UNITED STATES DEPARTMENT OF AGRICULTURE

MEETING ON HACCP-BASED INSPECTION MODELS PROJECT

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9:03 a.m.

Holiday Inn Rosslyn - Westpark Hotel
The Rosslyn Ballroom
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C O N T E N T S

P R O C E E D I N G S

9:03 a.m.

MS. WILCOX: Good morning everyone. I'm Caren Wilcox, the Deputy Under Secretary for Food Safety, and I'm pleased to welcome you to the fourth public meeting on the HACCP-based Inspection Models Project.

This meeting honors our commitment to meet with you, our constituents, at key stages during the process of this project to keep you up to date and to present any new data generated through the project.

As you know, USDA has carried out a science-based food safety strategy over the past five years and we've made very, very good progress on many fronts. HACCP has been successfully implemented and we are seeing substantial reductions in the prevalence of salmonella in raw meat and poultry products produced under HACCP. We're delighted that those efforts have been independently evaluated by CDC.

Progress has also been made through the President's Food Safety Initiative which set in motion a number of activities that have contributed greatly to reducing food-

borne illness. Improved surveillance and outbreak response, new food safety research and developments in the science of risk assessment are among these improvements.

The President's Food Safety Council is building on the achievements of the Food Safety Initiative through comprehensive strategic planning and budget coordination activities. This Administration is committed to continuing this progress until we can honestly say that the food supply is as safe as it possibly can be. That's why we're here today.

As with all of our food safety initiatives, this project has been developed through a very public process with ample opportunity for input. In addition to holding public meetings and publishing Federal Register notices with the opportunity for comment, we've consulted with the National Advisory Committee on Meat and Poultry Inspection and the National Advisory Committee on Microbiological Criteria for Foods. We welcome input on the models project because it will help us design a system that is the best it can possibly be.

We will not move forward with implementing the new system unless we are confident it is effective in protecting the public health. And I want to thank you in advance for all your interest and involvement, and I look forward to the day ahead.

MR. BILLY: My name is Tom Billy, and I'm the Administrator of the Food Safety and Inspection Service. I too want to welcome all of you to this public meeting on the HACCP-based Inspection Models Project.

Now we know that's a lot of words, so we very often refer to this project as HIMP, H-I-M-P, and you're going to hear that a lot today. But when we say HIMP, we mean HACCP-based Inspection Models Project.

As Ms. Wilcox said, we have made much progress in implementing our overall science-based strategy for change. HACCP is the cornerstone of that strategy because it provides a foundation, a structure for making continuous food safety improvements as science and technology advance.

The HACCP-based Inspection Models Project, the HIMP project, is the next step in HACCP implementation. By

extending HACCP to the slaughter line, we can build on the achievements that we've made so far.

Now I recently toured one of the young chicken plants that's in the project, the Rocco Plant in Virginia. I was very impressed with the commitment of both our inspectors and the plant personnel to making this system work to improve food safety. In talking to our inspectors we found that they were very enthusiastic about the new work they are doing. That is the different roles that they're playing. And that in particular they could focus more of their time on food safety checks.

I was also impressed with the plant's process controls. The birds that we saw in the plant looked very good and easily passed the FSIS verification checks as I watched our inspectors carrying out their verification activities.

Our initial experience with the new models is very promising, but we in FSIS are proceeding with this project very carefully, in a step-wise manner, because it represents such a significant change.

We will not make any permanent changes until we are sure that the new system meets or exceeds the achievements of the traditional system on a sustained basis. Data from plants operating under the new models will be compared to the baseline data collected under the traditional system. These before and after comparisons will help us determine how best to proceed.

Before we begin with the details of the information we want to share with you today, let me update you on where we are with this project.

Twenty-four plants are now participating; 16 plants that slaughter young chickens, five plants that slaughter market hogs, and three plants that slaughter young turkeys. At the moment, an additional 15 young chicken plants and one market hog plant would like to participate in the project. Those numbers, 15 and one, or 16 total, are in addition to the 24 plants now participating.

No beef plants are participating at this time, although there is interest on the part of the beef industry and there have been recent discussions with several

companies.

Just as a point of clarification, the project was originated for young chickens, swine and cattle and young turkeys were added at the request of the turkey industry.

Baseline organoleptic and microbiological data have been collected for the 16 young chicken plants, and if you will recall or participated in our last public meeting, at that time we had data for four or five plants, and now today, we will be presenting to you completed data for all 16 young chicken plants. These data will be presented later this morning.

Eleven young chicken plants and two of the market hog plants are now in the transition to the models testing phase. That means that they've not only completed the baseline, but now are at some stage in terms of the models phase. Often there's a time period before they actually get started in terms of our data collection. But we think that's good progress and we're going to be moving forward very quickly now in the last several months to collect additional data in all 16 of the chicken plants.

