg packer sorts eggs from his or her own production and has a flock of 3,000 or fewer layers it would be exempt.

Under the new system that we proposed industry would assume full responsibility for production decisions and execution and FSIS having set forth the food safety standards would monitor compliance with those standards and related requirements and under HACCP would verify a process control with pathogen reduction and control.

The egg packing facilities and egg product plants would develop and implement a HACCP system and sanitation standard operating procedures. We would also propose performance standards for both shell eggs and egg products and pasteurized shell eggs.

The performance standards that we would propose would spell out the objective level of food safety performance each plant processing these products would meet and allow plants to develop and implement processing procedures customized to the nature and the volume of their

production.

The performance standards at this point we believe would cover cooling and storage and we would move to eliminate prior label approval systems. We would require refrigeration labels on eggs and special handling labels on liquid or frozen egg products and we would eliminate the prior approval for blueprint specifications and equipment. We would also move to prohibit the repackaging for retail sale of eggs that have previously been shipped for retail sale.

Producers would be afforded a greater autonomy in decisionmaking affecting their own operations and would be expected to take responsibility for setting up the site and product appropriate process controls to achieve FSIS established performance standards.

We also expect that there will be new opportunities to incorporate new technologies and continuously improve food safety and that these technologies will be more readily identified once we give more flexibility to the industry.

So in conclusion, the further reductions in egg-associated in SE illnesses we believe are achievable and the government, states and industry will continue to work together to achieve these goals.

With that, I can take any questions that you might

have.

Yes, sir?

MR. NEAL: Ms. Riggins, one of the first things that you addressed that I'll address first is I'm concerned with the education, the public education, is are you planning to do a television as well as radio and pretty big work on the safe handling of eggs and how to cook and process them for people?

MS. RIGGINS: Yes. There is currently in place a collaborative effort among the Federal agencies, the consumers and the industry that have begun to develop messages for the consumers with respect to meat, poultry, seafood, fresh fruits and vegetables and other foods that we know are of concern with regard to pathogens.

This work that we are currently doing will feed into that effort and we do expect to have a very public process to develop the messages for safe handling and cooking of egg -- shell eggs and egg products.

MR. NEAL: Okay. Well, thank you. One of the other concerns I have is I noticed that you were talking about refrigerator temperatures of 45 degrees. It seems to me like the standard, that's very close to the tolerances. The standards basically for any product has been 40 degrees so why the difference in five degrees when it's not necessary and 40 would be better or below?

MS. RIGGINS: Yeah. The current provisions of the Egg Products Inspection Act direct the Agency to provide requirements at 45 degrees and that -- it's a statutory requirement and that's why we adhere to that.

We are aware that there is research underway that may impact that 45 degree temperature. If such research shows that there's a scientific basis for lowering it then we would move to take the appropriate action to go to Congress and have a change in the statute but currently it is statutorily 45 degrees.

MR. NEAL: Right. Well, I really base my question on the fact that meat and poultry are kept at 40 or below with those standards as part of our HACCP programs in the cooling.

MS. RIGGINS: Right.

MR. NEAL: The other thing I wanted to address was you're talking about going to the farm and I believe it was from the farm to the table, I know that's the major concern of FSIS in the future from farm to table, but when you get into a procedure where you have an individual that is producing eggs for -- and I don't want to touch on anybody, they could be anybody, Tyson's Foods.

I'm from Springdale, Arkansas. I grew up in the Tyson area and I know how it works and I was involved in it as a young man.

But you're going to have a farmer out there that has approximately eight houses and he may have 20,000 or 25,000 birds. Now when you start telling him he's going to have to have a HACCP plan this is -- we go back to the education -- you'd better get ready for it because they're going to have a hard time adapting to this because these people do take care of their pest control because of the loss of birds and not taking care of sanitation conditions will create a loss of birds and income for themselves.

But they're going to have a hard time adjusting to this without some major, major renovations. I've seen this first-hand and I know this will be a big problem for you all. I'm not attacking you. I'm just --

MS. RIGGINS: Yeah. I know. I need to clarify --

MR. NEAL: -- pointing that out.

MS. RIGGINS: As I was working through the slides, our farm requirements are going to be those that we have drawn from the quality assurance programs that are currently in place in the states. It is not HACCP on the farm. It will be biosecurity, rodent control, all of the ones that I walked through, let me go back.

But it is not HACCP on the farm. The HACCP would be at the egg packing facilities and then in egg breaking and pasteurization plants. That's our current thinking.

So I'm making a distinction between what would

happen on the farm --

MR. NEAL: Okay.

MS. RIGGINS: -- and what would happen at the egg packing facility. Yeah.

MR. GIOGLIO: Alice? I think you had your hand up?

MS. JOHNSON: Alice Johnson, National Food Processors. Judy, thank you for the presentation.

You talked about the exemption for processors of 3,000 eggs or less.

MS. RIGGINS: Right.

MS. JOHNSON: Is there -- to kind of piggyback on what John was saying, the smaller processors. Is there any reason why you picked that number? And I am to assume they will be exempt from any HACCP requirements?

MS. RIGGINS: Right now under the statute we are limited in what we can do. What we believe we will propose and at least our thinking is that there will be a very aggressive education effort for all of those producers who have fewer than 3,000.

We will have the same level of effort that we did for the very small plants, which was to have a videotape of HACCP training to provide them with guidebooks, workbooks, on how to develop a hazard analysis. How to conduct a hazard analysis, how to do a HACCP plan, how to develop

their SSOP's so that there are -- that the knowledge is there but we won't necessarily be able to actually take the same regulatory approach because there is this exemption that exists in the current statute.

But we do intend to have a very aggressive education effort and to work with that group of producers. So it isn't that we are, you know, going to completely ignore them and they will not have any involvement, but right now we are -- at FSIS we are limited in what we can actually bring about in terms of regulatory requirements for those.

MS. JOHNSON: Thank you.

MS. RIGGINS: Mm-hmm.

MR. GIOGLIO: Collette?

MS. KASTER: Collette Kaster. Could you elaborate a little bit on how FDA will apply their on farm authority? Will it be similar to what they do with feed mills and will they be the ones actually taking the environmental test? What will the environmental test be? I guess can you just elaborate on that whole --

MS. RIGGINS: Right.

MS. KASTER: -- process of on farm and the authority associated with it?

MS. RIGGINS: Right. Our current thinking is that the majority of the work will be contracted through the

states for both FDA and FSIS egg packing and FDA at the farm.

That would mean that the state officials would verify that those provisions that FDA would promulgate are, in fact, being carried out. They would then notify FDA at some frequency about the compliance with the requirements. But we are -- we have not yet worked through all of the nuts and bolts of how it would be done. But our thinking at this time is that we would contract with the states to do that.

MS. KASTER: Just to clarify one more thing. Then is FDA's authority for this a build on of their feed mill authority or do they in general have the authority to regulate on the farm?

MS. RIGGINS: Under the Food -- under the Food, Drug and Cosmetic Act FDA has authority for all on farm production, yes.

MS. KASTER: Okay.

MR. GIOGLIO: Dan?

MR. LaFONTAINE: Dan LaFontaine from South Carolina. My question is where we're -- where we are now and where we're headed. I want to zero in on the shell egg packers and I may be wrong so first let me give you what I think is the current situation and then we'll go from there.

As far as shell egg packers, they are not -- the involvement by the USDA of egg packers is with the

Agriculture Marketing Service on a voluntary basis for the grading of eggs. They do, or at least they used to and I believe they still do, require certain sanitary standards to be met if they're going to -- they contracted with to do the voluntary grading.

So can someone tell me, am I -- is that correct, first of all? Is that where we are now as far as shell egg packers?

MS. RIGGINS: Yes. The only -- USDA or other agency that is currently operating any program in egg packers is AMS.

MR. LaFONTAINE: All right.

MS. RIGGINS: For their grading program, yes.

MR. LaFONTAINE: Now I have -- I have a deeper question before we go to where we are. Who actually has the regulatory authority presently over shell egg packers?

MS. RIGGINS: USDA has responsibility under Section 5(d) of the Egg Products Inspection Act.

MR. LaFONTAINE: Now my understanding, and I may be wrong, the Egg Product Inspection Act covers -- clearly covers, you know, egg pasteurization plants, the breaking of eggs.

MS. RIGGINS: Mm-hmm.

MR. LaFONTAINE: Does it also cover shell eggs?

MS. RIGGINS: Yes, it does.

MR. LaFONTAINE: As far as regulatory authority?

MS. RIGGINS: Yes.

MR. LaFONTAINE: All right. I wasn't aware of that. So then where we're headed is to take that authority which you have in the Egg Product Inspection Act and expand on it into what you presented today --

MS. RIGGINS: Yes.

MR. LaFONTAINE: -- is that correct?

MS. RIGGINS: Yes, mm-hmm. That's correct.

MR. LaFONTAINE: And I'm going to ask the hard question one more time. The FDA has no regulatory authority at the shell egg packing plant, is that correct? You said exclusively USDA?

MS. RIGGINS: Yes.

MR. LaFONTAINE: All right. Thank you.

MR. JAN: Lee Jan. I've got a question also about the environmental testing, the verification. Is that intended to be done by government or by the producer? If by the producer is there a guide or a standard of what would be tested environmentally?

One of the issues associated with that in salmonella the litter beetle I believe is one of the carriers or one of the sources for salmonella at the layers. If a producer wants to eliminate that pest and some others is there a plan to do -- or is there currently any testing

of eggs done for pesticide levels?

MS. RIGGINS: I can't answer the second question. I do not know whether there is currently testing conducted for pesticide levels on shell eggs. With respect to the -- and we can try to get that information for you before the end of the meeting. I will -- I will look -- I will try to find out the answer to that question.

With -- with regard to the first question, the testing at this point would be done by -- our thinking is it would be done by the owner of the farm and that the state would be there to verify on some frequency that, in fact, the owner of the farm, the producer is, in fact, testing at the frequency, the one test, you know, per year that is required. So that is our current thinking. The responsibility would be that of the producer.

But with respect to the pesticide testing, I will find out and come back to you with that.

MR. JAN: Do -- do we know at this time what environmental testing will be -- consist of and is there a guidance for a small producer on what and how to test?

MS. RIGGINS: No. We are -- we are at the stage way before having developed the protocols is what you're really asking about.

We've had discussions, you know, with producers about the need to have flexibility given the different

designs of laying houses. We're aware of all of the issues that we are going to need to take into account in developing guidelines for the protocols. But, no, we've not yet completed that work.

MR. GIOGLIO: Mr. Hogan?

MR. HOGAN: I had a question that I want to direct to the committee members, particularly Michael Govro I guess and maybe Ms. Kaster because they're Food Safety Directors I gather in their respective states.

Do you have a responsibility for any egg inspection in those states or do any of the rest of you in your capacities with the states have a responsibility for egg inspection?

MR. GOVRO: Yes, in Oregon we do. Michael Govro, Oregon. We have a state law that addresses egg safety and egg grading. We also do egg grading work for USDA.

MS. GLAVIN: Okay. Dan? Why don't I just go down the state people?

Dan?

MR. LaFONTAINE; No, we do not have any responsibility for shell egg or broken egg in our state.

MS. GLAVIN: Okay. Does South Carolina have an egg program?

MR. LaFONTAINE: There is one large -- I'll expand a little bit -- there's one large egg -- I call it an egg

breaking plant that is under FSIS but the inspection is done by the South Carolina Department of Agriculture.

MS. GLAVIN: Okay. Thank you.

MR. LaFONTAINE: And I am not in the South Carolina Department of Agriculture. Likewise, shell eggs are -- the State Department of Agriculture's involved in shell egg grading.

MS. GLAVIN: Okay.

Lee?

MR. JAN: Texas has a program, part of it is in the Texas Department of Agriculture and they do the grading and I believe the shell egg on the farm type work. Then the Texas Department of Health in the Food and Drug Division, particularly drug manufacturing, then would have regulation over the breaking plants.

MS. GLAVIN: Okay.

Mike?

MR. MAMMINGA: No. The Iowa Department of Agriculture does not have responsibilities in egg inspection for food. That is carried out by the State Office of Inspection and Appeals which does retail food inspection, institution inspection and what egg inspection that's carried on. I believe they're all contracts with FDA.

MS. GLAVIN: Okay.

MR. HOGAN: The state equivalent of FDA or FDA?

MR. MAMMINGA: That would -- no, that would be -- it would be the state equivalent. The contracting agency with FDA.

MS. MORENO: Elsa Moreno.

MR. GIOGLIO: Oh, no. I guess we have one more state --

MS. GLAVIN: One more state person.

MS. MORENO: Sorry.

MR. MORSE: New York isn't a large egg producing state. Egon Markets was involved previously but I think now the FDA is more involved. We had a quality assurance program that was on a voluntary basis by the producers, but we're not a large producing state for eggs.

MR. GIOGLIO: Thank you.

Okay. I guess Elsa has a question.

MR. HOGAN: Thank you. I appreciate it.

MS. MORENO: Elsa Moreno. I just needed some clarification on what you were saying about the performance standards.

I wasn't clear on whether those performance standards were only for the cooling and storage or was there the thought of having performance standards before that?

MS. RIGGINS: At this point for shell eggs we are contemplating only for cooling and storage.

MS. MORENO: Okay.

MS. RIGGINS: Yes.

MS. MORENO: Okay. And then my second question had to do with the irradiation of shell eggs. Have you had any thoughts on that in terms of how that fits into the proposed regulations, especially the labeling and so forth?

In terms of what I mean by labeling, the labeling on handling for consumers? How to cook them and so forth? Irradiated eggs, of course, being like pasteurized eggs in that having the same hazards as a raw shell egg would have. Thank you.

MS. RIGGINS: None of the provisions that -- none of our ideas would preclude irradiation if it were approved by FDA, if that's what you're asking. You're asking whether we are thinking of doing something other than?

MS. MORENO: I'm just wanting to know if you're considering in the labeling requirements, refrigeration requirements, if you have a different requirement in terms of letting the consumers know, obviously, that they wouldn't have to cook these until the yolk is hard and things like that because of pathogens having been reduced greatly, if not eliminated?

MS. RIGGINS: Yes.

MS. MORENO: Maybe not at this time?

MS. RIGGINS: If irradiation of eggs were to become -- I'm not sure that FDA has even approved

irradiation in that. They have approved it?

MS. MORENO: Mm-hmm.

MS. RIGGINS: Well, then the labeling requirements that FDA would set forth would then govern the labeling of those eggs. FDA has responsibility for the labeling of shell eggs.

MS. MORENO: Okay.

MS. RIGGINS: And so any provisions that FDA would promulgate with regard to labeling requirements on irradiated eggs would apply in this case. Nothing would -- nothing here would change that or would, you know, impede that --

MS. MORENO: Okay.

MS. RIGGINS: -- if that's what you're asking. Okay.

MR. GIOGLIO: Mike?

MR. GOVRO: Michael Govro. You made mention of the retail Food Code. It sounds as if USDA is depending on the states to adopt their Food Code to be a part of the overall egg safety picture. I wondered if USDA is monitoring state adoption of the Food Code provisions related to egg safety or if they're waiting for AFDO's survey to come out?

MS. RIGGINS: No. The plan at this point would be that FDA would propose to codify, to make a part of it's

regulations, those provisions that are currently in the Food Code that apply to eggs and egg products.

So this would then become a requirement, a regulatory requirement, for all users, you know, of the product and all -- all users of the product -- but for all producers of the product.

So that it would be different in that, no, we would not have to wait for the state legislatures to pass all or parts of the Food Code because those sections that relate to eggs would be actually codified in FDA's regulations if a final rule were to -- were to be promulgated.

So it would be, you know, a much more -- it would not leave to chance, I guess is the way to say it, it would not leave to chance the adoption by some or all states of some or all parts of the Food Code with respect to eggs. It would be all of the provisions with respect to eggs would be a part of the rules.

MR. GOVRO: It's my understanding that FDA at this time has no regulatory authority at retail. Would this then be a change in that authority --

MS. RIGGINS: No. FDA has -- has authority at retail. What FDA ordinarily does is delegate its authority to states through contracts to carry out those requirements that are set forth for retail establishments. But FDA has

jurisdiction, had authority, at retail.

MS. GLAVIN: There -- there are a number of questions and comments coming up that have to do particularly with the FDA side. What I would suggest is after our break we will have Joe Levitt here and you might -- if, you know, raise those again or get further clarification.

You know, he's going to be captive for a while so I think it would be very appropriate to -- to raise those questions to him because I've heard a number of them from -- from people.

MR. GIOGLIO: I think we have Dale next and then come back to John.

MR. MORSE: Well, this may also relate to USDA/FDA. In July 1999 the General Accounting Office put together a report entitled "US Lacks a Consistent Farm to Table Approach to Egg Safety."

You outlined a number of steps that are being taken it looks like to get better consistency. However, we have different regulatory agencies that have responsibilities for eggs at different points in time.

So I guess the question is are there -- is there now consistency or are there still some disparities? For example, it's my understanding's that USDA's going toward HACCP, FDA may be -- quality assurance program may be not

HACCP, per se. So is that leading to inconsistency or disparities between the two agencies in terms of regulations as the eggs move through the system?

MS. RIGGINS: We've had discussions about this numerous times with -- in public meetings and, you know, within inter-agency discussions.

We believe that the approach that we have developed is consistent in that given the current authorities and given what we know we can achieve. We are moving in tandem to provide safety measures that don't currently exist or exists in some places but not others and to have a consistent approach across all 50 states.

We recognize that FSIS is in a HACCP environment but we also recognize that in order to really achieve what -- I guess the question that we asked ourselves was what was the best way to achieve the food safety objectives? Would HACCP on the farm necessarily be the best approach given the costs and given the -- the distinct and unique situations that occur from farm to farm? Or, would it be a more workable approach to have the best quality assurance practices in place on all farms?

So we have to look at the impact of it and then look -- in developing the safety action plan there were a number of discussions about the best approach given what we know about the industry, about -- as I said, the uniqueness

of certain farms, and what approach would best achieve the public health goal using a mix of tools, using a mix of statutory authorities and using a mix of approaches that we believe will move us in the right direction?

So that's what this thinking represents at this point. We don't see it as necessary conflicting or inconsistent.

MR. MORSE: I have a second question on the refrigeration. It sounds like you're adapting the 45 degrees. The GAO report also mentioned that if you use air temperature cooling it would take -- it would take three to six days for the inside of the egg to cool to that temperature if you just put it in a recommended more rapid cooling methods be considered, cryogenic gases and other things that could lower the temperature within 12 minutes and reduce the risk and multiplication of salmonella enteritidis.

MS. RIGGINS: Mm-hmm.

MR. MORSE: Has any further discussion taken place in terms of the rapidity of cooling, not just the temperature that refrigeration is kept at?

MS. RIGGINS: In the proposal, in the preamble, we will ask for information from the public on this issue so that we would develop a record, you know, for any further action that we might deem necessary.

But I think it -- you know, the proposal will lay out all of the issues as we understand them. We ask for comment. We know that we want to give more flexibility for new technologies to be introduced and that -- those sets of technologies could also include, you know, rapid cooling methods.

Nothing in this -- nothing in this set of proposals would preclude the use of rapid cooling methods if there is a way that is found that's, you know, that's doable and cost-effective then reaching 45 degrees, you know, at an earlier point would, of course, be conducive and would be in keeping with the goals that we've set. So there wouldn't be any -- anything that would preclude the use of the new technology.

MR. GIOGLIO: I think we have -- do we have one more question from -- from John and then we'll -- no? Okay. Okay.

The only thing maybe, Judy, if I can add here just to remind the committee. As Maggie said earlier, this is one of the issues that we will be posing to you this evening and expect a full discussion in that evening session and -- and in your handouts you have the briefing papers. But we will be posing some questions to -- yeah.

The first question there, just for the record, is what comments or suggestions does the committee have based

on its members experience with HACCP on the implementation of the proposed rule? What is the best way to achieve effective interaction and communication among state, Federal and local agencies involved in egg food safety? In which areas of the egg food safety plan should FSIS concentrate its limited resources?

So I expect that will be a full discussion this evening and then come back as a committee as a whole tomorrow morning with -- with recommendations.

MS. GLAVIN: Okay. We can have a break now. Let's try to be back in 30 minutes. Thank you. Thank you for sitting so long all morning.

(Off the record at 10:17 a.m.)

(On the record at 10:45 a.m.)

MS. GLAVIN: I'd like to -- I'd like to welcome and introduce Joe Levitt, who is the Director of the Center for Food Safety and Nutrition at FDA to give us an update on current activities with respect to the regulation of food at FDA.

Joe?

MR. LEVITT: Well, I might like doing it here. They've set me up up there.

MS. GLAVIN: Okay.

(Pause.)

MR. LEVITT: Again, Maggie, thank you very much.

It's a pleasure to be here. I believe it's the first time that I've been present at one of your Advisory Committee meetings and I'm happy to be here.

What I'm going to try to do is I'm going to try to give you a broad overview of FDA's food safety activities and then zero in a little more on some issues that I know are of particular interest to people here. But I thought it would be useful in the beginning to kind of give you a sense of the big picture.

I think what you'll find, and Maggie and I was just chatting a moment ago, I think you'll find that overall while there are many differences in specifics there are more similarities than not, especially when you look at the broad themes, the broad directions and the underlying goals of what we're trying to achieve.

I'd like to cover three things; (1) kind of review something you're all familiar with but give you kind of the FDA vantage on it, the farm to table strategy that all of the agencies put together several years ago; describe some recent FDA actions and then focus on some current issues.

The farm to table strategy, I have actually been in this job a little more than three years. The first speech I gave I put together this slide and I've been using it ever since.

The farm to table strategy was put together, and I

know that you're familiar with it, to me was most significant from an FDA point of view in that historically we have focused on neither the farm nor the table. We have focused mostly on that great area in the middle of food processors.

But what we found really when you look at where the food safety problems are they are at a much broader sense of the spectrum. The reality came to us which is that if we're going to fix the problems we have to go where the problems are.

So the general approach taken was that we need to develop through the entire food chain to the extent possible strong prevention programs. We will do the most good for the public if we can put in a good prevention program followed by education on how to implement that program and a verification system to be sure that it's in place.

We also recognize that no matter what we try to do in prevention we will never be able to be perfect and we have to have in place starting at the other end and moving back a strong system for early detection and containment of food safety hazards and outbreaks when they arise. Really, everything we've done since fits into this framework.

Now I think that if you look government-wide, and this includes us, FSIS, CDC, a number of other Federal agencies, state and local agencies, you'll see that if you

look over a three or four year period and kind of look back, what was different between then and now, you see some very fundamental changes that together we have put in place a strong foundation for pathogen reduction.

We now have surveillance systems developed and implemented largely through the CDC. The FoodNet, the PulseNet, the NARMS program for antimicrobial resistance monitoring. We have prevention programs that are growing and getting stronger. We have the seafood HACCP, the meat and poultry HACCP, we recently have a juice HACCP program. We have a good agricultural practices program you'll see. We've got an egg safety program we're developing and on and on. You'll see more about that.