These plants are responsible for meeting our FSIS established performance standards, both for food safety and for other consumer protections. Under FSIS oversight inspection and verification inspection.

In addition, these slaughter facilities must continue to meet all other applicable FSIS regulatory requirements.

After allowing some time for things to settle down once the plant starts assuming these additional responsibilities, that is some of the sorting activities and that kind of thing, then the data collection under the new models begins in order to compare the new system to the traditional system.

This data collection has begun in four plants, that is four young chicken plants. We do not yet have the data collected under the models in a form that we can make available to share with you, but it is our plan to hold another public meeting this summer to share that data and data from additional plants that will also have completed the models phase part of this project.

As we proceed with the presentations this afternoon, you will hear more about our progress so far under the models phase of the project, and in particular the performance standards that we've developed to this stage.

It's now my pleasure to turn the meeting over to Maggie Glavin who will be reviewing the agenda and the logistics for the meeting.

MS. GLAVIN: Thank you, Tom.

As Tom said, I want to quickly review the agenda. We have a very ambitious agenda today. We hope to keep moving at quite a pace.

But before I do that I'd just like to mention several groups who are here with us in the audience. I'm not going to go into individual names in the interest of time, but first of all, we have the agency steering committee on the HACCP-based Inspection Models Project, and many of those individuals are here at the table. We also have representatives of Research Triangle Institute and their subcontractors. Research Triangle Institute is the contractor who is collecting data for us in the models.

project. And we have representatives from plant management in the volunteer plants here with us today.

Today's meeting will focus on young chickens, because this is where we've made the most progress so far. I understand that you all have a copy of this sheet that shows the status of plants in the project, so you can see that we are farther along in the project with respect to young chickens and hence are focused on that today.

During the morning there will be a presentation by Dr. Karen Henderson and others who will describe the traditional young chicken inspection system. This overview we think will help to facilitate the comparison to the new HACCP-based system this afternoon.

After Dr. Henderson's presentation we'll have the opportunity for questions from the audience. Then if we're still on time we'll take a short break. If we're not on time, no break.

After the break Don Anderson of Research Triangle Institute will present the final complete baseline dataset for young chickens. As I mentioned, we have contracted with

RTI for data collection and analysis under the project.

Many of you will remember that at the last meeting Dr. Anderson presented preliminary baseline data.

Again, after his presentation we'll have the opportunity for questions from the audience.

We'll break for lunch at about 11:30. We'll try to keep that to an hour, again in the interest of getting everything in. Then return for afternoon presentations on the HACCP-based Young Chicken Inspection System.

Specifically we'll hear the following presentations, and we have this row of illustrious presenters here. Dr. William James will discuss how the food safety and other consumer protection categories were developed. Dr. Dan Engeljohn will describe our current thinking on performance standards for each of those categories. Dr. Harry Walker will outline the procedures followed in reviewing plant HACCP and process control plans in preparation for implementing the models. Dr. Hany Sidrak will describe how oversight inspection and verification inspection is conducted in plants operating under the new system. And Dr. Ken Peterson will

discuss in-plant control actions.

So that's going to be a very full set of presentations in the afternoon. Again, after those presentations we will again open up the meeting for questions.

We are scheduled to adjourn at 3:00. Again, I think we're being quite ambitious here to get all this done.

We have a number of handouts that are available and they will be very helpful for you in following the presentations. Although we have slides, we do also have hard copy handouts and if you haven't gotten those I would suggest before the presentations start that you take a trip to the table and make sure you have those handouts.

With that, unless there are any questions about the agenda, we will proceed with the first presentation.

For the morning session, Danielle Schor will serve as the moderator; and then this afternoon John McCutcheon will moderate the session.

Dannie?

MS. SCHOR: Good morning. I'm Danielle Schor and I will serve as moderator for the first session of the public meeting.

I'd first like to introduce the panel who is sitting over here so they don't block the view of the screen. First, Dr. Karen Henderson who is with the Office of Field Operations; Dr. William James with the Office of Public Health and Science; and Dr. Hany Sidrak with the Office of Policy Program Development and Evaluation.

We will begin with a presentation by Dr. Karen Henderson who will provide an overview of the traditional young chicken inspection system. This will set the stage for the presentation on the accomplishments of the current system later this morning, and a discussion of the new HIMP system this afternoon.

During Dr. Henderson's presentation I will be asking a few questions just to clarify some key points she'll be making.

Following her presentation the panel here will be available to answer any questions from the audience on the

current system.

So I'll turn it over first to Dr. Henderson for her presentation.

DR. HENDERSON: Thank you, Danielle. Good morning.

The United States Department of Agriculture inspection of poultry began on a voluntary basis in 1928 and became mandatory in 1959. Broilers, or young chickens, account for nearly all of the poultry slaughtered in this country. Most poultry firms closely control production of young chickens throughout their life cycle from hatching to slaughter.

The industry has been successful in limiting the occurrence of disease, chemical residues and other production-based contaminants. Under the current system less attention has been paid to preventing slaughter and sanitary dressing problems.

In order to understand the significance of the young chicken HACCP-based models project known as HIMP, it is necessary to know how the current slaughter inspection system works. FSIS conducts a number of inspection activities that

are related both to food safety and to other consumer protections.

Antemortem inspection is the examination of life young chickens by the FSIS inspection personnel to detect signs of disease on a lot-by-lot basis. Inspection determines whether the birds are passed, condemned, or identified as suspect.

Postmortem inspection is the continuous examination of young chicken carcasses and viscera on a bird-by-bird basis to detect and eliminate disease and abnormal carcasses and parts. Plants are required to provide an inspection station.

Carcasses must be presented by the plant so inspectors can thoroughly examine the entire carcass, including the internal and external body surfaces and all the organs.

A trained company employee called a trimmer or inspector's helper must be assigned to each inspector. This employee trims carcasses, removes condemned birds, marks the condemnation sheet, and generally assists the inspector in

routine inspection procedures. These company employees also mark carcasses that will be trimmed later in the process.

MS. SCHOR: Just to clarify, can the inspectors see what is going on at other points along the line?

DR. HENDERSON: No. The inspector is actually at a fixed location on the line and cannot view the entire inspection process.

MS. SCHOR: Also, how does the inspector know that the carcasses were appropriately trimmed?

DR. HENDERSON: Actually the trimming is done further down line and the process is actually out of view of our inspector and that is actually verified through our Finished Product Standards system.

One important food safety hazard that is reasonably likely to occur in the slaughter production process is contamination of carcasses with fecal contamination. After each carcass goes by the inspector and trimmer, FSIS checks a sample of these carcasses for fecal contamination. The check is performed before the carcasses enter the chiller. All plants must prevent poultry carcasses with fecal

contamination from entering the chiller.

FSIS performs checks for fecal material on a ten-bird sample twice per line per shift. If visible fecal material is found, FSIS documents the deficiency and notifies the plant. After notifying the plant, FSIS verifies that the plant has taken corrective action as prescribed in 417.3 of the regulation.

MS. SCHOR: Could you repeat again, how many times does FSIS carry out the zero tolerance checks?

DR. HENDERSON: They are twice per line per shift.

MS. SCHOR: Are these checks always conducted?

DR. HENDERSON: They are conducted unless, of course, we have a staffing emergency that will not allow our employees time to conduct the tests.

MS. SCHOR: What are the normal corrective and preventive measures that plants carry out when a defect is found?

DR. HENDERSON: Each plant is required to follow 417.3 of the regulation. To put that in simple terms, they have to identify and eliminate the cause of that fecal

finding. They bring their process back under control, and take action to prevent this from occurring again. They make certain that no product with fecal material gets to the consumer.

The Finished Product Standards system is the mechanism FSIS uses to check on other non-fecal defects which may be showing up on carcasses after they go by the inspector and the trimmer.

Finished Product Standards are criteria applied to carcasses before and after the chiller. They enable FSIS to determine if the process is in control. Criteria for making this determination consist of a set of standards for nonconformances which cannot be exceeded on a ten bird sample. These nonconformances may include such defects as ingesta, feathers, bruises, grease, blisters, sores, scabs, and other lesions.

The establishment is responsible for maintaining a system which is in control as reflected in the finished product standards checks. These procedures are conducted hourly for each line by the plant, while FSIS conducts its

tests twice per line per shift.

Because they do not address food safety issues, Finished Product Standards are not covered by the HACCP plan. Establishments follow 9 CFR 381.76 to determine when they must take action due to loss of control.

Under Finished Product Standards defects are categorized. The sum of the defects is calculated against the standard. Examples of FSIS test results would be on a ten-bird subgroup five birds are each identified with a defect of sores, scabs or inflammatory process that measure less than or equal to half of an inch in the greatest dimension. The five defects are multiplied by two, which gives them a subgroup total of ten. Two bruises greater than one inch are also found. These defects are also multiplied by two, equally four, which then is added to the ten. The subgroup total would equal 14. This total would not exceed the absolutely limit or the FSIS standard, and the process would be considered in control for trim non-conformance.

MS. SCHOR: Dr. Henderson, why do you multiply by two?

DR. HENDERSON: Each of these defects or non-conformances is weighted and each has a different weight. In this case the sores and the inflammatory process carries a weight of two and also the bruises will carry a weight of two. Other defects in the testing would carry only a five. They all have different weight --

MS. SCHOR: So it looks like chickens that reach consumers then may have a certain number of defects.

DR. HENDERSON: Absolutely. There's no system that we are aware of that is capable of removing every defect from the process.

In summary, the important components of our present inspection system include antemortem inspection which is conducted by FSIS personnel; postmortem inspection, also conducted by FSIS personnel; and Finished Product Standards to verify that the system is under control.