We have collaborated across the government on research and have what's called the Joint Institute for Food Safety Research, which really is a partnership of all of the Federal agencies being sure that we are devoting our research globally to where the highest needs are.

One of the early -- most early things that was done was a public/private partnership for food safety which developed the fight back campaign. There have been additional educational programs that have been developed.

We have I think gotten better collectively in outbreak response, by no means perfect, but I know at one point it felt like every outbreak was an adventure. We feel

now there is a greater semblance of -- while routine will never be the right phrase, nevertheless an experience base that this is kind of what we do in this kind of situation. I think it is commonly felt that we are catching outbreaks earlier.

Finally, I think, you know, in very major ways there is an entirely different picture in the world of both Federal coordination within the Federal Government and Federal, state and local coordination across the entire country.

Next week I know, as an example, at our HHS honor awards ceremony there will be an award given for what has been called E-Lexnet, which involved data sharing on laboratory findings. There's been a large pilot and FSIS contributed heavily to that. There will be people recognized from FDA, from USDA, from CDC and again from a number of state and local organizations. I think over 66 people are part of that team that have been brought in for that just as an example of the many collaborations, of course.

So all of this is good. What it means is that I think -- you know, you always talk about the -- it's very hard to kind of turn the battleship. I feel like what this means is the battleship is being turned. Now what we have to do is be sure it's kept forward in the right direction

and enhance what needs to be done.

I've already referenced this a lot. When you come down to an FDA point of view we begin with our seafood HACCP program, added to that our good agricultural practices program, again, going more back to the farm.

We have had a special program devoted to sprouts because of just an increased problem there and an increased need for focus. We just published our final regulations on juice HACCP due to a number of outbreaks for unpasteurized juice. We have our egg safety program I'll talk a little more about and I know Judy Riggins already talked a little about before I got here.

The Food Code, thinking into the retail sector. The Food Code is really what guides food safety at the state and local level in retail establishments, which is both stores and restaurants but also areas where our highest vulnerable populations; our nursing homes, our hospitals, our daycare centers, are all covered by the Food Code.

The FDA issues the Food Code but it is a set of state recommendations. It is up to the states individually to adopt those and to implement those.

Finally, through another part of FDA, our Center of Veterinary Medicine, we have implemented a very much strengthened program for monitoring antimicrobial resistance where we now have again through CDC the NARMS program, the

National Antimicrobial Resistance Monitoring System -- if I got that right -- where we are tracking nationwide the use of antibiotics in cattle and in evidence of resistance being developed to those drugs. That program is again working and functional.

Throughout this we've tried to take a risk-based approach. We have focused our inspections in the highest risk areas which so far have been devoted largely to areas of high risk for microbial contamination. At some point we'll be broadening that.

Within the FDA world we have an enormous challenge in the field of imports. Our imports since 1992 have quadrupled or, as I like to say, they've doubled and doubled again. Just to kind of give emphasis on it. I mean the curve is striking. It is just like that to the point that FDA now is testing less than one percent of the food imports that come across the border.

Well, the good news is we have systems to target that to keep it risk-based. We've also realized that we need to develop a new paradigm. That the old paradigm where most food was domestically grown and a little bit came over the border is no longer valid. So we have enhanced our border surveillance. We've also realized that we have to have a greater presence overseas.

So we are enhancing and strengthening and

expanding our foreign inspection program and we have developed together with USDA a foreign training program on food safety which was triggered by the good agricultural practices and we've combined it with more, broader food safety issues. This team has now gone to Central America, to South America, to New Zealand, to South Africa, and literally continued around the globe.

I can tell you, wherever they have gone they have been remarkably well received. People around the world recognize that the United States is not only a major market but is a market that adheres to high standards. They want to know what the standards are and they want to be able to comply with them. So we've gotten a lot of positive feedback but there's a lot more to be done clearly in the area of imports.

We have enhanced, together with the government as a whole, our research in risk assessment. I'll focus on risk assessment in a moment in particular. In addition to the Fight Back campaign we have worked with physician groups, we've worked with high school and other school curricula to try and broaden the sense of food safety, throughout.

Somebody -- a reporter I talked to -- I wish it was my line but it wasn't. The reporter interviewed me and came up with the line himself, but he said that -- we talked

about food safety education in public schools. He wrote that the FDA's goal, the government's goal, is to make food safety a staple in the American educational diet.

It's a little bit of a mouthful, staple in the American educational diet, but when you think of it it's the right point. We need to make food safety common knowledge and common understanding and you can't do that in one fell swoop. You need to do that as part of a continuing program.

Then, of course, you asked the question -- this is all good. This is all fine. You're doing a lot of stuff and you're energetic and you're rolling, but the bottom line are you doing any good? Are we improving the public health?

While we only have interim progress report we at least have a system now to track progress through -- one of the surveillance systems that I referenced earlier; the Foodnet, which is for tracking food-borne illness. It is a critical surveillance system. It will show the bottom line.

We began with five sites and it's been expanded to nine and those five sites also have expanded. So I think we're now covering more than 10 percent of the country as I recall.

That system which CDC reports on every spring is documenting some declines but also fluctuation which means and underscores that this will be a long-term effort. Our department has put out what we call the healthy people 2010

goals and that's probably about the right vantage point we have to be thinking of, that we're going to have to be focusing on this this entire decade.

Now some recent FDA actions, last December we issued a final regulation on egg refrigeration and labeling. So this is at the far end of the farm to table continuum. The refrigeration applies to retail and they require adequate refrigeration. Labeling will be safe handling instructions on egg cartons that you'll start seeing this Fall and they'll be very similar to what you're used to seeing on meat and poultry.

I mentioned a couple of times our final regulation on HACCP for juice safety that was published this past winter. We will be implementing that on a one year, two year, three year cycle, again similar to what you're used to with the meat and poultry HACCP to give the especially small and very small companies time to get up to speed.

One of I think the real advances and it has not been an advance without effort and some internal consternation I can assure you, but, nevertheless, the field of risk assessment in microbiological area is really an area that we are at the pioneering stage.

If you think back 10 or 20 or 30 years we're at that stage for carcinogenicity risk assessment, but today we have standard models, accepted procedures, you know. We

look at the chemical and we can tell you if it's 10 to the minus six or 10 to the minus 12 or 10 to the minus third and based on what the numbers are that has really different outcomes in terms of what we think that risk is.

We need the same kind of accepted models in the area of microbiological hazards and again throughout the government we are making some good progress, it is pioneering progress. It began with the egg safety risk assessment that was originated really at USDA with collaboration from FDA.

We have continued that with listeria. This past winter we published a draft risk assessment on listeria, again we are doing this in collaboration with all of the agencies. FDA had the lead on this one. That has really I think laid a groundwork for understanding, all right, if you have this hazard it's not the same hazard everywhere. Where is the hazard the most?

My usual slide that I use when I talk to public audiences is our bottom line always needs to be where do we do the most good for the consumer? So this risk assessment is to help us figure that out. We will always be a government of finite resources. Are we putting our energy and our effort where it's going to do the most good?

That risk assessment I'm pleased to say we had a public meeting on it and got very positive feedback. It's

also received positive feedback internationally. So the United States is here playing an international leadership role as well. We feel very good about that. We have tied that to also a listeria risk communication and risk management action plan, again working with FSIS and across government.

I'll digress for a moment because a lot of the concern, and a justifiable concern, is when the government comes out with a new report is the media going to pick it up correctly? Is the public going to understand it? Will it be unfortunately either a scare over nothing or, conversely, nobody notices something that's important?

So what we did on the listeria risk assessment and the communication action plan is we actually previewed with industry and with consumer groups what this was going to say, honed our public messages, so when it came out it was neither too scary nor too calming. It was basically kind of what we wanted right in the middle. So again we consider that a model of how to do that.

On a more narrow focus we also did a risk assessment on vibrio parahaemolyticus, which is a hazard in seafood largely in oysters and again that's more focused but that's rolling along in the same way.

I mentioned very quickly already that all the agencies worked together with the American Medical

Association, with FDA taking a lead on this, to develop a primer on food-borne illness that was made public I'm going to say last winter. Maggie and I were down there together with Art Liang from CDC at the Press Club when that announcement was made.

This is significant because again historically food-borne illness has kind of been relegated to, if you will, the tummy ache category. While the Jack in the Box incident certainly changed that forever, nevertheless, physicians have not been trained and focused that much on food-borne illness.

The AMA recognized that and has put together a very sophisticated set of brochures for their members. So it's by their members, for their members, on what to look for, what are the symptoms, what are the treatments and what are the reporting requirements so that we can get as good a sense and a track of these illnesses as possible. So I think that's a major step forward.

We issued an advisory to consumers on methylmercury in fish. Coming back to imports, we put out a proposed regulation, a fairly simple regulation, that basically just says, "If we refuse the goods we will stamp on there 'refused from the US.'" This is something that is commonplace in the meat and poultry word. So, again, we're learning from each other.

Bioengineered food, boy! We could spend a whole day just talking about that. But FDA did issue two proposals last winter, one was to strengthen, make mandatory and more transparent, our pre-market review process for new crops to come through us and, second, a labeling guide instilling with labeling. I could talk more about that if you need me to.

Channels of trade guidance on methyl parathion. What that means is we can't forget pesticides. With all of our focus on pathogens we have to remember there's broader food safety world out there.

One thing that happened a few years ago in Congress is Congress passed a law called the Food Quality Protection Act which really stimulated EPA to do a whole series of retrospective reviews on whole classes of pesticides. If they pull it off the market there's a split jurisdiction so that EPA, if you will, sets the tolerances but FDA does the enforcement.

So if they're pulling something off the market we have to kind of, if you will, usher it out of existence. But if they take something off the market today what about the stuff that was planted last year? That's not fair. So we've developed a system to allow, you know as I said, I call it an ushering off the market, not a precipitous ban of it so there's some realism built in there.

Finally, everybody had heard about StarLink corn and we've all been heavily involved in that and FDA last winter issued a set of testing guidelines for the industry that is I think one of the things that has helped maintain some control over that very troubling problem.

Short-term horizon. Clearly BSE and all the range of TSE's is very much back in the forefront. Every agency in government worldwide I believe is now relooking at all of their programs, looking at their safeguards, being sure that we're doing all we can to safeguard our domestic food supply and livestock supply from this very troubling disease.

While it's still a disease we know relatively little about scientifically we know the bottom line here which is to keep it out. So we are very much part of that, again working with APHIS, working with FSIS, as well as other TSE's.

The FDA has a TSE Advisory Committee that will be meeting at the end of this month. Among the issues we look at are things like within FDA, you know, blood safety. How you deal with blood donors from people that have traveled to England and other places and so forth. So we have blood safety policies and we have other issues related to gelatin that come under our framework.

We've also dealt with issues relating to chronic waste disease in deer and elk as an issue that has come up

recently.

Egg safety standards, a lot of efforts -- I know Judy Riggins covered this and I wasn't here while she covered it, so I'll simply say very quickly, can answer more questions within the broad farm to table spectrum. Between us and USDA we have worked to be sure we have the whole thing covered and that one agency, essentially, is responsible for one set stage of the continuum.

So that FDA will be responsible for the on farm section, work very closely as they clip it in the back with egg producers and other industry groups as well as consumers. We had our current thinking meeting last summer and we are trying to -- we have on our front burner to try and get out our proposed standards that we think will be a very major step forward.

FSIS will be covering the packing and processing plants. The Food Code will deal with the retail and again our safe handling instructions on the eggs deal with the -- deal with the consumer packages. So we feel we'll have that covered literally from soup to nuts.

I want to kind of make a special note of commendation and thanks to everybody that was involved in that process because that was, if you will, working together was what I finally referred to as an acquired taste. Ken is nodding.

When it began that process the industry says, "Oh, my gosh! What is going to happen to us now?" There was a lot of distrust and questioning and worrying but we worked out, as we had done earlier with our good agricultural practices, very much a partnership with the industry as well as with consumer groups in terms of being open and saying, "This is what we need to do" and then we came up with something rational so that at the end of the day we have something that is going to enhance food safety while also being something the industry feels this is something we can stand behind and we can implement and we can enforce.

So we feel very good about where we are now and look forward to that moving ahead.

In our seafood HACCP program this last winter after going through two or three years of it we issued what we called a mid-course correction, which to me is not a failure but a success. I believe that every program ought to have -- be subject to continuous evaluation or recalibrating when you need to.

What we've done here is while the beginning we focused on the whole waterfront and we've now kind of trimmed in to really focus on those areas of highest risk and be sure we get those attended to and then we'll branch out further again.

One particular seafood issue of particular

interest is a different vibrio than I mentioned before, vibrio vulnificus. This is a hazard that happens infrequently but when it happens it has a very high fatality rate and that is striking. This is handled through a group called the Interstate Shellfish Sanitation Conference, which is a conference many years old that is essentially run by the states and audited by the FDA. They meet every July and there is a plan to gain greater control mechanisms for vibrio prevention that will be coming up this July there.

We also -- and I referenced this a couple of times but it's worth reenforcing. Pathogens are very important, there's no question about that, but they're also additional food safety hazards beyond pathogens. All the agencies agreed last year that it is time to really kind of start branching out again and recognizing and bringing all of the food safety issues within the spectrum.

Usually what is focused mostly on that is the chemical side of the house but most recently within FDA we've had a real focus on food allergens. We did a survey with the states of Minnesota and Wisconsin over a couple of years.

There was a report this spring, you may have seen it in the paper, that looked at companies that make candy, that make baked goods, that make ice cream. These are not firms that would have been on a high-risk list for microbial

contamination. They would have been on the low-risk, FDA didn't have to worry about them. But, of course, we're thinking about microbes, we weren't thinking about food allergens.

So we looked at firms that make products that are -- some products with peanuts and some products without peanuts, some products with eggs and some products without eggs, to look at cross-contamination potential. The results were really sobering.

Of the firms that were looked at for peanuts 25 percent of the samples showed peanuts in products that they were not supposed to be. Of course, for persons with food allergies they could be -- you know, the presence of peanuts could be life threatening and they depend on the labels to know what they can eat and not eat. That has really been a wake up call.

I will say it is not -- we know it is not a representative sample. We know that there is not 25 percent of the food supply contaminated with peanuts but, nevertheless, it was a striking finding and it has accelerated a lot of efforts, both by us and by the industry. So you'll be hearing more about that.

A couple of things of particular interest to meat and poultry regulation, food irradiation. We have worked again with FSIS to make the process more streamlined between

us so that unlike what happened with the original red meat petition it kind of went all the way through FDA and then it had to come over to USDA and go all the way through it again. That certainly seemed inefficient, to say the least.

Maggie, is that a fair -- that's a kind characterization is to call it inefficient.

But the agencies worked together, with FSIS here really taking the lead, to streamline that process. So, functionally, they will be able to come out within the same time frame. There won't be a long wait at the FDA and then a long wait at the USDA.

Then at the FDA we are reengineering and streamlining our process so that something like that gets expedited review and we know we have the ready-to-eat petition which is -- which is very high on our list and hopefully getting closer.

Game meat, why the FDA regulates game meat I couldn't possibly tell you. Some good lawyers -- I was once a lawyer -- some good lawyers with history could tell you why that is, but through quirk of how the laws are written the FDA regulates game meat which means when there was a problem with elk and chronic wasting disease we got to deal with it.

It is an area that because of issues on TSE's is going to become more front burner for us so we're taking a

more careful look at that together, obviously, with anything that is basically related. I already covered that and antimicrobial resistance.

With that I think I will stop, conclude. Thank you for your attention. I've tried to convey kind of, if you will, more the breadth of FDA's food safety program than depth in any one particular area.

As you see, our breadth is quite substantial but the themes, whether you're talking about one product or whether you're talking about all products, strong prevention, strong follow through by the government, strong participation and involvement of the stakeholder groups and ultimately keeping our eye on the bottom line. Are we reducing food-borne illness? Tracking where we are and when we're not, being willing to make adjustments and refocus our programs because we are here really only for one reason and that is to benefit American consumers.

Thank you very much. I'll be happy to take some questions and the hard ones -- there is some FDA staff here that I'll not feel embarrassed to ask them to help out.

MS. GLAVIN: Lee?

MR. JAN: Lee Jan. I have some concerns. You know, your presentation was a good presentation, overview, but I have some concerns about food safety and consumer protection particularly at the retail area and I'll tell

you, from both allergens and the pathogen side.

MR. LEVITT: Mm-hmm.

MR. JAN: One side -- and I'll start with the allergen side, the product labeling, manufacturers and all those, are required to identify allergens in their ingredient statements and those kind of things.

But if you go to a restaurant they're not required to identify or even tell a consumer what products they use particularly in -- I have personal experience. My wife is allergic to canola, canola oil, and so many restaurants go to canola, but you go into a restaurant and try to find out what type of oil they prepare or they use in their products they're very reluctant to tell you and, you know, it's a real problem.

So it seems that the message is not getting to retail about the allergens. I know they can't have necessarily ingredient statements but if they were educated or have some requirement that they communicate those things to their customers.

You know, obviously the best answer is, you know, you just don't be a customer but, you know, you've got to find who -- you don't want to be a customer when you do that by -- through bad experiences, generally.

MR. LEVITT: Okay.

MR. JAN: The other side from a pathogen concern,

I have concerns that retail is a good place for producers or manufacturers to still continue to sell their products if they can't meet FSIS standards, particularly when you're talking about meat now.

There is a current issue -- and then also I'm thinking about the future, the ready-to-eat testing rule that's on its way from FSIS requires testing, environmental testing, or some critical control point step. I'm afraid some of those -- some of the smaller plants that are not going to be able to meet that requirement or have the -- don't feel that they want to spend the money to get somebody in there to do environmental testing or whatever are going to make the decision to go and sell their products retail.

In a current experience that has happened in Texas right now we have a producer that produces a sausage that's a ready-to-eat sausage. We've given them a year after HACCP through putting them in suspension and then abating the suspension while they tried to validate their process and they were -- they went through -- the lab at Texas A&M had them do some work and they could only show a one log reduction or a one and a half log reduction which was not acceptable. They could not validate the safety of their product.

So we were at the point of withdrawing their grant or withdrawing or not allowing them to use -- sell that

product under inspection and they said, "Well, we'll not sell it." They voluntarily withdrew and said, "We'll just sell it retail."

Well, it doesn't seem that that is in the interest of food safety and unless FDA can get a little bit closer to FSIS, when FSIS puts a requirement with food safety as an issue or initiative and a small -- particularly a small producer can't meet that or can't afford to meet that they'll just slip over and say, "Well, we'll just sell it retail."

I don't see how we did anything except move away from food safety at least in that small segment of the industry. I don't know if you can address that or not.

(Laughter.)

MR. LEVITT: Well, I can address -- I can certainly address it this way. I think clearly the area of retail -- kind of go back to my first slide when I said we traditionally have spent so much of our time at the food processor, neither at the farm nor at the table. Well, somewhat in retail but not to the extent of everything else.

The retail sector FDA has general jurisdiction there but it also is administered largely like the shellfish program through what's called a state cooperative program. In this case a conference on food protection. So you have that framework to work with them.

We have the fact that FDA puts out the Food Code based on what goes on at the conference but then each state has to adopt that and implement it and sometimes make some changes. So it is a confusing area, an area that we know needs more attention.

The whole area of labeling, for example, food allergens at retail is a real issue. I mean what we -- what you feel kind of as a consumer if you just walk in and you're somebody who doesn't have a particular problem what do you care about? You care about cost, you care about taste and you care about service. That tends to be what drives them.

More and more we have to be sure that food safety is an equal driver in it. I mean I found a lot of other areas, food industries are driven by things like natural and fresh kind of things because they're viewed as what consumers want. But we need -- and consumers need to speak up and say, "No. We want safety first." Safety first kind of ought to be the motto.

It's also an example just of the retail area, that's one of many areas and, like I said, we've only just begun. There's a lot more.

So I think your points are well taken. We don't want any part of the food chain to be the lowest common denominator which brings the system down as a whole. Each

area has its own challenge, retail has its own challenge.

We'll continue and we welcome those comments and your input, as well. You know, continue to try and do better there.

MS. GLAVIN: Dan and then Marty.

MR. LaFONTAINE: Dan LaFontaine from South Carolina. I've got -- I have two questions.

One item that's been in the news the last couple of weeks that you did not touch on is the issue of Jeonne's Disease and the possible link to Crohn's Disease in humans. Jeonne's Disease in cattle. Of course, the critical control point would be the pasteurization of milk and is it an activating microbacteria imperatuberculosis?

There's continuing news from Europe, from England primarily, saying that they can, you know, at least in England can culture the bacterium from pasteurized milk. The last time I worked on this issue or was aware of this issue the FDA's statement was that our current high-temperature short-time requirements for pasteurization in milk were adequate to inactivate the bacterium.

So my question is is the FDA currently visiting this issue in any way, shape or form? Is your position still the same that we have adequate temperature and time combination for pasteurization of milk?

MR. LEVITT: Okay. I'm going to let John Sheehan

comment in more detail, depending on what I say.

(Laughter.)

The answer from kind of my radar screen is that, yeah, it's on the radar screen. The impression I have is that the feeling is that, yes, our policy has been correct but we're always open to new data. We want to be data-based, data-driven, but to make a change that we want to be sure the data was strong and clear.

John, do you have anything -- can you give anything more specific on that?

MS. GLAVIN: Can you come to the mike, John? Otherwise, we don't hear you.

MR. LEVITT: You may have to come to the mike to say you have nothing more to say.

(Laughter.)

MR. SHEEHAN: Yeah. There's probably not much more we can add to that at this point, Joe, because the data is still very much equivocal and there's not much more we can say.

MR. LEVITT: I mean I think in general, and this is both a generic statement as well as a specific statement here, we want to be sure, you know, in a way, that we're all from Missouri, you know show me -- show me the data.

The newspapers are always quick to report, you know, whatever finding comes out from whatever experiments

and we want to be sure that our policy is based on not just the experiment of the day but has that experiment -- does it have credibility? Has it been replicated? Is it supported by a scientific community? And not just have a jigsaw -- you know, zigzag policy every time a new study comes out the policy gets changed.

So I think the feeling was that the pasteurization was -- is adequate for this. If the new data convinces us otherwise, well, sure, that's the kind of mid-course direction we want to take but we won't want to do something like that willy-nilly. We'll want to have a strong justification for that to be sure that it's the right thing.

MR. SHEEHAN: Joe, just one more thing. The UK study that was mentioned, there has been some discussion recently that the delay in issuing that report is due to the fact that the two percent positives that were reported may, in fact, be due to laboratory contamination and so not represent an inadequacy of HTST treatments.

MR. LaFONTAINE: I have another question completely changing gears.

MR. LEVITT: Okay.

MR. LaFONTAINE: The industry petition for the irradiation of fully-cooked, ready-to-eat meat and poultry I know it hasn't been working that long. Will you kind of give a feel of where it's at in the process at FDA?

MR. LEVITT: Sure, sure.

MR. LaFONTAINE: Where you're at?

MR. LEVITT: Yeah. What we tried to do to kind of reengineer our food additive petition process for these kind of things is two things; (1) if it's a petition that's going to enhance food safety and reduce pathogens like this one clearly is we have what we call our expedited review program, which means that it moves in front of the line.