Remember that with the present system the FSIS inspector is in a fixed position on the evisceration line and cannot view the entire evisceration process. Two, the verification checks for fecal contamination are covered in

the HACCP plan and are conducted twice per line per shift. Three, verification checks for other non-fecal defects are accomplished through Finished Product Standards and are also conducted twice per line per shift. Four, the present system is not perfect and there are defects that reach the consumer.

Thank you.

MS. SCHOR: We'll now open the meeting up to questions from the audience.

Are there any questions?

DR. LaFONTAINE: I guess somebody has to be first.

Dan LaFontaine from South Carolina, and I'm here today representing the American Veterinary Medical Association.

My question is this. It's on training of FSIS personnel under the traditional system. The question is, what are the minimum training requirements that an FSIS inspector and veterinarian need to meet to be qualified to work independently in this current system?

DR. HENDERSON: To clarify, are you speaking of credentials held by these individuals or the FSIS actual

training material or training --

DR. LaFONTAINE: Looking at the FSIS unique requirements, realizing there are certain baseline requirements to be able to be hired as an inspector of as a veterinarian medical officer.

So looking beyond the entry level.

And what is the FSIS unique training program, training requirements, that would qualify this person to be considered a fully functioning inspector?

DR. HENDERSON: I'm going to actually refer this question to a gentleman sitting in the back, Mr. Marlin Waller.

MR. WALLER: Thanks, Karen.

(Laughter)

MR. WALLER: If you're talking about formal training requirements, I know that within the agency that we actually send our inspectors, our new inspectors, down to our College Station training center for basic training.

In addition to that, inspectors are provided on the job training. They're always in a plant where we have other

experienced inspectors and they are provided on the job training that way.

Someone else can probably add to that. Mark?

MR. MINA: I'll jump in here and try to help.

We have an extensive training program for our food inspectors and veterinarians, and as Marvin mentioned, we have a formalized training program that consists of several weeks at the training center and also several weeks on the job training. That both applies to the inspectors and the veterinarians.

So there is an academic portion of it and we go through the regulation in great detail. Also what's expected from them when they work on the line.

So it's an extensive program.

VOICE: Just to dig a little bit deeper, give me an idea of the subject matter that's covered in the academic portion. I don't mean all the details, but what's the essence of the training? Likewise, what's the skills that they need to acquire on the job before they can make independent judgments? What is the technical part of this in

other words?

MR. MINA: Basically as we call it training is how you perform your job. Going through the mechanics of the inspection, what do you expect to see, what's acceptable and what's not acceptable, what kind of action you should take when X happens in the plant. It goes a little bit beyond just the postmortem inspection. It goes to the sanitation requirement for the plant and dealing with plant management and labeling and all sorts of other things.

MS. DeWAAL: Caroline Smith DeWaal, Center for Science in the Public Interest.

How did you come up with the sample size both for enforcing zero tolerance and also you have this ten-bird subgroup. Is that the same sample set that you enforce zero tolerance on? And I may have a followup.

DR. JAMES: Bill James. FSIS.

The ten-bird sample size for zero tolerance is a very convenient sample size because it tracks the same practical sampling that we use for finished products standards in poultry since 1983.

MS. DeWAAL: So you use the exact same birds that you're using for the non-conformance for the zero tolerance?

DR. JAMES: No.

MS. DeWAAL: So the entire basis of the sample size was convenience. Was there any other basis, was there any statistical background for why you chose that particular sampling size?

DR. JAMES: Is there someone here who was more involved with the zero tolerance development system?

Apparently not. We can probably get you a better answer to that.

Ms. DeWAAL: Secondly, are the birds chosen together? One set of ten birds together? Or are they chosen randomly throughout the course of the shift?

DR. JAMES: When a ten-bird sample is collected, the birds are collected randomly, ten birds at a time. They're not necessarily ten birds in succession, but they are identified randomly and selected from the line at the time that the inspector goes up there.

Regarding statistical basis for the selection, it's

important to remember that we look at these collections of birds over time, and a plant builds a history of compliance or non-compliance. So a ten-bird sample when you look at the results of that sample and compare it to the results of many subsequent samples overs succeeding days, we get a sense of the accomplishment of that plant for that particular process.

MS. JOHNSON: Alice Johnson. National Turkey Federation.

Dr. LaFontaine, you were talking about industry training, and I had the opportunity to work along with Steve Pretnick with some of the broilers and turkey folks involved. And the agency did offer the initial poultry inspector training to a lot of the pilot plants. It was a little over two weeks, if I remember right. A lot of the FSIS training focuses on documentation, non-compliance, and that type thing.

Since it's not really practical for industry to send everyone that they feel like they need to be trained to that kind of a course, a lot of the industry participants have come back and developed a curriculum outline similar to

what was done for HACCP. They have gone to the International HACCP Alliance and in the process of getting accreditation of this outline. It's very extensive, and it does involve a lot of the materials that the FSIS inspectors are trained on. The basic anatomy, in fact most of the programs I've seen actually have the little anatomy chart as part of a little quiz after the anatomy module.

So the plants are doing extensive training. And recognizing that there needs to be some type of standard outline that would be appropriate, have gone to a group like the Alliance which I know AVMA is a member. There's a lot of academic and industry representation to try to get the accreditation process.

MR. BILLY: One thing, it's important, particularly the first question of the day to try to be responsive, but we're a little ahead of ourselves. This morning we're devoting to the traditional system. The question about the training and now the further discussion, we're getting into what is really the meat of this afternoon's discussion. I think it will be better understood by everyone as we lay out

what the models are and the relevance of the training to what's expected.

So what I'd like to encourage is that maybe we could stop at that point, and then if there are further questions about the training or information that's needed we can pick it back up this afternoon.

DR. LaFONTAINE: Dan LaFontaine again.

Mr. Billy, I agree. I felt my question was appropriate because you were talking about the traditional system. My colleagues from industry jumped in because they could anticipate my question this afternoon.

(Laughter)

MR. BILLY: No problem.

DR. LaFONTAINE: I'll defer further dialogue until this afternoon.

MR. BILLY: We can come back to it. It's fair game. I just wanted to keep focused on traditional this morning if we could.

MR. BEHRENS: George Behrens, Food Safety Consortium.

I would like to ask the specific location in the line in which these two ten-bird eco-contamination checks are made. Specifically, is this before the birds are washed, or is it after they have gone through the final wash?

DR. HENDERSON: This is after the carcasses have gone through the final wash and prior to the carcasses going into the chiller.

MR. BEHRENS: This will have considerable importance this afternoon, but it's important right now to get that specifically for the tradition.

MS. NESTOR: Felicia Nestor, Government Accountability Project.

I wanted to follow up on Caroline's question and just clarify this.

You said that the trimmed non-conformance samples and the food safety samples are two different samples?

DR. HENDERSON: That is correct.

MS. NESTOR: And each sample is a ten-bird sample. So in total we're talking about 40 birds or samples, is that right?

DR. HENDERSON: That would depend on how many lines you have in a plant.

MS. NESTOR: But per line, there would be 40 birds per line?

DR. HENDERSON: Two checks per line per shift would be 20 birds for Finished Product Standards and 20 birds for zero tolerance.

MS. NESTOR: Thank you.

MR. BILLY: And if there were two shifts on a line then that would be double that amount for a given day.

DR. HENDERSON: That is correct.

I didn't mean to take the mike away from the moderator. I'm going to pass it back.

MR. BILLY: Other questions?

MS. HAUTER: Wenonah Hauter, Public Citizen.

Has the acceptance of defects in birds going to consumers been standard practice since the 1959 law?

DR. HENDERSON: There is no system that we have developed that has been capable of removing every single defect from a bird.

MR. BILLY: So the answer is yes?

DR. HENDERSON: Yes. That is correct.

MR. SEWELL: Alvin Sewell representing the National Joint Council of Food Inspectors.

For the benefit of the group you mentioned that at postmortem inspection that the postmortem disposition for disease is made with the visceral organs present. Can you elaborate on the importance of the presence of the visceral organs at the point that the decision on postmortem inspection is made?

DR. JAMES: The normal procedure when inspecting a chicken is to look at the inside, the outside, and the viscera of a carcass. Each of those may possibly present a lesion which would require trim or contribute potentially to an overall assessment of the suitability of the carcass. It could therefore, based on the lesions found in those three basic parts, potentially be condemned.

So the viscera is a part of the carcass that we currently use for helping us to make a total carcass disposition.

MS. JOHNSON: Have you looked at, I know we've had this discussion several times and a lot of the documentation for why the current regulations were put in place is sketchy.

Have you done any type of review and pulled out any type of documentation as to why certain, especially when you start talking about some of the reasons why we do things on the slaughter line now, some of the disease categories and some of the traditional procedures that may now not be as based in science?

DR. JAMES: We haven't done a formal evaluation and summarization of all the different regulations and directives, et cetera that we've published. I'm Bill James, FSIS. From the Foundation of Poultry Inspection.

We can say that in years past we did not have as complete an understanding of the public health significance of certain diseases and conditions present in young chickens. We did not have as good a method, the industry did not have as good a method of producing birds in 1959 as they do today.

As an example, our regulations still state that a young chicken is a bird 13 weeks of age or younger, and young

chickens today are generally birds marketed 42, 45 days of age unless they, we are producing something commonly called a roaster which might have a few more days.

But today's birds are marketed at a younger age so they don't have the opportunity to manifest as many diseases. Today's birds are more uniform. Today's birds are healthier than they used to be.