We still adhere to the same standards but we have long lines. Moving to the front of the line is not insignificant, I can assure you.

Second, is we've kind of reengineered our process to look at three distinct phases. The first phase really is the petition as comes in adequate or complete for full review. When it does review our -- what we call we file the petition. That could take anywhere from a couple of weeks to a couple of months. My vague memory on this one is it came in in the summer and we filed it sometime in the Fall.

We then have a second phase that we'll call a scientific review. This is -- you know, we go through all the studies and try to make a tentative decision among ourselves, is this a yes or a no and get feedback to the petitioner.

Then the last phase is all of our food additive petitions are issued as regulations. So that means a

Federal Register notice, that means writing up a justification for all of the scientific issues, but that's what I call the home stretch phase. So we are in home stretch phase. We're in the last phase of that and so if you could be patient just a while longer. We know it's important to the industry.

I think one judgement that was made -- and I can't tell you if it would have been any better if a different judgment was made -- but we always aren't quite sure how much to put in one particular petition. For a while it felt like the petitions were so narrow we kind of worked with an issue, you know, a little broader we can kind of do more in one swoop. So this petition was actually quite broad.

But now what we find at the regulation writing and justification stage that makes that process much more exhaustive by -- especially something like food irradiation, which while it is clearly very important it's also in some circles controversial, not unlikely to be a potential for a lawsuit and we wanted to be sure that we have all the i's dotted to be sure. What we know we try to balance that out but we feel it's a good story.

So we have a coordinator with FSIS to not have another similar process afterwards, that's been already worked out and published and so forth as a matter of procedure.

MS. GLAVIN: Marty, I think you're next.

MR. HOLMES: I was going to comment on something else but since you mentioned irradiation I think to make it a lot easier just to call it a food process and not a food additive and then we can move on.

(Laughter.)

MR. LEVITT: Right. You need to go to Capitol Hill for that one.

MR. HOLMES: I understand.

(Laughter.)

MR. LEVITT: When you're there maybe you can get the game meat done, too.

(Laughter.)

MR. HOLMES: The point I wanted to make, you mentioned -- I appreciate your first slide more than you know. The concern -- and I represent the processing industry, not even the slaughter industry or the packing industry but the further processors.

Specifically -- and I'll come to my point -- as it relates to pathogens in 0157:H7 typically that product is coming in in live animals to the packer and may not be being taken care of efficiently enough and comes into a grinding operation on our raw material. It's not typically being introduced at the raw processing plant.

We have a zero tolerance for 0157:H7 at the

processing plant and so it's very difficult when you don't have a cooking process and you're a raw-in, raw-out plant and you have a zero tolerance for a pathogen that can only be killed through the cooking process to have a critical control point that reduces, eliminates or prevents to an acceptable level of zero when you have no kill step involved.

My point being that as we look at you mentioned chronic waste and BSE and you mentioned everything from gelatins to other things that FDA considers, my curiosity is APHIS -- or my point to discuss here is that APHIS is worried about animal health and FSIS is worried about public health. There's not really a bridge between the two. However, because 0157:H7 doesn't necessarily have any harmful to the animal health but it does to -- 0157 does have harmful effects to human health.

BSE I think presents an opportunity for not only animal health but human health and there to be some way to bridge the gap between animal health and human health and pathogens or pre-ons, for example, that effect both human and animal health.

So I was just curious if you have any comments about that. I think that's -- you know, we were talking about we've done a lot of things in the middle and you mentioned not a lot on retail I think here's an opportunity

that BSE, although fortunately has not shown up in our country, it might be an opportunity for us to look at animal health issues that although they may not present animal health problems they do or do not show animal health problems, they do have human health problems.

Having some type of inspection or help in preventing those from being introduced into the food safety system.

MR. LEVITT: Well, I could just, if you will, tease for a moment and say I think you've made the case for why we've only just begun. You know, there is -- there is lots of interconnected issues.

There is I think more collaboration or coordination between the agencies that is necessarily apparent outside. For example, on our TSE Advisory Committee APHIS is represented on the advisory committee. It's just kind of one example.

There is a fair amount of contact I am sure, some of which I'm privy to because it's three way contact with FSIS and APHIS and I'm sure a lot that isn't. But it is a challenge getting all of these pieces of the puzzle to work together.

You've laid out some of them in terms of when is it an animal hazard but not a human hazard? When is it a human hazard but not an animal hazard? When is it both?

When is it neither? What is the right titration?

So that's why I think the only answer I can really give you is that we are constantly challenging ourselves to say are we applying our resources in the area that is doing the consumer the most good and is overall part of a rational scheme?

The kind of things that you've raised are the kind of things that we all have to be considering and dealing with but I don't think there's one easy fix to it.

MR. HOLMES: Thank you.

MR. LEVITT: Except that I think we're ensured of continued employment for a while.

MS. GLAVIN: Okay. Elsa and then Mike.

MS. MORENO: Elsa Moreno. I have two questions for you.

One is can you give us some more specifics on the mid-course correction, so to speak, for that seafood HACCP rule? Then my -- well, go ahead and answer that and then I'll ask you the second question later.

MR. LEVITT: Okay. Sure. Here's what we did in seafood HACCP.

There are about 3,600 seafood processors in this country of all sizes, shapes and forms, although they tend to be heavily on the small business side. Unlike what FSIS did with the meat and poultry in the three year phase-in and

unlike what we're going to do on the juice, here we had it apply to everybody all at once.

We also have, which for us it was a real uptick in annual inspection even though I know you're familiar with some -- with a different model, we committed to going through an annual inspection of each of those 3,600 each year.

This was an industry that, you know -- you know, some companies I'm sure had never seen an FDA Inspector before and while there has been a lot of training and a lot of build-up, nevertheless, a lot of small businesses, a lot of education and new knowledge building in. So we have had each year, if you will, an incremental progression of more firms coming into compliance.

We also put out a very elaborate, if you will, scoring system looking at 11 different kinds of hazards and, you know, tough guys that we are if you pass 10 and flunk one you get a flunking grade overall, you know. In college you got a 90 percent but not with the FDA. You've got to get a check on every one. That -- that contributed to, if you will, a smaller progression each year.

After three years of that we said, you know what? The areas that we are lagging the most in are the areas are the most acute gains could be gained in. The areas particularly of pathogens and histamines. What we worried

about was by focusing on everything at once it was diluting emphasis on that which was most important.

So we said what our shift will be is we will kind of, if you will, dedicate this year to really focusing on those firms that have particular needs or problems with pathogens or with histamines or who didn't have a HACCP plan yet. Hard to imagine after three years. That's less than half of the overall inventory.

So we can focus more on them, go back a second time if we need to for reinspection and really try to get that dealt with effectively rather than go on at a slow pace across the board each year. So that was the premise of the mid-course correction. We have a number of other activities that feed into that, but that's it in a nutshell.

MR. MORENO: Okay.

MR. LEVITT: The second question?

MS. MORENO: My second question is regarding the good agricultural practices --

MR. LEVITT: Yeah.

MS. MORENO: -- what have you learned from those guidelines that might be applicable to animal production on farm food safety?

MR. LEVITT: I don't think I have a -- I don't have a technical answer for that. I think the most important general answer I can give is that any time you

move into an area where that particular segment of the industry is not used to being regulated you need to take that into account as you walk in the door.

So before I talked a little about our work with the egg industry, well, we learned how to do that in sum because of the produce industry. I was in this job exactly three days when I was sitting at our -- in our conference room with leaders from the domestic produce industry, there had recently been announced the new produce initiative, as it was called at the time, and they were mad is the only way to do it.

They said, "We are being rolled over. You're putting in programs that don't make any sense and dah, dah, dah, dah, dah, dah, dah, dah." I said, "I've only been here three days. Time out."

What we did there we tried to do afterwards which I think would be applicable to any program whether it's for what you're talking about or any new area going into, is you have to involve them in the process and you have to be sure that we're talking the same language. At the same time you have to be sure that there is strong consumer involvement and so it's a balanced approach.

But I always go back to, if you could bear with me for a short story, one of my earlier experiences was we always had to go on these annual senior retreats. You know,

the fact is everybody hates these senior retreats. The thing we hated the most about them was whoever was brought in to facilitate always makes us go through some exercise, you know, and it's not sit-ups and squat thrusts, it's some exercise you have to do.

The exercise in this particular year was you break down into two groups or maybe several pairs of them depending on how big your retreat is. Group A is supposed to design the program and Group B is supposed to implement the program and you're given a little more about what the program is. Then you're given, you know, an hour to go out and come back and report.

The facilitators -- after we went through this I'll tell you in a minute what happened -- basically told us the same thing happens every single time.

What happens every single time is out of four of five groups that do it only once does the design group think to include the implementation group in the discussions. They just think, we're a design team. That's what we do, we design. They do implementation, let them figure it out.

But if the implementors are kept out of the design it's not going to be implemented well. Once we opened that up, once we showed up and we were going out and doing site visits that once we're here and because, you know, sometimes you say something in a way that either it doesn't mean

anything or it's like fingernails on the blackboard and we're not trying to. It's one thing if we're trying to but if we're not trying to why make that stupid mistake?

As I said, at the same time answering while you're doing that you also be sure that there's strong consumer involvement and that the same thing should be open and transparent and be sure that what is -- what comes out is both what I'll call user-friendly to the implementors but also acceptable from a consumer public health consumer protection standpoint.

But you've got to include them in the process so that what comes out everybody can own. At the end of both of those processes both the fruits and vegetables and what I hope will be with the eggs, at the end we're able to stand up together with the leading trade associations and endorse them jointly, again with consumers.

MS. GLAVIN: I think I promised Mike and then we'll go to Dale and --

Sandra, did you have your hand up?

MS. ESKIN: No.

MS. GLAVIN: Okay.

Mike and then Dale.

MR. GOVRO: Okay. Michael Govro. If the ISSC fails to address the vibrio bonificus (phonetic) problem this year as it did last year or if it fails to adequately

address it will FDA take independent action to address it?

MR. LEVITT: I think that's something we always -- we have to keep in reserve. I think as usually happens on TV when you hear these people interview they always say, "I don't want to speculate on what would happen."

I think there has been -- and I see Caroline Smith DeWaal sitting there -- there has been, you know, a lot of frustration over this issue. I think there is growing recognition that it is a public health issue. I think at some quarters in some places there's a question of the numbers aren't very high. But when you look at the fatality percent of that I think that overrides that kind of issue.

You do have an industry that is again very largely small business dominated and they're having a hard time seeing their way through it. Yet when it did not pass last year and it did not -- in a way it did not pass on a procedural vote which in some ways hurts more -- that there was a fair amount of backlash from more different quarters that this is a problem that needs to be dealt with.

So I think before the ISS meeting we will be working, you know, hard with others to try and get that issue dealt with effectively and if it doesn't we'll have to see where we are then.

MS. GLAVIN: Okay. Dale?

MR. MORSE: Prior to your arrival we had a lengthy

discussion on egg safety and with your comments and Judy Riggins' comments it seems like a lot of progress has been made in addressing the GAO's report on lack of a consistent farm to table approach.

Just one of the recommendations or a couple of the recommendations centered on use of HACCP and FSIS' using that approach. My understanding is the FDA is using more of a quality assurance program approach. Is that leading to any inconsistencies or disparities between the two agencies in terms of --

MR. LEVITT: I don't think so. I know we worked together on it. As I said, we worked with all of the involved parties. One of the interesting facets here is that there is an organization that is a consumer-based organization that operates agriculture unit on site.

Caroline, help me with the -- with the -- Richard Wood from -- yeah, can --

MS. DeWAAL: Food Animal Concerns Trust.

MR. LEVITT: Right. Through the Animal Concern Trust, is that right?

MS. DeWAAL: Yeah.

MR. LEVITT: Yeah. FACTS, right. I have his face in front of me so I apologize to him in absentia because he's done a very good job and has been a major contributor.

But by getting especially somebody there that has

that both perspective on how to handle it but also strong real experience on what it takes to run an egg producing facility that we worked out a system that is broadly acceptable.

You know, I think, you know, HACCP is important but we have to realize what HACCP is getting at. HACCP is getting at a strong system that's going to fix the problem.

What we had on the egg side is we had a number of state programs as well as industry programs that had a lot of experience in what was working. So we thought we should pick up on what's working and make that broadly applicable in uniform across the country rather than try to invent something new. I mean that essentially was the approach taken but I don't see a problem of kind of what you call it.

MR. MORSE: The second question related to that, any prevention program is only as good as its weakest link.

MR. LEVITT: Mm-hmm.

MR. MORSE: And the GAO report also talked about egg safety inspection resources are not directed to areas of highest risk under the current regulatory system. Most of the Federal resources are directed toward egg products even through processing mainly and that FDA's limited inspection resources the Agency almost never expects egg farms where eggs can be contaminated. At the time they wrote this report I think only 13 states had quality assurance testing

programs.

Given FDA's limited resources in this area have you been able to address that area in terms of farms?

MR. LEVITT: Well, again -- good question, Dale.

Again, this is another area where FDA -- again going back to the first slide that somebody liked -- going back to the, you know, the farm end this is an area that FDA essentially had no historical presence. Our presence on egg producing farms would be if there's a trace-back from an outbreak but really no program in terms of affirmative inspections.

So this is something that we're going to have to address through the appropriations process. This Administration has continued a high interest in food safety.

This year's budget proposal the President has submitted is a strong food safety budget for the FDA programs and we're going to have to -- we're going to have to continue to fight that -- we have, if you allow the pun, a little bit of a chicken and egg problem here in that we have a proposed regulation which is coming out and it's -- we have to -- we have to work to get the funding proposals a couple of years ahead of time in sync with the regulations that will be proposed to be implemented a year or two or three ahead of time.

Getting those both lined up with the right crystal

ball is a little challenging for us. But, nevertheless, I think overall the broader message is that we need to be devoting more time and attention to the food safety issues.

For FDA our biggest shortfall is in both inspections and in imports and that includes laboratory testing associated with both. But we want to be sure that the program is viewed as a well rounded program grounded in strong science and research that leads to good programs that are going -- that you're inspecting against.

So, yeah, it's a big need. It's a need we're going to have to keep working on and we hope you all support us as we go to Congress and try to get those funds.

MR. MORSE: Good -- good response. I think that means you haven't gotten a lot of new resources in this area and we'll try to support that.

The last question in terms of the egg safety was in an early slide you showed the strong foundation for pathogen reduction and at least on the farm there -- I guess there should be environmental testing --

MR. LEVITT: Yeah.

MR. MORSE: -- you know, looking and then if there's a positive then testing of eggs. Is that data available and sort of published so it could be looked at to follow what's happening on the farm in terms of salmonella enteritidis rates of infection and what's happening in terms

of looking at whether there's success over time in terms of pathogen reduction at the source?

MR. LEVITT: Okay. I'm going to answer the question two ways.

The current food addendum, as Dale is well familiar with, does track illnesses on salmonella and will subtype by salmonella enteritidis. One of the things that got us to build on existing state programs was the food -- was the food out there that was showing declines particularly in areas in which the programs had been heavily implemented. So you have that globally.

If your question is are the data from those environmental tests that are done are they publicly available? The honest answer is I don't know right now.

John, do you know what the regulation says on that or if it addresses it?

MR. SHEEHAN: Joe, the data that would be available would be from trace-backs and that has not yet been written up from previous years. That should be available sometime in September, later this year.

MR. LEVITT: Okay. Thank you.

MS. GLAVIN: Okay.

Alice and then Catherine Logue.

MR. LEVITT: I didn't realize I'd be so popular.

MS. GLAVIN: Why don't we say Alice and then

Catherine.

Anybody else have a burning question and we'll give Joe a break?

MS. JOHNSON: Going to give him a break, huh? Alice Johnson with the National --

MS. GLAVIN: So make this one really tough.

(Laughter.)

MS. JOHNSON: I'm Alice Johnson with the National Food Processors.

We've talked about HACCP with FDA with the juice HACCP and the seafood HACCP and we have the USDA meat and poultry HACCP. There's inconsistencies within the seafood HACCP and the juice HACCP.

Is there any thought within the FDA of going back and revising -- I think the juice HACCP is more consistent with the 1997 Micro Committee paper, particularly on the definition of hazards and that? Is there any thought that FDA will go back and revise or amend the seafood HACCP to be more consistent with the 1997 paper and the juice rule?

MR. LEVITT: I'm going to answer the question two ways. The first is the contrary question could be asked, "Why didn't you keep the juice HACCP consistent with the seafood HACCP?" The answer would have been that we believe we need to keep making improvements and each one do as well as we can do it.

The flip side then is, okay, when you go back and recalibrate and we're looking at that. We do have to balance that against all the other things we're trying to do and again kind of go back to my bottom line, what are we going to do overall that's going to do the most consumer good?

Is going back and looking at, you know, putting in say some performance standards for seafood HACCP, is that something that's going to do more good or is doing something over on egg safety or on sprouts or on other produce are on imports? You know, we are very much in the balancing game of, you know, we're going to put our attention where it's most cost-effective.

So that's kind of in the mix of things we're thinking about. I wouldn't say it's all the way at the front burner at the moment, but we're clearly aware there are differences.

MS. GLAVIN: Okay. Catherine?

MR. LOGUE: Hi! Hi! Catherine Logue, North Dakota State.

In all that you've talked about, I'm just curious as to where the FDA would stand in terms of training, education and teaching for not just consumers and producers and processors but even within your own group, within the staff? Where do you see that going for the future?

MR. LEVITT: Well, very important for a number of reasons. Number one, we have just started what's called a staff college within my center this past year to really try to enhance our training programs internally first.

That's not only for the obvious reason that you need to have a good training program, but it's that our demographics are such that most people that work in my center were hired in the 1970s. That was the last big hiring binge, if you will, at the good old FDA. What that means is we're approaching 30 years later and a lot of those people were retiring.

One reason it wasn't that much of a training program when I got there because I said the people had all been there forever and remarkably little turnover. We actually have within the food center the lowest turnover of any place within FDA. But now we're seeing those demographics change.

As we're bringing in new people the younger people, which is good, it's new blood, it's new energy, but it also means we have to have a stronger training program. So we are implementing that very aggressively.

We also -- and somebody else is here, Paul is here, Paul Raynor is here from ORA, our field operation, where also brought more broadly within FDA looking at enhanced training for our field inspectors. Our field

organization called the Office of Regulatory Affairs within FDA has -- is also instituting a whole series of enhanced training programs for the same reason.

Bringing in new people we want to be sure that our training is sound, the training is good and that the capability is sound, we're looking at certification of inspectors and so on and so forth. So I think the emphasis on that is very high.

We also have an active training program that reaches out beyond the FDA. We put on seminars for the states in different areas. We put on seminars that the industry folks come to, especially when we have new regulations and so forth.

So I think we recognize that that's an important part. Again if we go back to that first slide it had prevention education and verification. That when we put out a new standard we need to be sure that there's adequate education on how to implement that and then a verification to be sure it is being implemented well.

Does that --

MS. LOGUE: Well, that answers part of my question. My other question is what about outside alliances like going to other professionals for training of your staff? In other words, the likes of going to the universities or any other places that have these kind of

programs?

Now I know that they were considering this at FSIS at one point and, you know, train the trainer or make sure they got so many hours of course work. Does the same thing apply with you?

MR. LEVITT: Well, as I said, we are essentially, you know, going down the same track.

MS. LOGUE: Yeah.

MR. LEVITT: If you have particular suggestions of places we ought to be working with. We do have an inherent relationship with the University of Maryland with what's called JIFSAN.

MS. LOGUE: Yeah.

MR. LEVITT: The Joint Institute for Food Safety and Applied Nutrition. So they'll be working with us especially closely on things like education and training as well as a number of other things.

But if you have any particular suggestions by all means, you know, we're open to considering that.

MS. LOGUE: Thanks.

MS. GLAVIN: Okay.

Thank you very much, Joe.

MR. LEVITT: Okay.

MS. GLAVIN: That was above and beyond the call of duty.

MR. LEVITT: Well, no. It's a pleasure to be here and I hope to continue the association. So thank you for having me.

MS. GLAVIN: Thank you. Feel free to stay as long as you can.

One of our members has arrived who wasn't here when we did the introductions.

I promised that as that happened I would ask you to -- Carol, if you would introduce yourself and tell us a little bit about yourself, particularly the new members I think are interested so that they can get to -- into a working relationship as quickly as possible.

MS. FOREMAN: So much for trying to sneak in unnoticed.

(Laughter.)

I'm Carol Tucker Foreman. I'm with Consumer Federation of America. I head the Food Policy Institute there. From 1977 to 1991 I was the Assistant Secretary of Agriculture with responsibility for meat and poultry inspection and the food assistance programs. This is my third and final term on the committee. Okay. Thank you.

MS. GLAVIN: Now we have one more briefing prior to lunch and I'd like to ask Charles Edwards to proceed with his briefing on how we're trying to improve the accessibility of new technology.

Obviously, in a highly regulated industry such as the meat and poultry industry regulators can sometimes be inadvertently impediments to the introduction of new technology. So Charles is going to talk about some of the things we're doing to try not to do that.

MR. EDWARDS: As you're aware, in the preamble to the pathogen reduction HACCP final rule FSIS clearly stated that it would pursue a strategy that encouraged the development and the use of innovative technologies to improve food safety. That was in 1996.

We are now reexamining the Agency's functions and activities that are related to the testing and introduction of new technologies to make sure that we're on course with the pathogen reduction HACCP strategies and concepts that the Agency wants to pursue. This briefing is simply to inform the committee of some of the activities, not all of them that we're into, but some of the activities that we believe are related to achieving this.

Many of you know that back in January of this year, 2001, the Office of Policy Program Development and Evaluation was reorganized. The organization created the technology program development staff, which is the staff that I'm on.

The purpose of that staff introduction was to coordinate the development and to implement the Agency

programs to foster the development and facilitate the use of new technologies in plants that are under its inspection. The two or three activities that I'm going to cover are the ones that we're initiating in order to achieve what Maggie just said.

The first of these activities is to develop new regulations for technology. That may sound backward but it may be the best way that we can clearly remove the impediments and misunderstandings about what has to be done in order to introduce a new technology into the plants.

We fully expected that plants under HACCP were going to use technology in order to improve their food safety. The Agency committed to creating and introducing standards for processing and for procedures that would rachet down, if you will, the standards so that industry would be -- would provide -- would have the incentives to use technology to improve food safety. That's still a very important part of the strategy.

Now while the Agency actually encourages the use of technologies it's going to be under HACCP the responsibility of the plant to make the decision as to whether or not they wish to pursue new technology in order to improve the safety of their products or to change their procedures in some way or another or to meet the standards that the Agency establishes.

Since the early stages of HACCP concept development we've recognized that the use of innovative technologies was an extremely important piece of HACCP pathogen reduction success.

At the time that the HACCP rule was implemented there was an organization similar to this one that was created. That was the Technology Assessment and Research Coordination Division. But one difference between that organization and where we're trying to head is that the system that was put into place by that division is one that essentially required prior approval of all technologies that were introduced in the plan.