We also hopefully have progressed somewhat in the last 40 years and have a slightly better understanding of the public health significance of some diseases in young chickens than we did back then. And hopefully we no longer need to treat all pathology as equally important.

Does that answer your question?

MR. BILLY: I could add a little bit to that, I think, and I'm not an old timer as everyone knows.

We did make an attempt to pull out from the files and anywhere we could find them information as we prepared the HACCP and pathogen reduction regulation. The fact is that there's very little in our files documenting the basis for many of the earlier regulations or regulatory changes,

either of a scientific nature or otherwise.

The sense that I have, and this is mostly from reading about the time period was that when the rules were promulgated back in the late 50s they were largely based on what the industry was capable of accomplishing at that time. And that was captured, if you will, in regulation as the basis for getting started with the mandatory program.

But you're correct in your assertion that the preambles were not detailed, there was not a lot of explanation, in fact there was hardly any explanation. And clearly many of us believe that the current approach where we provide much more of the scientific basis and so forth is the better approach.

That certainly will be the approach that we plan to take if, as a result of positive results from this pilot, we move to the regulatory process, the rulemaking process.

Caroline?

MS. DeWAAL: Thank you. Caroline Smith DeWaal, Center for Science in the Public Interest.

Following up on Alice's question, can you talk

about a current veterinary condition, airsacculitis? Can you tell us a little bit about what the impact is on the chickens coming into the plant, how the current inspection system would address the hazard from airsacculitis or how the inspectors would treat the birds coming in with airsac, and also, what the public health implications of airsacculitis are please?

DR. JAMES: Airsacculitis is a condition which infects the air sacs of young chickens which come into the plant. It is a problem which can be manifested on a flock basis so that in some lots of birds coming in almost, many of them, perhaps almost all of them do exhibit some airsacculitis lesions.

I will be speaking a little bit more about some of that this afternoon so I don't want to get into a pathophysiology dissertation, but birds with airsacculitis lesions must have the lesions removed for the carcass to be passed. Those birds which exhibit a generalized condition evolving from the airsacculitis itself are subject to condemnation.

So for these airsac birds, to summarize what I just said, the lesions must be removed or the carcass must be condemned.

MS. DeWAAL: When you say a generalized condition is that septicemia? How does that generalized condition show up?

DR. JAMES: It can be manifested as a septicemia which is a word I intended to define this afternoon, but it denotes the presence of bacteria from some origin in the blood stream. That is I think a good, a workable definition for today.

The public health significance of that again is a subject I'll go into this afternoon, but airsacculitis, if it is manifested as a septicemic condition would be considered a food safety hazard.

MS. DeWAAL: But the lesions, are they treated under the defect standards outlined by our previous speaker? The sores and bruises, et cetera?

DR. HENDERSON: There is a category under Finished Product Standards that does address disease conditions for

which there is a weighted category. And please don't ask me what the weight is because I don't have that by memory.

Yes, there is a section in Finished Product Standards that does address disease categories. It's not just airsacculitis, it is disease categories.

MS. SCHOR: Any additional questions?

(No response)

MS. SCHOR: If there are no additional questions I'll turn the meeting back over to Maggie Glavin.

MS. GLAVIN: Thank you, Dannie.

Since we are ahead of ourselves I'd like to keep us going so I've asked Don Anderson if he would forego the break and go ahead and make his presentation, and he has agreed to do so.

So with that, Don Anderson from Research Triangle Institute will present the data on the traditional young chicken inspection system that has been gathered in plants over the past months.

DR. ANDERSON: Thank you very much.

My name is Don Anderson and I'm from Research

Triangle Institute. I'm very happy to be here today presenting the results from the baseline data collection at 16 young chicken plants as part of the models project.

I'd like to acknowledge that there are too many people that have been involved in the project to acknowledge all of them, but I would certainly like to acknowledge several people that I brought up with me from RTI today -- Sheri Cates, Shawn Karns and Becky Durocher who are sitting at the table over here, and Pat Brown, Dr. Pat Brown is also here from BioVet.

There are a couple of other companies that worked with us on the baseline data collection phase of the project. Silliker Laboratories did our microbiological testing and Harris Interactive did our data entry basically, our electronic data entry. So I would like to acknowledge them.

I'm going to limit my presentation today to the organoleptic and microbial data collection processes and results in the 16 young chicken plants, so we'll just be talking about that market class and we'll just be talking about how we collected the data and what the results of our

findings were.

I'll start out talking about the organoleptic data collection procedures and the results before I turn to the microbial procedures and the results from that.

I would again ask that people defer questions until the end of my presentation, and then Pat Brown and Sheri Cates and I will sit at the table and answer questions as best we can.

These are the names and the establishment numbers and the locations of the 16 young chicken plants that we completed baseline data collection in.

The project that we're talking about, that I'm about to talk about, the data that we collected, was a fairly significant and large project. The data collection represents over 400 days of organoleptic data collection during which we looked at over 32,000 passed and condemned carcasses. We collected microbiological data eight hours a day for 480 days. And that constituted a total of 4800 samples, actually closer to 5,000 samples when we were all done.