But at this stage in the game we're definitely moving away from the pre-approval approach to all technologies that are going into the plant. This doesn't mean that we don't still have some responsibilities that we still will have to fulfill. The Agency will still be concerned about anything that is going to affect its ability to inspect the food product or anything that it's going to jeopardize or hazardize -- hazardize, bad word --

(Laughter.)

-- anything that's -- anything that's going to create a hazard for our own inspectors in the plant.

So with that in mind, we're moving forward with regulations that are intended to enable plants to more

quickly and more easily introduce technologies that they choose. Under these regulations we certainly don't anticipate that plants will be required to submit for approval for all technologies. That was in 1975 and we think that we're farther down the road now and we're going to do it in some other ways.

We have identified initially the three or four areas that we believe we still have to be involved in. The first of these is obvious, any time that a technology is going to require a change in our regulations. The second, any time that it's going to require a change in the procedures that our inspectors use in order to inspect product. The third, obviously, is any time that it's going to cause a concern about the safety of FSIS inspection personnel. The fourth is any time that there is a question about the safety of the food product.

Now I need to make one intervention here and that's to clarify that inclusion of product safety doesn't mean that we're moving away from our belief that the plant or the manufacturer has primary responsibility for the safety of their product. Rather, it's simply to say that FSIS has a verification responsibility and that's what it is intended to reflect and nothing more.

At the present time we've assembled the work group within the Agency that's working on a new technology

regulation and we're expecting that a draft of that regulation will be prepared sometime by the end of this summer.

After the proposed rule is published in the Federal Register, which obviously the timing of will depend on the Agency and administration priorities, we expect to hold public meetings that will make sure that we get public views on what FSIS can and should do to encourage the development and use of innovative technologies to improve food safety.

The second activity that we're immediately embarking on is exploring ways to facilitate the development of technologies to improve food safety that will benefit small plants. The Agency firmly believes that innovative food safety technologies must be broadly applied across the entire industry if we're going to fully achieve the benefits that are envisioned for the food supply under pathogen reduction and HACCP concepts.

Obviously, the Agency has long recognized that small plants might need some help and that's reflected in our small plant demonstration project that was put into place when we were introducing HACCP in small plants. We have also proceeded to publish compliance guides to help small plants comply with the regulations.

We've come out with model HACCP plans for small

plants. We're going to obviously want to continue to do those kinds of things as we move through.

What we actually envision for small plants though, with respect to technology is being able to establish partnerships and agreements among all of the players, the industry, the plants, academia, government agencies, to bring to bear all of the resources that we can on introducing and implementing technologies that will improve food safety throughout the food supply.

This doesn't exclude the large plants, but we would hope that we could go into some kind of an arrangement where small plants might even choose to adopt a small plant. That idea has been floated around the Agency on other topics and we think it's still one that -- that might be viable.

The final activity is one that I think is fairly straightforward and that's trying to establish a method for disseminating information about new technologies. The first thing that we're going to be doing is establishing a technology web page. That technology web page we intend to be a resource for anyone that's seeking information about food safety technologies, particularly with respect to meat, poultry and egg products.

We expect to include within that guidance for the industry that will clearly explain what does and what does

not need to come to the Agency in order to be used within the plant. We're also considering ways of making information about technologies generally available to all of the plants that might want to avail themselves of them.

So in summary, the Agency is obviously still committed to it's original concept that technologies are an integral part of the success of pathogen reduction in HACCP. The first thing that we're going to be doing is publishing regulations.

In the interim we will probably issue a notice that will clarify what the Agency's existing policies are so that we can continue to move while the regulations are finalized. We'll be moving forward with the -- with the web page as quickly as possible.

MS. GLAVIN: Okay. Questions or comments for Charles?

John?

MR. NEAL: John Neal, Arkansas. I have one quick question because everybody looks hungry here.

(Laughter.)

Okay. So nobody has to -- Mr. Edwards, my question is is there -- are you applying the fact that it needs to be some low-cost technology?

MR. EDWARDS: Yes.

MR. NEAL: Okay. And I'm sure that's very obvious

with small plants, but I think that would be the biggest concern is a lot of plants can't afford to make even a $15,000 -- the very small plants can't afford to make a $15,000 investment even if it's in the long-run the better thing for them, they just can't possibly do it and that was my question. That's it.

MR. EDWARDS: One of the things that we would envision is working with the research organizations, working with the larger companies and academia, to find promising technologies that can be scaled down to the small plant budget and to identify technologies which are low-cost technologies that don't require a tremendous outlay of funding up front.

MR. NEAL: Thank you.

MS. GLAVIN: Carol?

MS. FOREMAN: Could you give me some examples of technology that would be particularly useful for small plants?

MR. EDWARDS: The things that come to mind right off the bat might be something like the organic rinses. Those are things which can be applied with relative inexpensive -- relatively inexpensively.

MS. FOREMAN: But they're also used extensively by large plants. I just don't understand what kind of technology is specifically appropriate. Give me some

examples.

I think Mr. Neal has a good idea going there but are there any examples where you've got technology that would just be used by small plants?

MR. EDWARDS: I don't at this point in time.

MS. FOREMAN: Okay.

MS. GLAVIN: But I also think it's adapting technologies. For example, some of the steam cabinets that the large plants have been using have not been available to small plants because of size and because of expense. I know Case State was doing some work a few years ago. I'm sorry, I don't know the status of it, to try to adapt that technology so that it was accessible to the small plants.

MS. FOREMAN: Thanks. That's -- that's a good example and leads to my second question which is those things that we never hear from again.

(Laughter.)

There was much made of ARS' development of a competitive exclusion bacterium for use in poultry. I remember the announcement. Is it being widely used within the industry? Is it okay with FSIS to use it?

MR. EDWARDS: I'm generally familiar with what you're talking about. This is work that was done down at -- in Georgia I believe. Those are the kinds of things that we would envision having our staff look into and to find ways

to move those technologies more broadly throughout the industry. We actually don't have in place a system for doing that. I think one of the first things that we have that will help us do that is when we get our webpage up and operating.

MS. FOREMAN: Maggie, is there any capacity to marry ARS and, you know, what happens to these things?

MS. GLAVIN: Well, on that one I was hoping maybe Alice could tell us from her former life.

(Laughter.)

MS. JOHNSON: Alice Johnson, National Food Processors.

As far as, Carol, what you're talking about with what ARS? It was approved for use in broilers and as far as I know we're still trying to get approval to use it in turkeys at the on farm level, the competitive exclusion.

MS. GLAVIN: Are the broiler -- is the broiler industry using it to your knowledge?

(Pause.)

Ah, yes. There we go.

MS. JOHNSON: There's been actually two different approaches to the competitive exclusion one that was developed by ARS and then one that's being developed privately but still in cooperation with ARS. I know this from our poultry sister company.

The two approaches are technologically different. Don't ask me any more about that because that's as much as I know.

(Laughter.)

But there's -- the interest is still very much there but I think it's getting to which of the -- the approaches that will be used for that.

But just to build a little bit on Carol's question, then is that type of on farm technology -- let's say carrying that into probiotics, for example, which is a little bit of a branch of that or other feed compounds, is that what you're looking at as examples here?

MR. EDWARDS: Included. I think that would be included. We have an animal production food safety staff that actually does move back to the farm. We would work in concert with that staff as well as our inspection staff to introduce whatever technology we believe can benefit the public health from farm to table.

MS. GLAVIN: Okay. Irene had a question back a way and I had neglected to go back to her.

MS. LEECH: Thank you.

I wondered whether you're trying to build in something to relate to consumer acceptance from the early stages of technology development?

MR. EDWARDS: I can tell you that about a year ago

when I was in another organization, yes, that was an integral part of it. I see no reason why it should not continue to be within our present organization. We just simply have not gotten that far down the road in deciding how all of the pieces are going to be integrated.

MS. GLAVIN: Okay. Marty?

MR. HOLMES: Marty Holmes, North American Meat Processors.

In answer to Carol's question, too, and maybe to help everybody, there is some technology that's been approved by the Agency. It's very similar to the organic spray situation. It actually is used on trimmings after it enters a processing plant.

So we're talking about after the packing plant you buy trimmings from a packer. You can actually spray those trimmings getting full contact on the external surface before or as it's going into the grinder. Those types of things which have never been available to the grinding industry are exciting for us.

There's a number of others, but that's one specifically that's relatively inexpensive and can be adapted to a small and very small plant.

MS. FOREMAN: What's -- what's the name of that?

MR. HOLMES: Alicide Sonova I believe is the name of the company.

MS. FOREMAN: Alicide?

MR. HOLMES: Alicide is I believe is the parent company. Sonova is the product.

MS. FOREMAN: Thank you.

MR. HOLMES: You can see it on their webpage if you -- I'll give it to you if you're interested.

MS. GLAVIN: Dan and then Alice?

MR. LaFONTAINE: Dan LaFontaine, South Carolina.

There's an intervention strategy that we've -- some of the plants, small plants, in South Carolina are using that's so simple and almost as shocking and that is called hot water.

(Laughter.)

We've had several plants that have had, you know, problems meeting the salmonella performance standard. I'm talking about pork slaughter.

I'll say my good friend, Kirk Castner from Kansas State, mentioned to me a number of years ago that, you know, we need to rediscover hot water. My bottom line is that if you put in additional hot water heaters and have an undiminished supply and wash those carcasses before they go in the cooler with 170 degree water it's amazing -- two things, they knock off some of the final debris that may be on there and they're a tremendous help in reducing the pathogen load. So I just thought I should -- it's an

opportune time to mention.

MS. GLAVIN: Thank you.

MR. LaFONTAINE: It's very simple but it's worked -- it does work.

MS. GLAVIN: Thank you.

Alice, I apologize for missing you.

MS. JOHNSON: Alice Johnson, National Food Processors.

I want to congratulate Mr. Edwards. I think this is a great thing to move forward on trying to remove some of the obstacles for new technology approvals. I know I've been one of your most frequent callers, aggravators, okay, to get through some approvals and try to figure out what's the best way to approach this.

So I think this is a great approach. I'm glad that you're looking at doing something in the short-term as far as some sort of notice as the rulemaking goes forward.

I would ask that in some of my struggles with getting things approved we do have to involve FDA and, you know, there seems to be at times a disconnect with where USDA is on approval processes and the relationship with FDA and it's made some of the -- my tasks more difficult. So as you go through this process I'm sure you're going to keep FDA in the loop.

Something now to Marty's point about Alicide and

some of these antimicrobial rinses that we're investigating. In the approval process we generally get it approved for one species.

Is there any thought to making approvals -- and I know you're getting out of the approval to some degree but there will always be a certain amount of USDA oversight in this so that once something comes into -- into view as a possibility that it's evaluated or looked at for all species and applications so that it's not going to have to go through and do additional processes to get approval for?

MR. EDWARDS: Some of that is going to depend on whether or not we have a processing aid which is safe or we have a food additive situation which might involve FDA and labeling.

But the idea would be to encourage as these things particularly go through the petition process at FDA that as many species as possible would be included so that when that decision is made we're able to move forward with it, as well.

MS. GLAVIN: Okay. Other comments or questions?

Yes?

MS. MORENO: Elsa Moreno. One thing I forgot to mention at the beginning is that I also represent the National Alliance for Food Safety. I'm the Chairperson of that organization for the next year, anyway.

We have recently in that organization divided ourselves and it's 25 universities all engaging in food safety research, education and extension activities. We have divided ourselves into centers of excellence and one of those centers of excellence is decontamination strategies.

I just wanted to hear your comments, Mr. Edwards, as to how such an organization can partner with FSIS or what is your vision of the kinds of partnerships that could be formed in order to accomplish what you're suggesting which is to help the industry and certainly the small processors especially when you go into cost benefit analysis of different interventions and things like that?

MR. EDWARDS: Okay. Obviously, a lot of what we're able to do is going to be determined by our statutory restrictions, by budget, by other resources.

But our intention is to engage with as many activities or organizations as we can. We would hope to include the state. We would hope to include trade organizations, consumer groups, individuals, small plants, large plants, anyone that has a stake in the food safety supply we believe is a legitimate player in the technology role -- in the technology area.

I don't know that I have exactly a vision of how all of these would come together just yet, but in my mind there is a place for that kind of an organization.

One other thing before I go, I have with me Patrick Burke, who is a senior industrial engineer on the staff and he hasn't said anything but he will be an integral part of whatever we're going to be doing. So that's why I asked him to join me here.

MS. GLAVIN: All right. With that I would like to declare us on lunch break and ask, since we are a few minutes behind time, that we be back by 1:25. There is a restaurant here in the hotel. At 4th and C Streets I saw a McDonald's.

I suspect there are other such eating establishments in the neighborhood, but this is a little far afield from our office for me to know exactly where they are. L'Enfant Plaza is about a three block walk and there are a number of places there.

So I'm sure some of the people at the desk out here can probably give you better hints on lunch availability. So 1:25.

(Off the record at 12:19 p.m.)

(On the record at 1:32 p.m.)

MS. GLAVIN: If the committee members will take their seats then I think we can get started again.

(Pause.)

Okay. It looks like we have close to everyone. A few people are missing but I assume they will wander in

shortly.

Our next presentation is on one of the issues that you will discuss in your subgroups tonight and that is the industry's petition for changes to the HACCP final rule, proposed changes to the HACCP final rule. Pat Stolfa is here to make that presentation.

I know you got here before lunch so I know you're ready.

MS. STOLFA: The materials on this subject are at Tab 7, so if you want to make sure you've got all the materials.

At the end of December in 1999 the Agency received from a coalition of industry organizations this petition to amend the Part 417 -- excuse me, the HACCP regulations. The petition itself is the last document in this -- in this set of materials. So if you would like to read the petition itself it is there although it has been made available in a number of other -- on a number of other occasions.

The petition was I believe referred to this committee and it was published in the Federal Register for comment a little more than a year ago. The comment period was extended on several occasions and so remained open through most of the rest of the year and didn't close until after the Agency's public meeting on Next Steps.

So there was a lengthy time during which people

could review and comment on the petition and then there was at least one public meeting in which it might have been the subject of discussion. I don't recall that it was heavily discussed at that meeting.

We did not receive an enormous number of comments and the comments broke out in a way that was somewhat expected. The industry organizations themselves and some individual companies tended to support the request in the petition.

Consumer representatives tended to oppose the items in the petition and they frequently cited the Inspector General report which had come out during that intervening period of time and was critical of the Agency's HACCP implementation. So that's just kind of a quick summary of the comments.

Internally, we've spent a lot of time considering the issues raised in the petition. We're at a point where we believe we have formulated a course of action that would be beneficial to all of the interested parties, although it was not a specific request in the list of items at the end of the petition, the list of regulatory language items in which the group wanted amendments.

There was and is much discussion in the petition about the Agency's failure to recognize prerequisite programs. Therefore, we have given that a great deal of

consideration and believe that we could issue proposed regulations with certain characteristics that did recognize prerequisite programs. So that is the first and perhaps the most important of the items in our current thinking document.

The characteristics that we want to have -- have in prerequisite programs is we want the prerequisite programs to, if successful, have some impact on the HACCP plan itself so that a successful prerequisite program might eliminate the need for some CCP's.

There are certain kinds of controls that actually are probably better handled with prerequisite programs than forcing all of them into CCP's. So we believe that. That's kind of the basis for our proposal or what would become our proposal.

We believe that the prerequisite programs can be voluntary. If an establishment didn't choose to involve itself in prerequisite programs that's okay with us, but if they did choose to involve themselves in prerequisite programs it could have an affect on their HACCP plan and we would need to have access to the records of the prerequisite programs.

We think that -- you know, we read the literature and although we did a review of the literature and the literature's not actually too extensive but there are --

there are a couple of recent excellent pieces. In most of the articles or most of the documents that talk about prerequisite programs there are lists of the kinds of things that might be treated by prerequisite programs.

We don't have a particular quarrel with the list, however, we do not wish to change 416 and we -- sanitation is very frequently on that list of things that might be treated by prerequisite programs. However, we wish to maintain 416 and so we would not accept something else in lieu of compliance with 416 for sanitation.

Historically, you know, that's why sanitation got separated out into a separate part of the regulations. Historically, sanitation has been a big, big issue in meat and poultry establishments. We think 416 is fine. There's a number of other kinds of things, however, that -- that could well be treated by prerequisite programs.

So in the current thinking paper that's another feature that -- that we've listed as an important element of our thinking on a proposed regulation to recognize prerequisite programs. We think there needs to be a period of successful operation of a prerequisite program which is more than a day and that you can't be switching back and forth between your HACCP plan and a prerequisite program.

So if you demonstrate success in a prerequisite program over a period of time we're willing to acknowledge

that and let that affect the HACCP plan. We think the standard of action in a prerequisite program -- and this is very much in the literature -- is quite different from the standard of action in a CCP.

417.3 talks about what you have to do if you exceed a critical limit at a CCP and those are the corrective and preventive actions. Prerequisite programs aren't like that. In the literature it makes it quite clear that you don't have this product by, you know, product concern in prerequisite programs.

The standard is really we don't want the operation of a prerequisite program to fall into a pattern of non-compliance. We don't want not making the prerequisite program to be more routine than meeting the specifications of the prerequisite program, but it is not the same thing as 417.3.

Generally, because of the type of things that are controlled by prerequisite programs it's not so much an incident by incident and group of product by group of product response.

So, at any rate, that is probably the biggest item in our current thinking in terms of how we would respond to the petition. But it's certainly not the only thing that people asked for and that we would like you to know what our -- what our thinking is.

In the -- in the current thinking paper that's attached to the summary paper the discussion on prerequisite programs is about four and five. People did also at the petition did also request very specific wording changes in key 417 definitions, food safety hazard, hazard analysis, significant severity.

We have looked not only at our own regulation and the seafood regulation, which are virtually identical, we have also looked at the FDA juice regulation. We believe we are not in a position to make these changes at this time, that we have an inspection force that would require considerable additional training to give us confidence that this kind of change could be successfully implemented.

So we do not -- these -- these terms suggest more judgment than is currently required by the language of the regulation. I suppose the most difficult item for people to interpret under 417 as it now stands is food safety hazard reasonably likely to occur. However, that is defined in the regulation.

We believe people are coming to understand that with increasing consistency and with increasing sophistication. We are worried about what might happen in terms of implementation with the introduction of terms requiring greater judgment and believe we need to reserve judgment on that. We will look with great care at FDA's

experience in its juice regulation. It has quite different language in its juice regulation and we will look at that with their experience with care.

We'll try and see how it's different from what they do in seafood so that we can come to understand what the difference in words might actually mean. But at the present time we are not in a position to make those changes in the definitions in 417.

There was another kind of definitional change which we -- which was brought to our attention and that was terms around enters commerce produced and shipped. Although we don't believe that a regulatory change is necessary we will be willing to make a regulatory change, not the one that was requested. We are not entirely the one that was requested.

We are quite willing to remove the term "enters commerce" which is extremely complex and doesn't mean the same thing under FDA statute, says it does under our's and, you know, we'll get rid of that in a second.

We don't think we should go to "shipped." We think we should go to "produced" because under 417 product is produced after the establishment carries out preshipment review under 417.5(c), I think, is where preshipment review is. It is -- it makes no difference where the product is.

The product may still be in the establishment but

the product may not be in the establishment. Since the first implementation meetings we have had that same definition of when product is produced. The establishment may have -- may send it to a warehouse, the people at the warehouse complete the preshipment review.

This may be sequential preshipment review where the preshipment review is performed as product moves from one part of the establishment to the next and the only thing that has to happen at the cold storage warehouse is that all the documents come together or, you know, they have a computer that says it's checked out of this department and this department and this department and this department and then the warehouse completes the preshipment review and tells them, "We completed 417.5(c)."

So we don't think "shipped" is the relevant term. We think "produced" is the relevant term, but we know the relevant action is the completion of preshipment review.

So the first thing we're intending to do is to issue a notice to inspection program personnel clarifying that point. If we need to make a regulatory change to further clarify that we are well willing to do it, but you know how long it takes to make regulatory changes. So we thought we'd try to do some instructional materials first.

Then the last one is inadequate systems determinations. We are doing some work on inadequate

systems determinations not along the lines that the petitioner's requested.

For some time we have felt that we needed to issue more instructions and guidance to our personnel about making inadequate systems determinations. So we are working on that. I'm hopeful that we might have something in the next few weeks. I've taken it I think about as far as I can on a policy perspective. Now I need somebody else to tell me what kind of process they want to have and that's more the operational people.

So we're -- I assure you that we are working on this. We do not contemplate a regulatory change. We do contemplate some further guidance and instructions to our personnel so that -- that those determinations will be made in a manner that's consistent across -- across the board and across the country.

And I think that's all I absolutely need to say and that perhaps the rest of the time should be guided by questions that you have or things that are on your mind regarding this petition.

MS. GLAVIN: All right. Alice is going to start off.

MS. JOHNSON: I have a question, Pat, in the current thinking --

MS. STOLFA: Yeah.

MS. JOHNSON: -- paper. You talk about data that the petitioners needed to provide. I know in a lot of the -- the separate comments there were situational examples that -- that were provided.

When you're talking about data as it's referenced in this current thinking paper are you talking specifically about economic data?

MS. STOLFA: I'm talking about impact data which includes economic data in some cases, but it's not limited to that.

MS. JOHNSON: Okay.

MS. STOLFA: All the -- the HACCP rule was economically significant and major. It has the most rigorous impact analysis demands and anecdotes don't make it for getting the rules like that cleared.

We have collected some data ourselves on prerequisite programs and the Inspector General's report also gathered some data on that topic, but those aren't anecdotes, you know, those are numbers. We're looking for numbers.

MS. JOHNSON: Okay. Thank you.

MS. GLAVIN: John?

MR. NEAL: John Neal from Arkansas. Something that I saw in the prerequisite programs is the fact that, you know, any prerequisite programs should only have a

positive effect.

It should include a history which USDA or FSIS has a problem recognizing even though it was taught specifically in all of the HACCP programs that we spent money on and went and attended and such as industry, myself, small plants and other people. It was all basically the consumer interest.

But any -- any prerequisite will have a positive affect on the program, it shouldn't affect it at all, unless there's something wrong with it. If it does affect it then you wouldn't vary from your HACCP system but a prerequisite is probably going to be better than what you have in your system to begin with so you can delete that.

One of the other problems is is an interpretation on the prerequisite and I think you kind of addressed that, you said you all are working on that to getting -- so we can get better determinations because you get different determinations by different inspectors or, you know, DBM's. I just wondered how you felt about that?

MS. STOLFA: Well, currently prerequisite programs can't substitute for HACCP systems and CCP's. What we're saying here is we believe that we can change that and that we could recognize prerequisite programs and successful prerequisite programs could have an affect on whether or not you needed a CCP. That's -- that's the basic idea when we say we could recognize prerequisite programs --

MR. NEAL: Right.

MS. STOLFA: -- in our regulations. That's -- that's our current thinking.

MR. NEAL: Right. So it basically goes to the history though? History has a big effect on that, something you've always done, correct?