Becky Durocher received somewhere around 17,000 pages of organoleptic data every day on our toll-free fax machine as all these data come back into RTI for quality checks and data entry.

Mike Grasso and Lenny Lang and I and others conducted over 16 site visits. Some of these plants had numerous site visits, or more than one site visit. So there was a lot of going out to the plants and talking to them about the project to get them started.

I was at, I believe all 16 of these plants. There have been a couple of more recent plants that I haven't been to, but I believe I was personally at all 16 of these. Pat Brown from BioVet was at a number of these and so were some of my other staff.

We've also received somewhere around 700 toll-free telephone calls from plant management, from the tech center, from other places where people have had questions or had comments that they needed to give us, so we fielded all those telephone calls that came in every day.

I would certainly like to thank the plant

management for all their cooperation and support during the baseline data collection phase from the 16 plants. I would like to thank the IICs for their participation and support. And in fact to the food inspectors themselves at all 16 of these plants who were supportive of the project as well. It's been a big effort, but I think it's gone fairly smoothly.

This is an overview of the organoleptic data collection procedure. Essentially you might think of it as being comprised of three basic parts. We start off the project by conducting what we call an in-plant correlation.

The organoleptic data is collected by RTI and BioVet veterinarians. We actually had nine veterinarians who participated in this project in data collection. We did have three veterinarians who have worked at only one plant, but we had five of our veterinarians, that is five of the nine veterinarians collected data at two plants. We had one veterinarian data collector who collected data at three of these plants. Several of these data collectors are continuing to work with us during the models phase of the

project.

The correlation essentially consisted of our veterinarian going to the plant, a tech center veterinarian also came to the plant to participate in the correlation and two weeks of data collection; a correlator came into the plant to make sure that everybody -- our vet, the tech center vet, and the plants that were participating and observing -- knew what conditions were being used to cull all the defects for the purposes of our project. And the plant personnel and others were also invited to participate and observe the correlation process.

The correlation essentially consisted of typically about one day of, if you will, classroom type activities to go over the criteria for culling defects and so forth. It was usually followed by one or maybe two days of practice data collection which was not so much, at least after some experience, it was not so much to practice culling defects on carcasses as much as it was to get used to the plant logistics that are different in each plant.

Then once the correlation was complete, our data

collector collected 25 consecutive working days of data. At multi-shift plants we collect data from both shifts -- night shift and day shift. And whenever feasible, and I think it always was in all 16 of these plants, when there were multiple lines which there were for all of these I'm sure, we collected data from all lines. So we collected data from all shifts and all lines as applicable and feasible.

There were three activities. There was the antemortem activity which was basically an interview process that we conducted once a day for five weeks. The heart of the project, if you will, was the examination of 80 passed carcasses per day for five weeks for a total of 2,000 carcasses, and I'll go into more about that in a minute. And those carcasses were observed after the final wash but before the chiller. We also conducted condemned carcass data collection, that is again each hour approximately or eight times a day for five weeks we would examine birds that were in the condemned barrel.

So over the course of the project in each plant we looked at 2,000 passed carcasses and 2,000 condemned

carcasses.

I'm not going to tell the names of all of our veterinarians, and if there are questions about that afterwards we can answer some of those questions, but all of our data collectors were veterinarians and as I said, a number of them, most of them, collected data from more than one plant and continue to work with us into the models phase.

But to give you a little more concrete idea of what they're doing, I've got a couple of photos that might help.

This is a photograph of one of our veterinary data collectors, Dr. Deidra Watson. She's actually in this photograph collecting data at Townsend's in Batesville and she's doing it in the models phase of the project. So we didn't frankly have the foresight in the baseline phase to take pictures of all of our data collectors, and we thought it would be nice to do that. So FSIS I guess during a plant tour themselves took a couple of photos of Dr. Watson doing data collection, as I say, at Townsend's.

Here she is examining one of the birds at an examination table.

Each hour after our veterinarian looks at the ten bird sample they of course have to make sure that all the information they've recorded on their forms is accurate and complete, so at the end of each interval of data collection they complete their forms. Those forms are sent back to RTI at the end of the day.

This is a photograph again of Dr. Watson doing her paperwork at Townsend's.

I'd like to get into some of the results. First the antemortem results. The antemortem results from the 16 plants are actually based on 380 days of data collection. The sample days for antemortem are somewhat less than the total possible days because there were not always, a veterinary medical officer was not always available for the antemortem interview.

We found during our data collection at these 16 plants, we found that at the time of the interview which usually occurred early to mid morning, that at the time of the interview antemortem activities had been performed by the VMO or the IIC approximately 68 percent of the time.