MS. STOLFA: Yeah. Or you could -- you could decide to have a new one if you wanted to but you would need to decide what it was and what your standards were going to be and you'd have to practice it for a while and make sure you could do it. But you could -- you know, you could add them.

MR. NEAL: Okay. Thank you.

MS. GLAVIN: Carol?

MS. FOREMAN: I'm not sure why we're having a discussion of prerequisite programs or why the Agency has done anything except reject them.

The Office of Inspector General and the General Accounting Office were really very specific and vigorous in their criticism of this. The GAO said, "This practice limits the consistent implementation of the HACCP system nationwide as well as USDA's oversight of food safety at these plants."

The OIG said, "Using prerequisite programs such as GMP's, SSOP's and plant operating procedures outside HACCP

is justification for determining that a food safety hazard is not likely to occur, is not acceptable."

MS. STOLFA: I think that that speaks to the fact that we don't have access to those records. We have access -- and I think both of those comments speak to that.

We have access to HACCP records on a continuous basis. We don't have access to prerequisite program records and have not forced that issue in establishments. We have not instructed our people to go chase down the prerequisite programs. Routinely we don't see that information. That's the problem.

MS. FOREMAN: Well, I accept that that is a problem but GAO and OIG do not limit their remarks just to the lack of access to records. It is a much more general condemnation of the use of prerequisites as a substitute for HACCP.

MS. STOLFA: I read those reports with some care and I believe that their problems would be largely solved with prerequisite programs of the type that are described in the literature and of the -- with our access to records.

MS. FOREMAN: Well, you know, we have -- the consumer community has had some difficulty with HACCP based on what we view as already a limited access to HACCP records for both the inspectors and the public. Again, the OIG really said that they believed that since the implementation

of HACCP that the -- the responsibility and the balance of power to protect food safety in these plants had shifted too far toward the plant management and away from the responsibility to protect public health.

You know, all these products go out of that plant with the USDA stamp on them and there has to be some reason to believe that as long as USDA's going to put that stamp on there the department has the final say. OIG and GAO don't seem to think that's the case and we don't really think so, either.

MS. STOLFA: Fine.

MS. GLAVIN: Sandra and then John.

MS. ESKIN: Okay. Just for clarification. What role does Government Inspectors have over these prerequisite programs? Is there any sort of oversight? Any sort of sampling? How are they checked?

MS. STOLFA: At the time none.

MS. ESKIN: Nothing?

MS. STOLFA: Right. At the current time nothing. We don't look at them. Now the OIG suggested we could force the issue and we could look at them but we have not -- we have not done that. We have not instructed our people to do that.

From the beginning also we have been very careful about the -- what we believe is the proprietary nature of

HACCP systems. While we have access to all the records we don't routinely copy them and that sort of thing, but we certainly expect our people to be thoroughly familiar with the system and the records in analyzing information from the systems. But that is not the case.

MS. ESKIN: That's just HACCP, right?

MS. STOLFA: That is just HACCP and SSOP.

MS. ESKIN: Right. Thank you.

MS. GLAVIN: John, you had a question?

MR. NEAL: Go ahead.

MS. GLAVIN: Oh.

MS. MORENO: Elsa Moreno.

Pat, am I understanding correctly that what you're talking about is GMP's, SSOP's, with HACCP and not -- we're not talking about one versus the other? We're not talking about getting rid of HACCP in place of the prerequisites, of course? It's putting them as a basis underneath HACCP and perhaps having to revise the HACCP plan because now you are using these prerequisite systems as well?

MS. STOLFA: Right.

MS. MORENO: But you're not talking about doing away with HAACP at all?

MS. STOLFA: Oh, no, not at all.

MS. MORENO: Of course not.

MS. STOLFA: Not at all. We are talking about 417

stays as it is. 416, a special prerequisite program called sanitation stays as it is. 415 is available on a voluntary basis. If you want to handle some other types of things, training and personnel, employee hygiene, if you want to handle those via prerequisite programs you may do so under the authority of proposed 415, a separate section.

If you don't want to you don't have to. If you do so successfully you may be able to minimize having to have a CCP in 417 to address something that might actually be better handled via a prerequisite program.

MS. GLAVIN: Alice and then Carol.

MS. JOHNSON: I want to be sure as one of the signers -- one of the groups that signed on the petition that everyone understands that, as Dr. Moreno said, prerequisite programs the intent was not to substitute those for HACCP but as all of the training material and the Advisory Committee papers states prerequisites are a foundation for HACCP and work in conjunction with HACCP and we've all seen Dane Bernard's little pyramid and how they all work together.

In that line, Pat, when we talk about using the prerequisite programs and providing access to the records which, you know, would be an added benefit I think for what the Agency is trying to do, you talk about the inspector will have availability and then you also talk in the current

thinking paper about, you know, how you're upgrading your workforce training and you feel like you're not quite there yet.

Is there any thought on the part of the Agency if you move forward with prerequisite programs and record availability, you know, on training the inspectors and helping them understand what the records mean and how they are being used in HACCP and would there be a separate training course for inspectors? I know if --

MS. STOLFA: We -- we do anticipate that -- that if we put in a new section it would take training to establish the appropriate relationship between that section and the existing 416 and 417, you know, including training and verification techniques and that sort of thing.

However, we think we just need training, period, on some additional items. So like the inadequate systems the area is one in which we think that training or additional guidance would be appropriate so -- in both instances. But we certainly agree with your characterization of prerequisite programs.

MS. JOHNSON: And just to follow-up on that. We've talked in the past about joint training between the Agency and inspection and not on the regulatory issues and determining compliance but just on the science behind certain issues.

I know there's a lot of good prerequisite courses offered by a lot of the universities that industry attends and would recommend that you look into some of those just for the basics on prerequisites and what they mean, not necessarily carrying out the enforcement part.

MS. STOLFA: Well, we would appreciate any information you'd be willing to share with us.

MS. GLAVIN: Carol I think was next and then Dan.

MS. FOREMAN: Carol Tucker Foreman.

Pat, how does the Agency verify a prerequisite -- something that's been handled through a prerequisite program?

MS. STOLFA: Now?

MS. FOREMAN: Or as you propose to do in the future? At any time?

MS. STOLFA: Now we don't. Okay.

MS. FOREMAN: How would you do it?

MS. STOLFA: We'd look at the -- we'd look at the prerequisite program that the -- that the company had established, which would consist of this is our standard, this is how frequently we're going to check it. This is who's supposed to check it. This is the outcome we expect.

We would look at that and we would verify it using the same kind of techniques we use to verify HACCP plans. Now we observe -- we look at records, from time to time we

take samples.

I think those are three very basic techniques. They have an infinite number of variations as they are applied but I believe those same kind of techniques would be applicable.

MS. FOREMAN: I sense that we are getting back to a definition of HACCP that caused a large part of the community to reject and oppose the Department's adoption of HACCP all the way through the 1980s because there was an assumption, there were no performance standards. There was an assumption that HACCP would work. The verification was extremely vague.

I see the prerequisite programs, especially if you get to do those and give up a HACCP point, you're just getting HACCP minus. You are -- you are losing some very specific ability to verify that what's going on there is, in fact, going on as it's supposed to.

It -- it seems to me that it's -- it's -- it may be consistent with what the Micro Advisory Committee suggested but they have never talked about HACCP in the context of a government regulatory program designed to protect the public health. That's FSIS' responsibility.

When you think about how HACCP -- it has to be in the terms of protecting public health and it seems to me that substituting a prerequisite for a HACCP control point

is taking a step back from that. It is -- it is a very fuzzy sort of verification there.

MS. STOLFA: I think that that is not at all what prerequisite programs would do. That the effect of prerequisite programs is to give us access to more information and more ability to verify that the infrastructure to support a HACCP system is in place and working well.

MS. FOREMAN: How can you say that if you're going to allow a plant to do away with a critical control point and replace it with a prerequisite programs?

MS. STOLFA: That's not what I'm saying.

MS. FOREMAN: Oh, that's funny, that sure seems to me what the purpose is.

MS. STOLFA: That may have an effect. No, I don't think that's what it says. There is a fundamental difference in the kind of controls that are addressable by prerequisite programs as opposed to those that require critical control points, critical limits, virtually continuous monitoring, verification, etcetera.

There is -- it is a difference in kind and, you know, that's in the Micro Committee document. It's in the document. It's in the documents that have been written specifically on prerequisite programs. As I say, I believe we gain information rather than losing information.

MS. FOREMAN: Are -- are you telling me that it -- that this paper -- I can't find it now -- that your current thinking paper does not say that you could alter and perhaps reduce the number of critical control points if you have a prerequisite program?

MS. STOLFA: You may choose to alter your HACCP plan based on the successful operation of a prerequisite program.

MS. FOREMAN: Would that include --

MS. STOLFA: It might. I don't know. You might have a totally different design. It's not likely that you're going to be able to construct a prerequisite program that is a direct substitute for a specific CCP.

However, there might be an adjustment all over the place because the infrastructure is working. So we don't need all of these CCP's. Forcing everything into CCP's presents certain kinds of difficulties with certain things that need to be controlled in establishments.

MS. FOREMAN: And the OIG just criticized the Agency vigorously because many plants have only one CCP. They said, "You don't have enough CCP's, not that you have too many.

MS. STOLFA: I'm not -- you know, I'm not -- you know, I know what the OIG said.

MS. FOREMAN: Do you -- you suggest they didn't

say that? Because I think that was very clear.

MS. STOLFA: They did say that.

MS. FOREMAN: Okay.

MS. STOLFA: I know they said that.

MS. DESKINS: Dan and then Sandra.

MR. LaFONTAINE: Dan LaFontaine, South Carolina. I want to put a different spin on this for a moment. I want to publicly support FSIS' thinking. Here's where I'm coming from.

Currently -- well, first of all, being an implementer in 110 plants, or a regulator I should say of the implementation, being a HACCP instructor, one of the bedrocks of any HACCP program or any HACCP course if it's worth it's salt is spending at least a half a day talking about, using Alice's words, the bedrock that you build on the prerequisite programs, pest management, inspection of incoming ingredients to make sure there's no -- nothing wrong with them, employee hygiene, you name it.

Right now GMP's is a bad word. It shouldn't be that way in our regulatory environment. I know why it's a bad word, because you can't use it in lieu of a CCP. So I'm not saying that we can across the board start substituting GMPs for CCP's.

What I am saying is we've got to change the mindset among the industry and the regulators that says

GMP's are good things and let's do everything we can to encourage industry to implement, to develop them, implement them and make those records open to all parties concerned.

So that's my main point is let's change the mindset somehow that brings the GMP's, which is a real add-on, and make them open and useable. Thank you.

MS. DESKINS: Okay. Sandra and then we'll go to Marty.

MS. ESKIN: Sandra Eskin. I just wanted to follow-up on what Carol was asking Pat.

I want to understand that if -- you're saying that if a prerequisite program proves to be successful that it may, again it may, result in the reduction of CCP's -- a CCP --

MS. STOLFA: (Nodding affirmative.)

MS. ESKIN: So is the thought then if you implement a prerequisite program theoretically you could -- you'd still have that CCP in operation until the success of that prerequisite program is established?

MS. STOLFA: Yes.

MS. ESKIN: Okay. I just wanted to clarify that. Okay.

MS. GLAVIN: Marty, I think you were next.

MR. HOLMES: Marty Holmes with North American Meat Processors Association.

Dan, I appreciate your comments, too, because I think as the petitioners signed -- signed our thought was actually to -- we've been in support of GMP's and SOP's for number of years and felt like those were the right places to put some of these things. The Agency's trouble with that was that we can't get to them.

It's kind of look -- we generate the records, they're not hurting us at all, here they are, just kind of, well, we don't have regulatory authority. Then you get attorneys involved or whatever. It's kind of, look, here they are. You know, it's not that big of a deal.

I don't think that the petitioners saw this as a way to reduce CCP's because if it truly meets the definition of a CCP then GMP or an SOP cannot take it's place.

MS. STOLFA: That's right. That's right.

MR. HOLMES: Okay,

MS. STOLFA: That's right.

MR. HOLMES: Anyway, that's not my point. I just wanted to --

MS. GLAVIN: Well, actually could you talk a little bit more about that? I mean I think that's -- I think you've hit an important point. Can you talk a little bit more about why a GMP can't replace a CCP?

MR. HOLMES: Well --

MS. GLAVIN: And what would be a true CCP in that

-- in that --

MR. HOLMES: GMP's and SOP's are -- are essential and important to an operation but they may not be critical in terms of a food safety -- a food safety hazard. I don't know if I can elaborate much more than that. I mean I --

MS. GLAVIN: Okay.

MR. HOLMES: Does that help a little bit?

MS. GLAVIN: Can you cede for a minute and let Dan --

MR. HOLMES: Sure.

MS. GLAVIN: -- try to help you out?

MR. HOLMES: Yeah.

MR. LaFONTAINE: I want to go back to the basic definition. For it to be a CCP it has to one do of three things, prevent it from beginning a hazard at all, eliminate it or substantially reduce it.

So if it -- if a hazard meets that definition it has to be a CCP. There's probably very few GMP's that will prevent, eliminate or substantially reduce --

MS. GLAVIN: Okay.

MR. LaFONTAINE: -- when you get right down to the very basics.

MS. GLAVIN: Okay. I want to go back. Marty still didn't get his question out.

MR. HOLMES: That's okay. Did that help a little

bit?

MS. GLAVIN: Yeah, thank you.

MR. HOLMES: Okay.

I was -- Pat, I just wanted to talk a little bit since I'm not on the subcommittee tonight and I just -- I was a little concerned or surprised I guess.

We talk about risk-based inspection and yet -- and the petitioners felt that risk and severity of a -- of a hazard in terms of -- of defining what a hazard is was supportive of a risk-based inspection system.

So I really -- you made a statement -- you made some statements to the effect of that -- that the inspectors would -- were not adequately trained to be able to make that determination but my understanding right now is the inspectors don't make a determination currently as to whether or not a CCP is -- is adequate or not.

So I was a little -- I kind of got confused as to why they were inadequately trained to determine risk and severity if we change that definition compared to what they're adequately trained to do now.

MS. STOLFA: They do receive training in food safety hazard reasonably likely to occur and the regulatory language.

We simply foresee that terms like "severity" and "significant" would not lend themselves to -- to equally

clear regulatory language. We believe that that's kind of a recipe for an endless series of arguments because those terms are more judgmental. We just don't think we're ready for it at this point.

MR. HOLMES: Okay. I guess -- I guess my -- my point there really is that if -- if there's -- if you don't mandate and approve or disapprove CCP's, whether it's based on risk or severity now, if -- why it would necessarily make a difference?

I mean if the proof is in the pudding in the HACCP plan of whether or not you're -- you're producing a product that's safe or not I don't know why the definition would -- would make a difference.

MS. STOLFA: Oh, I think it makes quite a bit of difference in regulatory terms. Also, we do expect that our inspection program personnel will get better at their verification of HACCP plans. You know, we're planning on that.

(Laughter.)

MR. HOLMES: Right.

MS. STOLFA: And -- and working on it. So, hopefully, they'll be coming along and bringing to the table more sophisticated types of verification activities.

MR. HOLMES: Okay. And my other quick question, if I can, is in terms of the way that you've removed inner

commerce -- or your suggestion here of "inner commerce" versus "shipped" and a product isn't shipped until it's met its preshipment verification, a product is not produced until it passes its preshipment verification.

That product could actually be on a truck --

MS. STOLFA: True.

MR. HOLMES: -- I'm just giving you an example, it could be on a truck moving across the United States --

MS. STOLFA: True.

MR. HOLMES: -- while data -- let's say that you're -- you're doing some -- some testing, whether it be listeria testing or whatever and you're waiting on that data to come back and it takes a significant amount of time for that to come back that product could be on the truck moving from California to New York while that data -- before that data is received.

Although it's still on your truck it hasn't been produced because you haven't done your preshipment verification to allow it to be offloaded to a customer.

MS. STOLFA: That's right.

MR. HOLMES: Thank you.

MS. STOLFA: Mm-hmm. We think people are getting a little confused on the physical shipment. We've decided that maybe that was a little distracting for making that judgment.

MR. HOLMES: Okay.

MS. GLAVIN: Okay. Collette and then Carol.

MS. KASTER: Collette Kaster. Just a quick question to build on what Marty was asking with the -- the term "significant" and "severity."

Then in the current thinking you referenced -- you said the Agency has carefully reviewed the specific language of the FDA juice final rule. Did they incorporate some of that into the --

MS. STOLFA: Yes.

MS. KASTER: -- juice rule?

MS. STOLFA: Yes.

MS. KASTER: So are you looking also then at how they're training their personnel to make those judgments again kind of a line --

MS. STOLFA: We're looking at how they implement, yes.

MS. KASTER: Okay. Thank you.

MS. GLAVIN: Carol?

MS. FOREMAN: Again, both OIG and GAO were very critical of this and I don't think I can be supportive at all of where you're going without seeing how -- a list of each of the points that GAO and OIG made about this issue and your response about how what you propose to do responds to that criticism and makes it go away. I think that we

have -- I think we're justified and, in fact, it would be irresponsible not to ask for that.

MS. STOLFA: I think we respond to both of those reports not -- this is not designed specifically as a response although I believe some of the -- some of the concepts would be -- they would be found to be useful. But the Agency does respond specifically to both reports like that.

I don't know exactly where that is, Maggie.

MS. GLAVIN: Yeah. We have responded to them but I don't think that's what you're asking. You're asking for a side by side --

MS. FOREMAN: Right.

MS. GLAVIN: -- of our current thinking as to the GAO issues.

MS. FOREMAN: Right.

MS. GLAVIN: Yeah.

MS. FOREMAN: That -- that -- that would --

MS. GLAVIN: Yeah. We don't have that --

(Multiple voices.)

MS. FOREMAN: alleviate my concerns.

MS. GLAVIN: Okay. Okay.

Oh, Elsa?

MS. MORENO: Elsa Moreno.

I'm going to say I agree with Carol on what she

just said, that that would be of benefit to see what was their thinking in criticizing this.

I wanted to relate to you all a story, just a couple of minutes, a couple of hours.

(Laughter.)

No, a couple of minutes. Some years ago I went to a Central American country and they took me on a tour of a slaughter plant. They wanted me to go in there and tell them what they needed to do to implement a HACCP plan.

So I go in there and walk into the slaughter floor and the splitting of the carcasses was done with an ax that was -- that hadn't been sharpened in who knows how long and it was laying on the floor. There was no refrigeration in the room at all where they were doing the cuts.

In fact, they were slaughtering cattle as well as hogs and one of the pigs got loose and was running around the slaughter floor. They got to put the carcasses in the cooler and the cooler wasn't working at all. Then they loaded the meat cuts and the carcasses on the back of pickup trucks by hoisting them over their shoulders and kind of putting them into the trucks. At that time it was raining and so there was water coming on the product.

What I'm trying to tell you is that when I got to sit down with the owners he says, "Well, what do you tell me now, Dr. Moreno? What can I do? Where are my CCP's?"

(Laughter.)

MS. STOLFA: Where aren't they, right?

MS. MORENO: Exactly. Where aren't they, right?

(Laughter.)

Every single thing was a CCP in the sense that because they had absolutely no prerequisites, they had no sanitation, no building IPM, there was trash outside the building. So that's a very crude way to show how if you don't have those prerequisite programs then you have, you know, 30 CCP's perhaps.

When you institute the prerequisite programs, which SSOP's are a prerequisite programs as you said, Pat, it would clean that operation so much and they would start doing the things that they're supposed to do before they even think of HACCP that when they are ready for HACCP the critical control points are, indeed, critical control points.

So that's I think what you're probably getting at, is that the prerequisite programs they're not going to substitute a true critical control point, as Marty said, but if there's something that you should be doing as a matter of conducting business such as not putting an ax down on the floor that you're going to use to split the carcass open, and that is part of a prerequisite program that you would take care of then that -- no longer that -- once that no

longer becomes a CCP. That's all.

MS. GLAVIN: Thank you.

MS. MORENO: And they lived happily ever after.

(Laughter.)

MS. GLAVIN: Michael?

MR. GOVRO: Just a quick question. Michael Govro.

Does the production of meat products require at least one CCP in USDA HACCP?

MS. GLAVIN: We --

MS. STOLFA: Well --

MS. GLAVIN: Go ahead, Pat.

MS. STOLFA: The preamble to our final rule says that we're not aware of processes that don't have any food safety hazards reasonably likely to occur. Therefore, our -- and that's the definition of a situation that requires a CCP. So it's indirect.

We have had some discussions with people over the years about some processes but, by and large, we think that there's not much you can do with meat or poultry that doesn't involve some food safety hazards reasonably likely to occur.

MR. GOVRO: It seems to me that that's a significant difference between USDA HACCP and FDA and seafood HACCP in that seafood HACCP does not necessarily require a CCP and on page six of your -- in the discussion

of the definitions it says that USDA and FDA HACCP are virtually identical and I would -- I guess with that difference I would take exception to that statement.

MS. STOLFA: Fine. I have a side by side which -- of the regulatory language which I think shows like a one word difference.

MS. GLAVIN: Are there other questions or comments on this? Do you feel you have enough to have your discussion tonight and come back?

(No response.)

Okay. Thank you very much, Pat.

Now the presentation of the third of the issues that the subgroups will be considering this evening and that is Federal, state and local government relations. We have two presenters for this, Ralph Stafko and William Leese.

I don't know how you have planned to proceed but proceed.

MR. STAFKO: Thank you, Maggie.

I think most of you know me and Dr. Leese to my right. We're colleagues and partners in the -- in the management of the new Federal, state and local government relations staff.

I'd like to spend just a few minutes giving a little background on the new staff and then I'll turn it over to Bill to talk a little bit more in depth about our

activities regarding the oversight of and assistance to the state MPI programs, which is the area that he's been working in in the past.

Then he'll turn the mike back over to me and I'll expound a bit on some of the things we've been doing with regard to expanding our cooperative agreements and programs and activities to areas outside the traditional MPI and meat and poultry inspection activities. We'll both try to give you the short version so we should have some time at the end for questions and answers.

As you know from the briefing documents the new office was put together earlier this year in response to the Agency's perception that needed to elevate the function of Federal, state and local government relations a bit more in the pantheon of Agency activities.

The office is basically comprised of two small offices, the one that Bill was Director of previously in the Office of Field Operations, again that oversaw the cooperative programs for state meat and poultry inspection programs and the office of which I was in charge that was looking to -- to put some flesh on the bones of our farm to table food safety strategy.

In combining the two offices into one the Agency is in a position to coordinate better all of its activities that impact on other jurisdictions. It will foster more and

better collaborative food safety activities and will improve our ability to support our cooperating agencies.

The new staff is located in the Office of Policy Program Development and Evaluation. Our office reports directly to Dr. John Prucha, who I think just walked in there back there. Not coincidentally, Dr. Prucha also has responsibility for the import inspection activities.

That office and our office have roughly parallel kinds of functions in terms of the oversight that we provide and evaluation and certification of other inspection programs that -- that produce meat and poultry for our domestic market.

Our purpose today is to again first introduce our new staff to tell you a little bit about its current activities and to seek your advice on our agenda and how to better serve our stakeholders. Specifically, we've posed two questions; (1) can the Advisory Committee suggest other activities beyond those which we're going to be talking about that will advance the Agency's food safety goals; and (2) can the Advisory Committee offer advice on building more effective partnerships with state and local food regulatory agencies?

With that, I'll turn it over to Bill to talk about the MPI programs.

MR. LEESE: Okay. Thank you, Ralph.

As we look at the Federal authorities and oversight state meat and poultry inspection programs over the last 30 years I think we can see that there's a lot of changes in thinking, especially within the last let's say five or six years.

As we go to the integrated, seamless national system for food safety there would be a rethinking in the types of relationships. We're talking more in terms of partnerships where I really question that back 30 years ago there was much talk about this oversight of the state programs as being a partnership entity. Maybe there was, I hadn't thought about it at the time, at least.

Now, of course, we're stressing this more of a working, joint relationship. At the same time we do need to recognize that there are authorities defined in the Federal Meat and Poultry Inspection Acts that we have to keep in mind as we work within this framework. It's basically the same for the meat and the poultry.

So I tend to focus my remarks with respect to the Federal Meat Inspection Act, although it's a comparable situation for poultry.

Of course, the Secretary of Agriculture is authorized under the Title III of the Federal Act to cooperate with states in developing and administering at least equal-to programs composing, imposing mandatory

requirements defined in the act, anti-mortem, post-mortem, reinspection, denaturing of product, maintaining records, providing access to the plants, registration of people within the industry, the brokers or renderers, controls over dead, dying and diseased animals.

Now the cooperation that ties with these factors is that the Federal programs provide advisory assistance in planning and developing state programs, providing technical and laboratory assistance and training and funding up to 50 percent.

Now this is contingent upon administration of a state program in a manner which the Secretary in consultation with Advisory Committee, which brings us right here to where we are now, deems adequate to affect the purposes of the Act.

So that these are the cooperative items. The fact that there's an Advisory Committee who has an opportunity to consult on this issue and to help with the process and here we are today with that. Now that's on the -- the positive side, the incentives.

On the disincentive side of the process, the state program can be designated, in other words turned back to Federal inspection if the requirements of the Federal Meat Inspection Act are not met and that covers the various titles of the Act defined in different ways, but it still is

the -- it covers the titles one, two, three and four, which covers the whole gamut one way or another.

The Secretary of Agriculture at least annually reviews the requirements including enforcement thereof with respect to slaughter preparation and storage, et cetera.

Now as far as state programs coming into existence we've had three state programs come about over the last very few years, Minnesota, North Dakota and Missouri are the states interested in initiating the program. They request in writing from the Governor to the Secretary that they're interested.

Before implementation there's a great deal of interaction between the state people and our staff in developing the process. We look at their laws and regulations in context with the General Counsel as far as whether they are considered to be at least equal to and they develop -- the state develops a state performance plan which is basically the essence of the program in writing.

At this point there are nine criteria which are defined and addressed in this report. At this point we're in the process also of looking at these criteria as part of redefining the whole process not only for meat and poultry inspection but to have these criteria compatible with comparable criteria for retail, for seafood, for various other aspects as the effort continues on to have this

overall food safety system that integrates well among the various parts.

The things we relate to are laws, regulations, the funding, the resource management, the facilities and equipment requirements, labels and standards, implant review and enforcement, various specialty programs such as residue testing and laboratories.

That's as it's designed at the present time and there are going to be modifications coming up rather shortly as this program progresses. When approved an announcement is put in the Federal Register, which removes from the Federal regulations the designation for the particular state that's involved.

FSIS on an annual basis certifies each state program and this is based upon a review of their performance plan and related reports. The state's own assessment of their program and the basis of comprehensive reviews of the state program, on-site reviews, which could occur anywhere from one to four or five years depending upon the findings and could be input from other outside sources.

The comprehensive reviews again cover the same basic items, the inspection -- the field inspection program, HACCP,. SSOP, salmonella, E.coli labeling, compliance, laboratory reviews, research management, budget and finance reviews, civil rights.

Now in addition in our working relationship and partnership with the states, of course, we've been involved through the years in other cooperative agreements and, of course, this process now is expanding by leaps and bounds into many other aspects within the whole food safety community.

But I just wanted to mention, too, that it has been ongoing with the meat and poultry inspection program and that's under the Talmedge-Aiken Act, the states and the Federal can work together when it's a situation in which it would be practical and feasible for state individuals to perform Federal inspection and they are fully trained to do this process then the state people can operate in Federal plants.

At the current time there are nine out of 27 states with inspection programs that have cooperative Talmedge-Aiken agreements with USDA and about 307 plants. The way this program operates is that the states supervise the state employees in the Federal inspection and the Federal program has oversight over that overall process and can direct the process.

Essentially, the state person is functioning as a circuit supervisor. The supervisory state person is functioning as a circuit supervisor within the Federal program.

On a small scale, a very limited basis, with less than 10 staff years of state people working in Federal programs it's done under a cross-utilization agreement where the direct guidance of the state inspections are performed by Federal individuals.

There's also cooperative agreements with the state inspection people in three states to perform the annual reviews or, more often if necessary, the reviews of the custom exempt plants where inspection is not required but there needs to be examinations to determine the sanitation and labeling requirements are in place. In the case of states with state inspection programs the states do this on a routine basis, as well.

Basically, this covers the overview of things as they currently are. Of course, what we're looking for is new innovative and practical systems for improving what's happening at the present time or changing it to meet the new perspectives.

Ralph?

MR. STAFKO: Thanks, Bill.

As many here have observed already the hazards to which meat and poultry products are exposed extend beyond those hazards present in inspected establishments. There's a complex network of transportation, storage, distribution, retail and food service facilities all of which play a part

in the safety of the food that finally reaches the consumers.

It's estimated in terms of retail and restaurants alone there's over a million establishments out there, the number is staggering. Certainly our Agency's resources are very much constrained by our mandatory inspection system and the other obligations we currently have. We can't begin to be a physical presence in these facilities out there.

At the same time we recognize that there are well over 3,000 state and local and tribal jurisdictions out there all of which have some authorities and some resources that could be brought to bear on the issue of food safety. We are working under the proposition that we can through collaboration with these other jurisdictions improve food safety better than if we try to do it on our own.

Apologies to Donne John, but he might have said -- that's John Donne -- "No food safety agency is an island unto itself." The notion that we are to -- that we can do better in collaboration is one that has been adopted by a number of observers including GAO, the National Academy of Sciences, the Office of the President, all of them, are encouraging us to improve and enhance the cooperative approach towards -- towards food safety both at the level of the Federal agencies that have food safety responsibilities and in coordinating the food safety -- the Federal food

safety activities with those at the state and local and tribal levels.

Certainly we can do a better job at getting the most bang for our public buck in working together. "Leveraging assets" is the term we often use.

At the same time, if there's a failure by any one of us in many ways it's a failure for all of us, or as John Donne would say, "Ask not for whom the bell tolls, it tolls for thee."

(Laughter.)

So I mean we're all part of the same -- the same system.

(Laughter.)

I've been waiting for a chance to use that. for years.

(Laughter.)

MS. GLAVIN: And you did.

MR. STAFKO: The FSIS has -- has used often the term Tom Billy has of a "seamless system" as being the concept that we've embraced that reflects this proposition. The notion that we can work towards a national food safety system that builds on each jurisdiction's strengths and uses all available public assets to the best effect in protecting consumers from food-borne illness.

Our office has in that light undertaken a number

of activities and initiatives. I'll start just going through some of the things we're doing and at the end if you have any questions we can get into them in a little more detail. I think most of you are aware that in terms of meat and poultry inspection we had supported new legislation to revise the cooperative agreement provisions in the Acts to permit the interstate shipment of state inspected product.

That is something which did not pass in the last Congress. We're not quite sure what the status is in this Congress, but the concept is still something barring a change in policy that we expect will be continuing to work towards.

Increased -- we are increasing our level of participation with FDA and CDC in the area of retail food safety. In particular we're working in the context of food protection and on developing food safety policies at retail and on updating and promoting the use of the Food Code.

We have been working with FDA in the context of the national food safety system project which has brought together people from Federal, state and local agencies and have been working on a variety of projects to -- to develop a framework for this national food safety system. One which we have kind of embraced in our promoting is one to develop a national system of food safety laboratories.

There are basically three legs to this, one would

be to develop uniform standards for the operations laboratories using the ISO 17025 standards. We have a pilot project involving Federal, state and local labs to work through what it takes to become accredited under those ISO requirements.

We're just about getting -- getting ready to harvest some of the fruit from that project and hope to have models and guidance available for the general laboratory community out there to help them become accredited.

The second part is to develop standards for validated methods. The regulatory community has kind of gotten away from the use of standardized laboratory methods. It's gotten to where the inability for one jurisdiction or one agency to rely on another's data is causing duplication of effort and a food safety outbreak situation. Delays involved can actually have a public health significance. The ideal is to have data that we can rely on and methods are an important part of it.

One -- one Lab Director was famous for having said that he would be much more likely to use someone else's toothbrush than someone else's data.

(Laughter.)

That is indicative of the need to really have data that we can rely on. The third part is to have actually mechanisms for sharing data real time. So that's the

laboratory project and we think that's a foundational piece to any national system.

A couple of other areas we've been working on is a manual for improving coordination among jurisdictions when there's an outbreak of food-borne illness. Another one is developing a set, a model set, of standards or criteria for food safety programs across the spectrum of different product types.

We are working, taking the lead, on a model for meat and poultry inspection programs, one which is derived very much from our current directive and the criteria that Bill just covered but which would be expanded to be more in keeping with the criteria that would be applying across the board to all food products.

We also have a number of collaborative training and outreach projects. This is the first year we've had both the authority and a few bucks to spend on cooperative programs in areas outside of meat and poultry inspection.

We have been supporting the development and have, in fact, a training program for meat and poultry processing at retail. We developed this in collaboration with AFDO and the University of Florida. It's been pilot tested. We have a really good manual and starting this year AFDO is going to be putting it on over the next year and a half in their six affiliate areas with the goal towards getting a trainer from

each of the states trained and equipped to go back and train people on safe meat and poultry processing at retail.

There is a series of cooperative agreements that we also hope to enter into shortly with 10 states around the country to conduct educational programs, to promote safe processing and handling of meat and poultry in distribution channels at retail. We're going to give them a little latitude to innovate and see what those states can come up with in terms of training and outreach within those states.

They're not huge grants but we're hoping that we can provide the seed money that can get some things going that will enhance that part of our goals.

We are also planning cooperative agreements for some universities, 10 universities. Our target here is to look at the more economically disadvantaged sector or sectors of our population and we're going to be working closely with some of the universities, some of the minority 1890 schools and the Hispanic schools as well as land grant schools to work with the associated state and local and tribal officials to provide better outreach on food safety in their sectors.

We have been supporting collaborative projects with FDA and our own Office of Education and Communication on food safety training and educational alliance, FSTEA. I think the most notable accomplishment there has been to

support the National Agricultural Library's Food-Borne Illness Education and Information Center. They have a website where they can make -- they have available a wide range of training materials, information, focused on retail food safety.

Another area we're working on that's still a little bit in the concept area is the area of a national food safety university. The concept there is to pull together a lot of the training that's out there and make it available in a uniform, Federally-supported and nationally recognized system of training for board inspectors. The idea would be to have a uniform approach to the training required for inspectors, be they Federal, state or local that are doing comparable activities.

Finally, we're undertaking a variety of small more issue-focused kinds of workgroups that are looking at issues of concern to our collaborating agencies out there. We have work groups that are looking at meat and poultry program review criteria. I mentioned that already. We'll be working with the National Association of State Meat and Food Inspection Directors, right?

MR. JAN: Right.

MR. STAFKO: Lee is currently the President of that group. It consists primarily of all of the Directors of the state MPI programs.

We're also working primarily with AFDO and in this case FDA on recall procedures. There have been a number of concerns about how we in FDA work with or in some cases don't work as well as we should with state and local officials on recalls. There's another one on the question of our testing enforcing of the E.coli 0157:H7 requirements at retail and yet one more that we're just starting that is going to be looking at our oversight of custom slaughter facilities and the guidance that we provide states on that.

So that's I think enough to get us started. If you have any questions for myself or for BIll at this time I'll be happy to entertain them.

MS. GLAVIN: Okay. Questions? Comments?

Elsa and then Dan.

MS. MORENO: Elsa Moreno. I just had one question.

The National Food Safety University, are you talking about -- I may have missed it if you said it -- a virtual kind of a thing?

MR. STAFKO: Yeah. That's the notion, a virtual university. Yeah, it is, to not invent new courses but rather to put them in a context where they're most available and most beneficial to our regulatory agencies and partners.

MS. GLAVIN: I think Dan was next.

MR. LaFONTAINE: Dan LaFontaine, South Carolina.

This evening I've been appointed Chair to look at this topic, so my question to you is kind of an open one.

You've got an awful lot of initiative started and very broad. I'm not saying that in a negative way, but my question is what do you want us to accomplish tonight?

I've got your questions here which are, you know, also very broad and generic. So I don't want to get off on the deep end and -- I want to bring back something tomorrow that you feel you and your staff will be of value. Do you want us to look at these things and help you prioritized or still additional brainstorming? What's your -- what do you want us to accomplish?

MR. STAFKO: I'll let Bill take a stab at this, too, but from my perspective I think additional brainstorming.

We are, as I mentioned, a brand new staff. We're kind of going in a lot of directions, as you noted. What we want to do is just -- especially given the nature of what we're trying to do -- make sure that we're on the same wavelength as our stakeholders on what it is that's needed out there and where we -- we should be going if we're not going and where we shouldn't if we are.

MR. LEESE: Yeah. To add to that, there's so many times when someone has come up with a point and I said, "Well, why didn't I think of that it was so obvious?"

So I think that we are looking for some things that maybe they're obvious and we've totally overlooked it or maybe they're not obvious and we need to have someone get us going on them, but anything that you can do to add to the situation or perhaps expound upon any one of the individual initiatives if you think there's something there that you'd like to tinker with.

MS. GLAVIN: I'm going to answer that question, too. I'm going to tell you what I want.

(Laughter.)

And that is --

MR. LaFONTAINE: All right. I'm ready.

MS. GLAVIN: Okay. I think a prioritization and it doesn't -- you know, I mean you can do categories. It doesn't have to be one, two, three, but some categories of priorities for the things that they've already identified and then along the lines of the brainstorming are there some things that are missing that ought to be on that list?

So if you don't -- if we came out with -- with those two things that would be -- I think that would be a great place for them to -- to take the next step from. You know, obviously they've done a lot of thinking and a lot of work on this already, but I think that would really help.

MR. LaFONTAINE: We've been working together too long. I wrote down two things, prioritizing and

brainstorming. I wrote them both down because I think you're right on.

Let's take a look at what's already on the table and try to give some guidance, but also is there something missing that --

MS. GLAVIN: Great. Great.

I think Katherine had her hand up.

MS. LOGUE: Yeah. Just -- just to get back to some of the things that Dr. Moreno mentioned. I'm fascinated by this idea of your national food safety university.

So my question was along the lines of where are you going to go looking for these courses or this type of training that you're looking for? Are you going to look at universities as probably vendors that can supply you this kind of training? Have you considered that?

MR. STAFKO: That's -- that's part of what is being considered.

MS. LOGUE: Yeah.

MR. STAFKO: I think the principle focus though is going to be on those training activities and courses that are in the public domain.

MS. LOGUE: But a lot of these would be in some form -- form of public domain --

MR. STAFKO: Yeah.

MS. LOGUE: -- if they're in a university system.

MR. STAFKO: The primary -- or one of the primary goals is to make low-cost, if not free, training available to collaborating food safety agencies out there.

There -- you know, there may be ancillary issues involved here. I'll be honest with you, the folks are actually working on that -- include our training people and Gary Gurmen out there in FDA and a number of other folks, CDC and EPA also --

MS. LOGUE: Mm-hmm.

MR. STAFKO: -- have a piece of this. On our staff it's a fellow named Dan Vitiello.

Dan, do you want to stand up back there?

(Pause.)

Dan has -- has got the ball on this particular project for us. It is still very much in the developmental stage. Certainly before we get too far down the road we're going to be putting something out for public comment and wanting to get people's input on it.

Dan, do you want to add anything to that?

MR. VITIRLLO: I think that --

MR. GIOGLIO: Dan, would you come to the microphone?

MR. VITIELLO: Just for perspective, how this came up was through the NFSS project that we were talking about

before and that was to get a seamless inspection system and there was a need to be able to provide training to state and locals as well as, you know, Federal employees across the board and to make available the training that was available already was the concept.

MS. LOGUE: Okay.

And then the second part to my question is considering the way you're looking at it why not go -- why not think about something on the lines of distance ed where it would be accessible to everybody or this kind of learning anywhere, anytime, initiative? Is this something you could consider?

MR. STAFKO: Yep.

MS. LOGUE: Okay. Thank you.

MS. GLAVIN: Lee and then we'll go to Charles and then to Dale.

MR. JAN: Lee Jan. I think you covered what I was thinking but maybe I'll get just a little more clarification on the school or the university.

Would this have a future to train our inspectors on the computer and not send them to A&M or is this going to be more of an ancillary to support more just basic knowledge in food safety, microbiology and those kind of things and before you answer that -- because I think that's probably where you're going.

But what I would like to know, too, or at least have you consider -- what I would like to do but it may be a money issue than it would be a training issue -- but to get farm to table continuum. As you know the state meat inspection program has the same authority as the FSIS and that's inside the plant and would have no authority or no real role at the -- at the farm level.

What I would like to do in Texas -- and I need to know, you know, maybe this would be the avenue if you can put those training programs for veterinarians who already have the science and the knowledge and the degree all they need is just a focus on food safety and how animal diseases affect food safety and what are the -- what are the appropriate measures they take from a regulatory standpoint.

If that was available through that type of training I could contract with in Texas the Texas Animal Health Commission, who has a lot of veterinarians out in the field a lot more than we do that could do finals and get that link from farm to table. We'll start to having them link up and be able to be in the plants, get -- make some of the decisions, the final decisions, and then bring that back.

Another benefit that I see would be a better surveillance for foreign and animal diseases which at least right now has a little higher interest. It's always been

the interest of the Texas Animal Health Commission and APHIS, but I think now it has a lot more public interest as well. That would give us more veterinarians available across the state and Texas is on the -- on the rather large size and it helps to have more -- more people. I just can't afford them all.

So, you know, as you're developing this that would be something I'd like to see at least on that part, where we wouldn't have to send try to send them all to A&M.

MR. STAFKO: Okay. Two -- two points. Number one, Dan was taking notes.

(Laughter.)

Number two, the kind of context here it kind of transcends just meat and poultry inspection, as Dan mentioned, this kind of stemmed from the NFSS discussions and as we got into talking with the various people from various jurisdictions this was one of those areas where there's really no standards out there. Everybody has their own notion of what training is required for various kinds of activities.

We're, of course, a little more structured in meat and poultry inspection but that is very much the exception. The notion is that if we put together a regime whereby if you're an inspector for seafood -- since Joe is not here to defend himself -- that that inspector would have been

expected to have had certain kinds of training, perhaps a core course of instructions on microbiology, you know, basic sanitation, those kind of things. Then maybe another level of studies in that area of specialization, things unique to seafood.

In our area we would have a hierarchy that might include, you know, the basic inspectors having a core set of -- and I think we already have some of this -- but then a level for veterinarians would have their own set of -- of instructions. Again, these would be available on the Web not necessarily to replace in-class schooling but as an adjunct.

Even in our case even though we provide the training at College Station we don't provide the travel and per diem and it costs. This is another way to get training out at a low cost to as many people as possible who need it.

MR. GIOGLIO: I think next we had Charles.

MR. LINK: Charles Link. I'm with Rocco. I'm not sure my question is for you, maybe for the next presenter.

But as an outgrowth of the HACCP-based inspection models project there was an in-distribution models project that was started over a year ago. Haven't heard much about it. Wonder if that falls under your purview or if that's under the HIMP project or just what the status of all of that is?

MR. STAFKO: The in-distribution project has been kind of -- I wouldn't want to say subsumed, but we're coordinating with the office that is working on in-distribution and outreach.

A lot of the initiative has been kind of refocused in our -- that the recent listeria and the proposal that just came out and the notion of finding some ways to extend HACCP controls beyond the plant through performance standards of some kind.

The in-distribution activity up until now has remained limited to a fairly small group of people who are really just experimenting with a new job series that is really not doing anything different than the Agency has done before, it's just a new set of people doing it rather than Compliance Officers and seeing how that job series works out.

I don't know if Charlie or any -- actually, Mike's here. Maybe --

Are you -- you -- can you add anything to that?

MR. GRASSO: I think it's -- be it all the main points we are doing IDI kind of like separate from the actual HIMP activities in the plants and so they're really looking hard at the activities that the IDI inspectors do and that's different types of scenarios with those inspectors.

MR. STAFKO: Okay.

MR. GIOGLIO: Dale?

MR. MORSE: Dale Morse, New York. I think the concept of a national food safety university is a good one to increase the level of training and standardization and accessibility and availability.

But I think there might be some academic sensitivity over the use of the term "university." I don't have my Webster's dictionary but I guess I was under the impression there are set criteria that makes something a university in terms of types of programs offered and degree programs and undergraduate and graduate.

So I didn't know if other terms had been considered like training center which -- or training institute? Maybe that hasn't been raised by academia but you aren't going to actually give degrees, it's basically a facilitator and clearinghouse and sort of a center rather than a university-type degree institute?

MR. STAFKO: Yeah. I think they would just be a number of sets of accredited courses that would contribute towards different inspectors being deemed qualified, hopefully, in a way that would allow them to be deemed qualified anywhere in the country. That's kind of the ultimate goal.

We're, in effect, building a profession -- a

professional series for inspectors that may contribute to people being able to move more easily to promotions presumably in another jurisdiction, Federal, state or local. The more standardization you have the more you can have that kind of series.

MS. MORENO: I just wanted to see if you were going to have a football team, that's all.

(Laughter.)

MR. STAFKO: I suppose we could call it -- how about something like the graduate school? Has that been used?

(Laughter.)

MR. GIOGLIO: I think Carol had a question.

MS. FOREMAN: I think you have, obviously, an enormous array of activities and that you're working vigorously to try to make this work better.

I hope the subcommittee will take into consideration the context in which all of this is being done. All of these efforts are a little bit like running around with teacups trying to bail out enough water to keep the Titanic from sinking because there is an overarching flaw in the law -- the laws that have -- that make it virtually impossible to have a coordinated Federal, state and local system.

It cannot be seamless because of the 12 or so

different agencies and 35 or so different laws under which we do food safety inspection just at the Federal level, not getting down to the state and local.

GAO has recently made the point that while 20 percent of the cases of food-borne illness come from USDA-regulated foods, or 15 percent, USDA has 85 percent of the resources. While 85 percent of the problems come from FDA, FDA has 15 percent of the resources. The two agencies use completely different approaches .

With one FDA assuming that the food produced in a plant is safe until it makes somebody sick and USDA not allowing any food to leave a plant until the Agency is persuaded that it is safe. This -- then you get down to the Food Code, which has not been adopted in many of the states.

So I just ask the subcommittee when you start to work on this to make some reference to the fact that these efforts are and will continue to be less effective than they might be until we have -- until we sit down and begin to deal with some of the basic problems of a severe misallocation of resources and authorities.

MR. STAFKO: I would -- I would just note that I think Martin was going up on the Hill to fix a number of things. Maybe you could go along with them.

(Laughter.)

I think the bottom line is at our level we've got

the resources and authority we've got and our goal is to do the absolute best we can with what we've got.

MS. FOREMAN: I absolutely understand that. I'm sympathetic. I'm asking the subcommittee to please note the context in which your activities take place.

MR. GIOGLIO: Are there any more comments or questions?

(No response.)

Ralph, did you have anything that --

(Shaking head.)

No?

Then I guess we can go to break if I can ask anybody -- everybody to be back by 3:40. We've still slipped a little bit on our agenda, but if we can all be back at 3:40 promptly and then we'll finish up for the afternoon.

(Off the record at 3:12 p.m.)

(On the record at 3:34 p.m.)

MS. GLAVIN: Our next briefing is on the HIMP Project. Mike Grasso is here to give you a brief update on where we are with that project and the most recent information on performance of that project.

So, Mike, if you'd like to go ahead.

MR. GRASSO: Thank you.

Good afternoon to everybody. While you were on

break I passed out a colorful little booklet on the HIMP. This is an update to the material that was mailed to you several weeks ago. What I'd like to accomplish this afternoon is give you a status report of where we are with the project.

If you could turn to Status Report No. 23, which is the third page in, as you can see there we are providing you with a copy of the plants that are in the project, both on the broiler side, the market hogs and the turkey plants.

We continue to collect data by Research Triangle Institute. We are fast approaching 16 plants and redesign on the broiler side. We should be finished with that sometime this summer.

Now we have several new plants coming into the project. We are getting ready to go back into some of the market hog plants. We're going to have a coalition session between RTI veterinarians and FSIS veterinarians. We are issuing our second draft on market hogs, which is similar to the Broiler Document No. 5.

We've been blessed with the GAO doing an audit of the HIMP project. They have visited numerous plants and spoken to industry personnel and they're in the process, as I speak, in issuing a survey to all inspectors, IIC's, SVMO's, that are in HIMP plants to get their opinion on the project.

We have attached our most recent data on the broiler project. So as we turn the pages you can see the list of broiler plants. There's 13 currently in the project. One plant, Keagles Keystone Albany dropped out but we do have data from that 14th plant. On the swine side we have three plants and the five turkey.

The following page is our redesigned achievements of performance standards in the young chicken plants. This here is based upon the U.S. Court of Appeals decision and our redesign of the project in November of last year.

What I added this time is a narrative which is on the next couple of pages which actually explains each column in detail. This data has been collected since September of last year right through April and we have looked at over 600,000 food safety samples by FSIS inspectors performing verification sampling.

The column on the right is the average over that period of time. There are days when you have a spike that goes above that standard and you also have -- on days that it's below that standard.

Also, on the OCP, or other consumer protection, we have almost 200,000 samples collected by the FSIS inspectors performing verification sampling and those numbers look very good, also, on average. So this is the updated info. The one that was sent to you only had information up through

March and this is April.

MS. GLAVIN: Okay. Mike, am I correct that this is not RTI data, this is our inspector's data?

MR. GRASSO: This is FSIS inspectors performing verification tests in the plants, 80 food safety samples per day per shift and a minimum of 50 OCP samples per day per shift depending upon how many lines.

MS. GLAVIN: Okay.

MR. GRASSO: So if the broiler plant like Rocco's has four lines FSIS is looking at 80 OCP samples.

Is that correct, Charles?

MR. LINK: (No audible response.)

MS. GLAVIN: And when might we see additional RTI data?

MR. GRASSO: I'm hoping to conclude the redesign data based upon the Court case by the end of the summer. I think that RTI would then issue a report on the 16 plants redesigned similar to the 16 plants that they issued for baseline. Okay.

MS. GLAVIN: Yeah.

MR. GRASSO: And I hope this narrative has helped to explain it that we've attached this time.

I also attached for your information the three standards that we have developed based upon RTI data collection, the broiler data, the market hog data and the

turkey data. Those are the performance standards that we're using in the market hogs and the broilers.

Once a turkey plant goes into the models project and the change they would be using these performance standards and we have indication that we have two to three turkey plants that will be coming into the project in the later part of this year.

We have had several questions over time and I thought that I would include the very last page of this document so that you have a feel for the type of training that's taken place within FSIS, both for industry and for FSIS inspection personnel.

We have trained so far 335 inspectors in HACCP and slaughter HIMP training. We have trained 150 management people from the SPMO circuit supervisor, the IIC, the people in the district, and we have future training sessions that are scheduled for the next four plants that you see on this document. As they come into the project all of the FSIS personnel have to be trained prior to the start up of the plant in the change phase.

We also have provided to industry to date 13 classes in College Station for slaughter training. Most of the plants that enter the project kind of do train to trainer where they send some personnel from the plant usually on the QC side. They receive the FSIS slaughter

training and then they come on back and they do in-house training with the -- most of the plants in the project have in-house veterinarians that assist in their training.

In addition to that, we have provided industry with two statistical process control courses so they have some conceptual idea using SPC to control their process once the birds are making their way into the plant.

We have future training coming up every other month for industry as the plants come into the project June, August and October.

MS. GLAVIN: Thank you very much, Mike.

Are there questions or any comments that people have with respect to this?

Dan?

MR. LaFONTAINE: I'd like to ask just a couple of big, broad questions.

You know, as some of us have been following the Court case and what -- you know, what's been made public so my understanding is that with the current status that we're really not expecting a decision from the District Court until probably early next year, is that a fair --

MS. GLAVIN: Well, we actually had a decision from the District Court but the Court of Appeals has scheduled oral argument for I believe late January --

MR. LaFONTAINE: Okay.

MS. GLAVIN: -- of 2002.
MR. LaFONTAINE: Okay.
MS. GLAVIN: So we would not expect a decision before that.
MR. LaFONTAINE: Yeah. I used the wrong --
MS. GLAVIN: Okay.
MR. LaFONTAINE: -- Court.
MS. GLAVIN: Sure.
MR. LaFONTAINE: Actually, going back and forth, so --
MR. GRASSO: Actually, a hearing's scheduled for the 11th of January --
MS. GLAVIN: The 11th of January.
MR. GRASSO: -- 2002.
MS. GLAVIN: Okay.
MR. GRASSO: And the Agency and the AFGE will be exchanging documentation to the Court.
MR. LaFONTAINE: In the follow-on --
MR. GRASSO: In September or November.
MR. LaFONTAINE: Yeah. A follow-on question.
I'm hearing that the Agency may go ahead and try to get a proposed rule out in the interim, is that a fair statement?
MS. GLAVIN: Well, we are in the early stages of looking at rulemaking for broilers, which is the area where

we have the most experience and the most data.

Obviously, any proposal would be based on all of the data so, you know, we're working on it as data is coming in. Our plan is to have a proposal before the end of the calendar year.

Carol?

MS. FOREMAN: Carol Tucker Foreman.

Because we have a number of new members on the committee I think it would be useful to just spend a couple of minutes, if you would, going through how the HIMP project was set up initially and what change was made as a result of the Court decision.

MS. GLAVIN: All right. Initially we set up the HIMP program -- and I'll use broilers because it's easiest to speak about, only one kind or species at a time.

We set up a system where we had an oversight inspector who provided oversight to the plant sorting of carcasses. That oversight inspector was not on the line but was behind the line, could move up and down the line to see how the sorters were doing.

In addition to that, we had a verification inspector who was responsible for doing a certain number of verification checks each shift, each line. Again, that varied depending on the species.

The Court of Appeals -- the District Court ruled

that we had the authority to change our inspection in that way. The Court of Appeals did not agree and stated that by having an inspector oversee the sorting by plant employees we were not having a government inspector actually do the inspection.

So we -- the redesign that you see here is that where the data is -- well, interestingly, we had comparable data to this under the original model. By the time we got the Court ruling we had gathered comparable data which was virtually identical to what we're getting here, you know. Sometimes the .001 will be .002 or, you know, maybe in the other direction. So, you know, it's -- it's not identical but it's very, very comparable results.

In any case, the redesign maintains the role of the verification inspector which is to do verification checks on a regular basis throughout the day, throughout the shift, throughout the lines.

In addition, on every line there is an inspector inspecting every carcass prior to it's entering -- in this case of broilers -- prior to its entering the chiller. So that's -- that's the change. Instead of having this oversight inspector we've taken that person and placed that person permanently at the end of the line prior to the carcasses going in the chiller to do a -- make a --

What was the wording?

MR. GRASSO: A determination that the product was --

MS. GLAVIN: A determination that the product is not --

MR. GRASSO: -- not adulterated.

MS. GLAVIN: To make a determination that the -- each carcass is not adulterated.

MS. FOREMAN: Thank you. I've got a couple of questions. What does the inspector at the end of this -- this -- the new inspector at the end of the line do?

MS. GLAVIN: That inspector visually inspects every single carcass.

MS. FOREMAN: Does the inspector touch the bird?

MS. GLAVIN: No.

MS. FOREMAN: Mm-hmm.

MS. GLAVIN: The inspector can, if necessary, have a bird removed from the line, can have the line stopped or slowed so that he can do more inspection. But in the -- if things are running as they should he would -- he or she would not touch the bird, would simply do a visual inspection of the bird.

MS. FOREMAN: Let me --

MS. GLAVIN: I'm going to let Mike answer the rest of these questions --

MS. FOREMAN: Oh.

MS. GLAVIN: -- because I'm putting in to details I probably don't know well enough.

MS. FOREMAN: Mike, does -- does the inspector ever look at the inside of the bird? You know, if you go into a plant and the inspector is working under the traditional system, looks at the front, turns around and looks at the back, tilts it and looks inside, palpates the viscera.

What does -- does the inspector now on the end of the line -- clearly doesn't do all of those things?

MR. GRASSO: The verification activities that we perform within the plant are the means that we look completely at the carcass both internally and externally.

The plant has an opportunity with the CI to sort, to wash, to trim, prior to the CI's activity and --

MS. GLAVIN: You need to say what the CI is.

MR. GRASSO: Carcass inspector. Before the CI is the verification inspector, who's collecting the 80 samples per shift per line at a minimum on food safety and they perform the verification of the process that's taking place.

MS. FOREMAN: But how -- but how does the carcass inspector know that there's no fecal contamination inside the bird?

MR. GRASSO: They wouldn't know.

MS. FOREMAN: They would not know?

MR. GRASSO: They would not know.

MS. GLAVIN: The -- the design of the program is that by the plant doing the sorting and making the adjustments that need to be made, the trim, et cetera, or washes that need to be made to those birds and by the intensive verification work going on that by the time it reaches that final inspector --

Well, first of all, what our inspectors tell us is they can see anything coming down the line because the birds are so clean by the time they get to them that it stands out like the proverbial sore thumb.

But that the -- that if the system is out of whack in a way that causes contamination inside or outside of the carcass or if there's a flock of birds that have a problem the verification inspector is the person who will catch that.

MR. GRASSO: Maybe you would remember the trip that we took to Wampler Foods where the traditional inspectors were positioned upstream looking at birds prior to the pack man operation where the separation of the viscera and the carcass takes place where there's potential contamination. Also, after -- there is trimming that is being done by the plant establishment.

So looking, in my opinion, at the carcasses upstream is not taking a look at the carcass after all of

the processes have taken place in the plant.

MS. FOREMAN: Yeah. When somebody asked me what the difference was between traditional and HIMP after we were in the Rocco plant, I think I said 12 feet, the difference between where the inspector stood in the traditional plant and where he was standing in that plant.

The -- but I am concerned. As a -- as a matter of course, what percentage of fecal contamination that you find would you find inside the bird? In a traditional plant if you're going to find fecal contamination how much of it's likely to be inside the bird?

MR. GRASSO: I don't think that's --

MS. GLAVIN: I don't think it's -- obviously, we don't have that data, but if -- if it exists we can get it for you. I'm not sure it exists. Actually, one place -- it might exist in the RTI baseline data. They might have made that kind of a distinction.

MS. FOREMAN: I -- I think it might.

MS. GLAVIN: That would be --

MS. FOREMAN: It would -- it would be useful and I say to those of you who have poultry experience, does -- does the contamination occur inside the bird fairly regularly or is it usually an outside phenomenon?

MS. GLAVIN: Let's call on Charles to answer that.

(Laughter.)

MR. LINK: Charles Link at Rocco.

More times than not it's -- it's typically found on the outside of the bird around the wing where the viscera is pulled out and hung on the side of the bird. So that's been most times where you find it.

Occasionally, you know, if the intestine happens to get broken you may see some in the -- right in the inside of the back area, right in the very tail of the bird. But the majority of it's on the outside around the wing and down the side, you know.

MR. GRASSO: And, again, the traditional system has the inspectors before that process and then the birds are moving on down the line through the wash and then the company trimmers.

Under the traditional system FSIS would look at 20 birds.

MR. McCUTCHEN: Well, Carol, I'd also like to mention if you go to the data and you look at the FS-2, which is the fecal contamination measurement we certainly with a verification inspector that is doing a complete whole carcass examination as part of these data, you're seeing a 1.7 being the percentage for the traditional system and we're down -- I'm sorry, a 1.5 and we're down to 1.1 percent or considerably below that in terms of overall system performance.

So wherever it is, whatever is coming through is being examined and determined by the verification inspector.

MS. FOREMAN: John, it's not that I doubt the FSIS but Maggie was good enough at the beginning to make clear to everybody that the third column is not RTI data but FSIS data. Until I get data from RTI --

MR. McCUTCHEON: Okay.

MS. FOREMAN: -- you know, it's just got to be consistent across the board. I know you need to show something in progress, but I've got to see what RTI says in order to make a descent comparison.

MS. GLAVIN: Absolutely. We have said from the beginning that it is the RTI data that will play the biggest role in our decisionmaking.

However, as Mike pointed out, we have this huge amount of data, huge compilation of observations, so we wanted to share that.

MS. FOREMAN: I got -- I got -- I got a couple of quick questions here.

MS. GLAVIN: Sure.

MS. FOREMAN: But does the carcass inspector have the ability to stop the line and --

MR. GRASSO: Has the sole authority as the traditional inspector.

MS. FOREMAN: -- and look -- and look inside the

bird and see if --

MR. GRASSO: If -- if they see something on the outer surfaces they have the ability to stop the belt. Plant employees need to come to deal with the defective carcass, remove it, okay.

The carcass inspector could communicate to the IIC and request an unscheduled verification test of -- of 10 additional birds beyond the 80 that we normally look at to see if there's something wrong with the process.

MS. FOREMAN: Okay. And one last question. It is still the Agency's or the Department's intention to go through notice and comment rulemaking on this before you move any further.

MS. GLAVIN: Absolutely. Yeah.

MS. FOREMAN: Thank you.

MS. GLAVIN: Yeah. I have -- so far I have Lee, Charles and Dan.

MS. FOREMAN: Okay.

MS. GLAVIN: Lee?

MR. JAN: Lee Jan.

I have no problems with the process or with the concept of a HACCP-based inspection at slaughter but I am concerned, and this is a concern that has been brought up before, but I'm concerned that there's not a requirement for professional education of the industry sorters.

I'm particularly concerned now and I think it maybe ought to be relooked at by FSIS in light of the foot and mouth disease in England. That was identified by veterinarians in -- at anti-mortem at a slaughter plant.

I know the foot and mouth disease is not a human or a food safety issue but it certainly should be the responsibility of the government to try to keep that out of our livestock and that's an ideal -- probably the first place that it's going to be found, that or some other foreign animal disease.

When that -- when the veterinarians are removed from the plant or the requirement that the plant can just present -- they can do their own sorting of live animals and present what they intend to slaughter for inspection and the rest goes on or is taken care of I'm concerned that a foreign animal disease might get into this country and be here while the -- and it could have been detected sooner.

It will be devastating any way we go, but certainly the sooner it can be identified if it gets here the better off the country is. I really would like to see it relooked at and require -- it doesn't have to be a government veterinarian but I think you need someone that's professional trained at identifying animal diseases.

MS. GLAVIN: Okay. Thank you. Good point.

Charles?

MR. LINK: Charles Link from Rocco. Just a comment to your point on training.

We recognized early on -- the industry I'm speaking of -- that the sorters, the carcass sorters, would need training and we put together a training program and got it and sent it out to the International HACCP Alliance and they accepted the training program.

So we actually have a certification process for plant sorters, that they actually have to go through the training and they have to do on-line side-by-side training and they have to understand what they're looking at and what and what they're calling and part of the requirement is that a veterinarian do that type of training with the employees.

But my question -- and Mike would never leave here satisfied if I didn't ask this question, but we've had a lot of conversation over the years, the past two years I guess, on the inclusion of turkey plants in this project and there are five plants that are listed on the -- in the booklet. I know of one, anyway, that would like to get in but can't because we slaughter yearling breeders.

I know we've had a lot of discussion and I just wondered if you could give me a little status update of where you are in your thought process as far as inclusion of the yearlings?

MR. McCUTCHEON: Well, I think the project was

designed for the young birds and the young animals. That's been our position all along and we've been very public about that and that's been a very fundamental piece of the guarantee that the Agency has made that we are only going to be including the young animals or the young birds.

So at this point we haven't changed our policy on the turkeys, on the breeder thing, saying that they have to be the young turkeys.

MS. GLAVIN: I think tomorrow late in the day we talk about the next meeting and issues that the committee would suggest as possible topics. I think the question of the yearling turkeys is one that we might put on the table as a possible subject for this committee to consider.

As John indicated, the project has from its inception been designed for what I'll call market animals and in most kinds and species that's a very clear break line between market animals and cull animals. The turkey industry has some data to indicate that the line might not be quite so bright in that industry and there might be arguments for including something other than market animals in the project.

So I would ask you to, you know, bring that up again tomorrow when we're talking about things -- I think this committee could provide a lot of insight into that.

MR. LINK: Thanks.

MS. GLAVIN: Dan, thank you.

MR. LaFONTAINE: I want to comment on training and add to Lee Jan's comments.

I recognize that the International HACCP Alliance has developed a protocol so -- a training protocol, so to speak, and there's been an awful lot of cooperation obviously between FSIS and the industry to include helping the industry -- helping train the trainers, as was mentioned earlier.

Also, an important part of this equation is that I think it's fair to say that the firm set of volunteered under HIMP are probably progressive firms that have an interest in doing things right. That doesn't mean that others do not want to do it right, but the point I'm leading up to is all along FSIS has said that if this ever becomes -- goes through rulemaking it's going to be across the board, everyone will have to do it. There's no traditional inspection and HACCP-based.

I've made this recommendation before and I'm going to -- I will keep making it as we go through. In your rulemaking I think it's absolutely essential that you have some baseline training requirements for the industry or that that industry must have -- accomplish certain types of training to assume this responsibility.

I'm not saying that FSIS do it. I'm not saying

FSIS say how it should be done, but for it to be successful nationwide eventually you're going to have to have some type of -- in the regulation some type of mandatory training they must accomplish for everyone to be successful.

Of course, I'm going to use the example of HACCP where you had some baseline requirements that had to be accomplished and I think that's served as an excellent example of what you need to do in this case.

I'll also mention, and I don't have the particulars, but I noticed the Canadians I believe have just finished finalizing their improved poultry inspection program and it mentions that they have some mandatory training requirements in their -- for their industry.

So I'm looking at it -- I'm trying to look at it from the big picture that it won't -- I do not believe it will work if you make it strictly voluntary. What I believe you have to have is some minimum mandatory requirements that the industry must accomplish before they can assume this tremendous responsibility of antemortem and post mortem. Thank you.

MS. GLAVIN: Thank you.

Alice?

MS. JOHNSON: I have a couple of questions.

You talked about that the Agency was targeting the proposed rule sometime hopefully at the end of this year.

Is the intent to go ahead with the publication of a proposed rule when it's ready? I know timeframes are hard to work out. But even if there has not been a -- if you've not heard back from the Appeals Court?

MS. GLAVIN: That is our current thinking.

MS. JOHNSON: Okay.

MS. GLAVIN: A lot can happen between -- you know, as we exchange -- as we file -- meet our filings and the other side meets their filings and as the Agency moves through the process. But our current thinking is that it would go forward as a proposal.

MS. JOHNSON: Thank you.

And, Mike, on the discussion that Dr. Jan had with the foot and mouth, has the Agency done anything as far as decreasing the number of vets in the plants, the number of vets from the USDA government-side is the same as what --

MR. GRASSO: On the HIMP project?

MS. JOHNSON: Yeah.

MR. GRASSO: The answer is no. I would suggest that he talk to some of the veterinarians that are in HIMP plants. They may get a very, very positive response.

MS. JOHNSON: So you haven't altered the number of veterinarians in the red meat? I knew what was going on in poultry.

MS. GLAVIN: Right.

MR. McCUTCHEON: No. I'd like to build on that a little bit and go further.

Mike has said that some of the comments we get back from our veterinarians in the HIMP plants is that instead of having to spend time on the line and doing a lot of the other administrative tasks that they do in traditional plants. They now have a lot of freedom to be able to do much more professional activities and analyze the data and be in a very different role in the plants than they have in traditional plants.

MR. GRASSO: And I'd like to add on that.

We identified the IIC and the SVMO at the plant that the system inspector who is receiving all of the information, whether it be laboratory data, verification data, carcass inspected data, and they're the ones that render the decision on how that system is working in that plant, whether it's meeting our standards or whether it's not meeting our standards.

MS. JOHNSON: Thank you.

MS. GLAVIN: John?

MR. NEAL: One thing to say about your results, Mr. Grasso, and what was Ms. Foreman's concern.

If your results come in the same or real close, your RTI results, then at that point does it not really become the point of the safe handling sticker? We all know

that you should wash poultry real well. I mean that's kind of the long-term deal. Safe handling will probably eliminate any other contaminants that are on there. , won't they?

MS. GLAVIN: Well, this is --

MR. NEAL: Or pretty close?

MS. GLAVIN: -- this project is about trying to improve how the product comes out of the plant.

MR. NEAL: Well, and I -- and I understand that.

MS. GLAVIN: But it is not -- yeah. And it --

MR. NEAL: But you come into that minor limit that you get, almost zero tolerance, whatever's left should be handled by the --

MS. GLAVIN: The -- the -- I don't think that we are anywhere near close to not -- no longer needing consumers to handle their products safely.

MR. NEAL: Okay. That's fine.

(Laughter.)

Thank you.

MS. GLAVIN: I -- I wish we were.

MR. NEAL: Okay.

MR. GRASSO: The project is probably about a year behind schedule because of the lawsuit. Originally when we were looking at the process of looking at X amount of plants to establish the baseline in those 16 plants and then fairly

quickly move into the change phase and have RTI go in. Okay.

There was a limited amount of samples. There would be 32,000 samples and baselines that RTI would have collected to set the performance standards. Then there would be 32,000 samples that they would have checked in the change. But because of the lawsuit we have FSIS inspector results.

So we're capable now as managers to take a look at FSIS results and does that indicate to us that this project has merit? Probably in September we're going to get RTI results and that's also going to tell us whether this project has merit, that we should move forward with rulemaking. Then both sources of data are going to allow us to make good decisions.

MS. GLAVIN: Okay.

Carol?

MS. FOREMAN: If every -- if everybody else is finished.

I think I would like to have any RTI data that -- that do indicate how much of the fecal contamination is inside the bird or just where it occurs. If that's -- if that's there I'd sure like to have it --

MS. GLAVIN: Yeah.

MS. FOREMAN: -- if that's made available -- and

because --

You don't think so, John?

MR. NEAL: RTI is -- is scoring the birds. We're not getting data in terms of it. It -- either there's fecal there or it's not there. We're not getting a location on the bird.

MS. FOREMAN: How about in the baseline?

MR. NEAL: Neither. We didn't gather the data that way.

MS. GLAVIN: Could we query them to see if they could run it that way?

MR. NEAL: They could query --

MS. GLAVIN: Could they look their raw data and come up with something?

MR. NEAL: Yeah. But -- we can.

MS. GLAVIN: Okay.

MR. NEAL: And I just -- I just didn't want to mislead you in that. They may not have gathered the data that they could really answer that question.

We can ask our -- our own veterinarians, our own staff, to give us estimates of whether they're seeing it the way Charles did in what normally occurs in a plant.

MS. FOREMAN: And -- thank you. Whatever you think you've got if it's meaningful --

MR. NEAL: Sure.

MS. FOREMAN: -- it would be useful.

Just second, because there have been -- there's -- there are comments on the record now about the importance of having training in order for plant employees to do this work and I agree that that's very important.

I want it to be on the record as well that I think we will most assuredly insist that plant employees be extended the same kind of whistleblower protection that is now extended to Federal inspectors in this program.

It can't have somebody get fired because they say, "You're not running the program well enough for me to keep my line moving fast." I think that's particularly true if we're going to go nationwide as a mandatory use of this system. I'm sure we'll have a chance to discuss all of that in the rulemaking.

MS. GLAVIN: We -- we certainly will and, of course, the -- in designing a regulatory system we -- we look at -- a regulatory inspection system we look at what our inspectors can do to make sure that, you know -- whether the line is running fast or running slow, that the results are the ones that we're requiring.

Other questions or comments on this?

(No response.)

Okay. Thank you.

MR. GRASSO: I'd like to make one more statement.

MS. GLAVIN: Mike, you're asking -- you're asking for trouble. You know you're going to get yourself in trouble here.

(Laughter.)

MR. GRASSO: I know.

MS. GLAVIN: Go for it.

MR. GRASSO: Okay.

(Laughter.)

But I think what the real beauty of this system is, is say the plant wanted to run as fast and they can and do nothing, okay. It won't last long because we're verifying a whole bunch of samples every day and we're going to find out quickly whether the process is in control or not.

So long as the process is in control FSIS is not going to have impact on your operation. When your process is out of control then FSIS is engaged, okay. We are going to stop the line. We're going to slow the line. We are going to write NR's. We are going to be involved.

MS. GLAVIN: Okay.

MR. GRASSO: And with that, I'll go home.

(Laughter.)

MS. GLAVIN: Thank you for that presentation.

We have one more briefing and that is Pam Ogasawara is going to give us a briefing on FSIS Next Steps.

Thank you. She's behind me. No wonder I couldn't see her. Then -- then we have public comment.

(Pause.)

MS. OGASAWARA: Thank you very much for this opportunity to give you a briefing on what FSIS is anticipating in the next three to five years. One of the things that we'd like to do is give you where -- where we're headed and what would we want to do during that time period.

In January of 2000, of course, you all know that FSIS has finished the third and final implementation phase of the pathogen reduction and HACCP rule.

The successful implementation of the regulation is resulted in significant reductions in the prevalence of salmonella in products produced under this particular process. Furthermore, the data from the Centers for Disease Control and Prevention, CDC, showed reductions in the incidence of food-borne illness that CDC believes can be partially attributed to the new requirements.

The implementation of the pathogen reduction and HACCP system requirements has also improved food safety and consumer protection. However, FSIS -- the data shows that FSIS in industry can also improve this process.

For instance, FSIS sees a great variation in the quality of the HACCP programs. FSIS enforcement records show that some small and very small plants are all having

difficulty adhering to some of the requirements.

FSIS believes the quality of the regulatory verification can be improved. FSIS continues to strive to improve the consistency in the interpretation of the regulation by FSIS employees. The quality of the verification can be improved by Agency training. Also, we have established the Technical Service Center that assists employees and industry.

You're all quite familiar with the HACCP hotline in which you can call in for information. I understand, too, that they're going to be setting up the same thing for HIMP. So if you call the HACCP hotline you can also call that for HIMP questions.

FSIS believes the quality of the regulatory verification can be improved. FSIS continues to strive to reach consistency and interpretation of the regulation by FS employees.

The Office of the Inspector General and the General Accounting Office have made recommendations to improving the HACCP implementation. FSIS is reconsidering the needs to be -- to be accomplished next to refine the inspection program under HACCP the Agency has come up with two objectives.

The first objective is the industry will improve the quality of the HACCP programs itself. On the other

hand, the second objective is FSIS will improve the quality of its regulatory verification of the industry system for meeting the regulatory requirements in protecting the public health.

The FSIS Senior Executive Team with the assistance of various taskforces and advisory committees has developed a process for determining the ways to extend the HACCP concept to more effectively prevent food-borne illness in the United States. The Agency held a public meeting on December 13, 2000 to present the Next Steps.

By studying this they have come up with a particular program, an initiative, of five basic issues that they feel will address this. These issues are the risk-based program design, the infrastructure and resources, the communication issue, training and education and workplace environment.

The risk-based program design because HACCP systems are the centerpiece of the package reduction program FSIS wants to strengthen the HACCP risk-based design and clarify authoritative issues within the context of the HACCP regulation requirements.

This area includes the modernization strategy that's been shown -- that has been put on a slower track because the intense focus on the implementation of the pathogen reduction and HACCP system regulations. This

modernization strategy, which you just heard a large portion of, is the HACCP-based inspection models project called HIMP. The other area is the residue control and HACCP environment. The third area is incorporation of risk into processing and import inspection.

Now let us look at the second issue that FSIS -- FSIS will address, infrastructure resource. The Agency must align its organizational structure to support its public health goals and employees must be equipped with the proper tools to analyze and integrate its scientific policy, inspection, enforcement functions.

The infrastructure and resources are a broad category. It also encompasses the assignment of the work, the expertise and training, data analysis and decisionmaking, communications and workplace environment.

The third issue that we'll be addressing on our Next Steps is communication. FSIS needs to establish and maintain effective strategies to ensure that the rules, procedures and other information are clear, complete, easily understood and accurate and truthful.

The effective communication is needed within the Agency itself, within the regulatory industry and with all stakeholders. The fourth issue -- and also the Agency will be using communication methods to -- and new technologies to use the better -- to communicate better with our

stakeholders.

The fourth issue will be training and education. FSIS must have a workforce with knowledge and skills to support the Agency's food safety programs. The Agency must begin focusing its training and education needs on the scientific rationale. The Agency must also commit using whatever means there are, necessary to make training and education available to all employees.

The fourth issue also includes expanding its training and educational partnerships with industry, with academia, with state and local agricultural agencies, with the public health agencies and with other Federal agencies like FDA and EPA.

The fifth, and final, area that the Next Steps will involve is the workplace environment. For FSIS to accomplish its mission it must value employees and their contributions. They must ensure that the workplace is non-threatening and healthful and promote mutual respect with each other.

The workplace environment addresses such issues as worker safety and quality of worklife and workforce diversity. The Agency has set up for each one of these particular issues a committee that is working right now to develop where we are headed for our Next Steps.

Are there any questions?

MS. FOREMAN: Yes.

MR. GIOGLIO: Carol.

MS. FOREMAN: Hi!

MS. OGASAWARA: Yes.

MS. FOREMAN: Carol Tucker Foreman down here. Two points.

I don't see anything under number one, you're addressing five major areas, about use of additional performance standards. For example, a performance standard for campylobacter or increased carcass testing for E.coli 0157:H7. Somehow I thought that was part of this.

MS. OGASAWARA: I think when they talk about risk-based design it's almost inclusive that that type of microbiological data will be used to design what type of programs we're going to approach.

I think when we talk about risk-based design this is the actual scientific basis on how we make decisions. It's almost imperative that that type of information will be taken into consideration.

MS. FOREMAN: Well, CDC says that campylobacter is the single largest source of food-borne diarrhea and it is virtually all contracted through poultry.

We have advocated in this committee and consistently in every public meeting that's been held that FSIS adopt a campylobacter performance standard. The risk

is clearly there. So I don't know why this increased use of risk -- of performance standards isn't part of this.

MS. OGASAWARA: Well --

MS. FOREMAN: It simply doesn't fall under any of your categories here.

MS. OGASAWARA: Well, I think when you're talking about -- it would fall under the risk-based area in terms of the evaluation of what emphasis we do and what type of rulemaking we'd make. I don't see why that wouldn't fall under that particular category.

MS. FOREMAN: All right. But you have a specific reference to residue control and other specifics but there is no reference to performance standards.

MS. OGASAWARA: Okay. What I think you might want to -- if you look at this and -- these are some of the things that we have not focused enormous attention on and we're looking at going in that particular direction. It does not preclude that we would not include the campylobacter information and data.

MS. FOREMAN: I -- I really feel very strongly and, you know, I'd like to express it to the Agency. We have advocated this at every step along the way, increased use of performance standards. It almost seems that it's rejected, that it is not here.

MS. RIGGINS: No. I don't -- I want to clarify.

What Pam has presented does not necessarily preclude our going forward with additional performance standards, but that's being handled under a different rubric, under a different set of initiatives.

We are working with the Office of Public Health and Science. We have approached the Microbiological Advisory Committee regarding the issue of campylobacter and that work is continuing. It just isn't a part of this overall Next Steps umbrella. I mean it's not -- it's not -- it's not articulated that way.

Yes, we are -- we are -- we are continuing -- continuing to look at the possibility of establishing different and new performance standards but it isn't under this particular umbrella that -- that Pam is --

MS. FOREMAN: I -- I am troubled that it is not and I strongly advocate that it should be because you began this presentation with a reference to the successful implementation showing significant reductions in salmonella and then the statement that CDC shows reductions in the incidence of food-borne illness that believes can be partially attributed to these new requirements.

In fact, CDC has not said that. They hinted at it at one point and they promptly backed off. The most recent mortality and morbidity reports indicate and CDC says it very specifically that food-borne illness occurrence is kind

of on a level plane across the board. There have been no reductions.

So it's really not appropriate to say that but it's particularly inappropriate, it seems to me, to suggest that this is a public health-based operation and then not say anything about performance standards for those things that make people sick. Thanks.

MR. GIOGLIO: Alice?

MS. JOHNSON: Pam, thank you for your presentation.

It's my understanding that part of the Next Steps is really to look at HACCP plans, to -- I think there's a district correlation to try to get uniformity within inspection and that is what Pam was presenting here, too, was, as Judy said, the National Advisory Committee I think is -- is doing a study on performance standards and coming back to make recommendations.

I think that's, you know, probably the appropriate places to -- to determine, you know, the appropriate role for campylobacter, salmonella, E.coli 157:H7 than it would have -- I think our group actually in referring to performance standards suggested that -- that recommendation was made that it go to the National Advisory Committee for microbiological criteria for foods for their recommendation.

Do you know when the committee, the Micro

Committee subgroup, will meet to talk about performance standards? Has there been a timeline set on that?

MS. RIGGINS: I don't know. But tomorrow a person -- I'm trying to think. Who is it?

MR. GIOGLIO: We -- we do have tomorrow Brenda Halbrook --

MS. RIGGINS: Brenda Halbrook.

MR. GIOGLIO: -- who's the Executive Secretary for the Micro Committee, will be making a briefing here, making a presentation, to -- to your committee and she can then elaborate on the timelines and how exactly they are set up to deal with, you know, the various issues and so forth.

MS. JOHNSON: And so we can get an update on --

MR. GIOGLIO: Yeah. Brenda will be here tomorrow afternoon.

MS. JOHNSON: Thank you.

MR. GIOGLIO: Marty?

MS. HOLMES: Marty Holmes, North American Meat Processors.

I just want to reiterate that -- that when performance standards, sampling programs, that type of thing, come to this committee if we can notify the Micro Committee far enough in advance so that they have an opportunity to delve into those issues. Apparently, that's being done.

But I know that sometimes in the past when I was not actually sitting at the table that this committee was not given information in a timely fashion that really -- the Micro Committee was given the information after this committee had worked.

So I commend (1) the Agency on getting that stuff to the Micro Committee ahead of the time that this committee needs to work on some of those things.

I want to make two points, though, one is I want to commend the Agency on the Technical Service Center, the opportunities that our members and our associations had to work with them and with the IIC or circuit supervisor, in getting issues resolved. They have been a tremendous help and Ron Eckel sitting back here, too, being -- being here from the Tech Center. They've done a tremendous job and I want to commend -- commend the Tech Center on that.

One question I did have, though, you talk about communications, it's Item Number 3. I was just curious, is there any further discussion on the Ombudsman's Office that was being developed? Are you aware of anything --

MS. RIGGINS: No. As far as I know, we haven't developed that idea any further.

MR. HOLMES: Okay. The last I had heard --

MS. RIGGINS: It doesn't mean --

MR. HOLMES: -- from Ron Hicks was there was

actually a job description and I guess an opening that may be on hold since we don't have --

MS. RIGGINS: Yeah. I'm not sure.

MR. HOLMES: -- all of the positions.

MS. RIGGINS: I mean I know that -- that they did work on a position description that, you know, described the duties and responsibilities of that person but I'm not aware that it has been announced and I'm not sure what the time table would be for an announcement.

MR. HOLMES: I think from the communications standpoint that would only enhance --

MS. OGASAWARA: Yeah. The communications group is being headed up by Linda Swescina and I would -- they just -- all these groups have just formed and are starting to work together among their own committee members.

I would suggest that that be put to Linda if she knows anything about it because she's heading it up for field operations. This is a field operations --

MR. HOLMES: Right.

MS. OGASAWARA: -- initiative to try to respond to some of the issues that have been brought up by various committees including yourself.

So -- and this is the five issue areas. We're starting off on this particular journey and we wanted you to become familiar with the different issue groups so when we

talk -- talk later you will understand when we say the workplace issue or the communications issue or the infrastructure or the design issue so that you have an idea of where we're coming from.

That was the idea, to give you an introduction to where we are headed at this particular point. These committees have just started again so I would suggest that we refer those questions back to those committees if -- if they would know anything at this point.

MR. HOLMES: Thanks, Pam.

MR. GIOGLIO: Sandra? Did you have a question?

(No audible response.)

Any other questions or comments from the committee for -- for Pam?

(No response.)

Thank you. Okay. I guess we've got back on schedule after all.

(Laughter.)

We should move to public comments. I have two folks who've identified that they would like to make some public comments for the record. Ken Klippen from the United Egg Producers. I believe he was sitting here in the general seating, I guess, if he's ready.

If you would step up to the mike and identify yourself.

MR. KLIPPEN: Thank you.

My name is Ken Klippen. I'm with United Egg Producers. It's a cooperative that represents 80 percent of all of the shell eggs produced. I also represent the United Egg Association, which represents 95 percent of all further processed egg products. I'd like to thank the committee for this opportunity just to offer a few comments.

It's been a most interesting morning and afternoon listening to these issues. We're very proud of the fact that in the egg industry the incidence of salmonella enteritidis has gone down over the last four years. We'd like to think that a lot of that's due to the quality assurance programs that are being implemented within the states and, of course, our national program which is the United Egg Producers Five Star Quality Assurance Program.

There are three points that I wanted to make that deal with some of the conversations this morning and it deals with exemptions, temperature and new technologies.

On the exemption issue during Ms. Riggins' presentation she talked about the exemption from regulation flock owners with 3,000 or less laying hens. Our concerns are that you're exposing yourself to a million opportunities for a food-borne illness.

If you look at the 1997 census it shows that there are over 7,800 farms that have between 50 chickens and 3,000

chickens.

So if you exempt all those farms those eggs that are being produced which aren't necessarily just for consumption within that immediate family that you're going to have over 1.3 million eggs on the market that could pose problems because it's most likely that those smaller operations are not implementing quality assurance programs. We'd like to see quality assurance programs implemented to all egg farms.

The second point I wanted to mention was on the temperature. FDA's current thinking documents, and we listened to Mr. Levitt this morning talk about some of the -- the current thinking of the Food and Drug Administration, one is that the proposing refrigeration within 36 hours after the egg has been laid.

The problem with that kind of a proposal is that when you take eggs that have been under refrigeration at 45 degrees and then you take it through the washing, which is a process that's mandated by law, at temperatures of 90 degrees you have a temperature gradient that's going to increase thermal checks which is going to expose the internal contents to a greater likelihood of contamination if there's any salmonella present. So we see that as a weakness, as well.

The third item was new technologies and it was

delightful -- delightful to listen to some of the discussions on new technologies. We think that there's a new technology, if you will, it's vaccination. We're seeing some very positive results in Europe, specifically the UK and Germany, as it relates to vaccinations for salmonella enteritidis in chickens.

So we think that upon sufficient evidence the Federal Government may wish to treat vaccination in a manner that it treats a kill step like Strategy Two in the Egg Safety Action Plan.

The last item I wanted to mention was something that did not come up today but I'm sure that many of you have heard about this and that is a process that we call molting our chickens.

It's a process where we restrict the feed from the chickens, actually remove the feed for a period of time and that throws the entire flock into a molt. It's a natural process but there was some connections that were being made between research that had come up from the Agriculture Research Service and the incidence of salmonella enteritidis and eggs.

I have some excerpts from Dr. Holt. Peter Holt is the one that actually did the research and he said you cannot draw parallels between his research and commercial production for three reasons. He said that the strain of

chicken that he was using for his research was not a commercial strain of chicken, number one.

Number two, are the way that chickens are exposed to salmonella enteritidis may influence their susceptibility and then, number three, chickens will be exposed to other bacteria in the commercial setting that may alter their susceptibility. So the final thought was that a laboratory setting cannot adequately mimic commercial settings.

The industry is looking at finding alternative ways of molting, not withdrawing the feed. There are three universities right now that are conducting that research, Nebraska, Illinois and North Carolina State. When those results are available and do demonstrate an effective way of molting the birds without withdrawing the feed the industry will follow those procedures.

I thank you for this opportunity.

MR. GIOGLIO: Thank you.

Okay. Collette?

MS. KASTER: Can I just ask you a question because I'm on the subcommittee that's going to be discussing this?

You know, the whole molting question has come up under the welfare issues, right? I mean that's really why the universities were doing that. So I missed the first part about where you were relating molting to enteritidis levels and why. I didn't make the connection why he was

responding that way. Could you --

MR. KLIPPEN: Right.

MS. KASTER: -- reiterate that, please?

MR. KLIPPEN: Dr. Peter Holt had shown in the laboratory that there was an increased incidence of salmonella shed in molted birds. So then the animal welfare groups, and I was watching to see if they were present, have linked this as a food safety issue but he has -- Dr. Holt himself has indicated that we cannot draw that kind of parallel. He said there's been no epidemiologic studies to demonstrate that.

MR. GIOGLIO: Okay. Thank you, Ken.

Next we have Tom Corbo from Public Citizen.

MR. CORBO: It's actually Tony Corbo.

MR. GIOGLIO: Oh. Sorry.

MR. CORBO: Actually, I have a question.

About three weeks ago the Center for Food Safety and Public Citizen sent a series of comments to both Mr. Billy and various officials at the FDA expressing concern over a body of research that is -- that is emerging that shows that a chemical that is formed when foods are irradiated, in certain meats, fruit and eggs, and it's called 2DCB, can cause chromosomal damage in laboratory animals when they are injected with this chemical and when this chemical is exposed to human cell cultures the same

thing happens.

Do you know when we can anticipate a response to -- to that -- to those letters?

MS. RIGGINS: No. I'm sorry. I honestly do not know. We can try to find out where that document is in the Agency, but at this point I don't -- I don't know.

MR. CORBO: I appreciate that.

MS. RIGGINS: We'll have to find that out for you.

MR. CORBO: Okay. Thank you.

MS. RIGGINS: Okay.

MR. GIOGLIO: Okay.

MS. RIGGINS: I do have one more thing.

MR. GIOGLIO: Sure. Go ahead, Judy.

MS. RIGGINS: This morning Dr. Jan asked about the residue -- whether or not we were testing egg products for pesticides. So we gathered as much information as we could to this point and we'll continue to try to gather more.

But when we assumed the program from -- the egg products program from AMS in 1995 FSIS started testing egg products for chlorinated hydrocarbons and organophosphates. In 1996 there were 238 egg products analyzed and in '97 402 egg product samples were analyzed for -- again for chlorinated hydrocarbons and organophosphates. No detectable residues were found in either '96 or '97.

Then in 1998, 359 egg products were analyzed,

again for chlorinated hydrocarbons and organophosphates and no violations were found.

In '99, 384 egg product samples were analyzed for chlorinated hydrocarbons, organophosphates, phenylbutazone and no violations were found. In 1999, 60 egg product samples were tested for arsenic and sulfonamides and no violations were found.

The residue plan for FY 2000 scheduled 460 egg products to be collected and analyzed for arsenic, chlorinated hydrocarbons, organophosphates, phenylbutazone and sulfonamides and the results of those tests are not currently available. They will be available later on this year.

So I just wanted you to have that information. Okay.

MR. GIOGLIO: Okay.

Before we adjourn, Mr. Hogan, did you want to add anything at this point?

MR. HOGAN: I would. I apologize for being absent, but I had to go back for a seminar that they were putting on back at the Department and I had to respond to some correspondence.

But I wish everyone well tonight from 7:00 until 9:00 and we'll await the answers you come back with tomorrow morning. Thank you.

MR. GIOGLIO: Okay. Thank you very much.

I'll just finish up with some housekeeping. The subcommittees will be meeting this evening, as was stated, from 7:00 to 9:00. The breakout rooms that we will be using -- when you go out these doors as -- you go out as if you were walking out toward the lobby, take a left and go past the guard desk that's there and those breakout rooms -- I guess we're in the Jupiter, Saturn and Venus rooms. You'll see it on your agenda.

I guess we're going to have an out of this world evening session.

(Laughter.)

With that, thank you very much. We'll see you. Our staff will be there to assist during the breakout sessions. Thank you.

(Whereupon, at 4:44 p.m., the meeting was concluded.)

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Docket No.

Washington, D.C.
Place of Hearing

June 5, 2001
Date of Hearing

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