The mean number of times that antemortem activities were conducted by the IIC each day was 1.3, so as you see, that implies that at most plants antemortem maybe takes place once a day, but at some plants, at least at the time of our interview, antemortem inspection may have occurred twice so the average is a little higher than one.

We found that again, during the 480 days of data collection, that in two lots out of the total a lot of poultry arriving was found unsuitable for food. That represents less than one percent of the lots that were interviewed on.

Records were made on antemortem activities about 27 percent of the time.

This simple pie chart shows the organoleptic results again for passed samples. It just breaks essentially conditions into three categories. We show food safety conditions attributable or caused by disease, food safety conditions that are essentially zero tolerance failures, and the green area represents no food safety conditions.

Notice first that again, we in some sense by

design, we would have looked, over 16 plants we would have looked at 32,000 carcasses. In the end we actually examined approximately 32,075 so there were a few extra carcasses that we observed.

And in one-tenth of one percent of those 32,000 carcasses, which is a total of 43 out of 32,000, our data collector observed after the final wash that there was evidence of septicemia, toxemia, or airsacculitis with systemic change so that it started to appear septic.

So one-tenth of one percent of the carcasses that we looked at did exhibit disease conditions that are considered food safety problems.

One percent of the carcasses that we examined, approximately 300, in fact precisely 306 of the 32,000 carcasses we looked at, had some evidence of fecal contamination. There is a zero tolerance for fecal. We found just one percent in the 32,000 carcasses we examined.

As you see, the vast majority of the carcasses, approximately 99 percent of them, exhibited no food safety conditions whatsoever. Now some of these carcasses that

you'll see when we go to the next slide had OCP conditions, that is other consumer protection defects, but not food safety defects.

These next two slides, if you'll bear with me, and I see many of you flipping through your handouts, the next two pages describe the other consumer protection conditions that we examined for in passed carcasses, extraneous material, lung, oil glands, et cetera. I've got actually two pages of them here. And it not only names the condition, names the other consumer protection issue, but it also has a brief description of what our data collector was looking for and what they were in effect calling a defect or a discrepancy.

Let me give you a couple of examples that will highlight an important difference here, and that is the difference between how RTI data collectors were calling defects and how Finished Product Standards work.

Feathers is one example. The Finished Product Standard for feathers is essentially not a zero tolerance kind of a condition. That is a carcass under Finished

Product Standards, a carcass that has five or more feathers less than or equal to an inch long, that constitutes a defect; or a carcass that has one or more feathers of greater than an inch, that constitutes a defect in Finished Product Standards.

Our data collectors were taught and correlated to call one or more feathers of any size a defect, and that will show up in some of the data we look at.

Another example which is similar but maybe illustrative here is hair. Our data collectors, our veterinarians were told to call a defect or to score a defect as having hair if they observed one hair or more of any size on the carcass. Whereas Finished Product Standards are different. In Finished Product Standards, a carcass is said to have a single defect if it has 26 or more hairs one-quarter inch or longer.

So those are important differences, and there are others that I won't go into between Finished Product Standards and the way we called data that showed up in some of our results.

These are the results, the other consumer protection results from the 32,075 carcasses that we looked at in the 16 young chicken plants.

Again, let me highlight a couple of numbers here. Again, feathers is an example where the percentage of carcasses that scored, if you will, defects in our scoring system was fairly high. Forty-eight percent, that is almost half of the carcasses that we examined after the final wash had feathers. But again, you need to remember that we were calling all carcasses that had any amount of feathers whatsoever.

Likewise on hair, you see that about 40 percent of the carcasses that we examined were scored as having some hair on the carcass. But again, we were calling any number of hair of any length a defect in our scoring system.

So you can examine the results in those two tables and if you have questions about them later, we'll try to answer those.

Before I turn to the microbial results I want to briefly mention the results that we found from our condemned

barrel sampling.

Once again, the design of the project was for our data collector to observe ten carcasses from condemned barrels every hour, eight hours a day, for the duration of the project which was five weeks.

During the course of the project we examined a total of 33,436 carcasses, so we actually looked at quite a few extra carcasses. I think what probably happened here, I think the reason we probably looked at more than 32,000 is sometimes our data collector would look in the condemned barrel and see there were maybe 10 or 12 or 15 carcasses so they would just go through the barrel and examine all the carcasses. So we picked up quite a few extras in that process.

Again, we've got the results of this classified three ways. Approximately half of the 33,000 carcasses that we looked at had generalized conditions that presumably is what led to those carcasses being in the condemned barrel in the first place.

Approximately 40 percent of those carcasses had

what we call localized conditions. So they weren't generalized but they were localized defects. And approximately 12 percent of the birds in the condemned barrel didn't exhibit any abnormal conditions at all. They may have been think or scrawny or something, I suppose, but they didn't have other consumer protection defects or disease defects that we were trained and correlated to look for.

I would like to thank again the management, all 16 plants, for setting up and enforcing to the best of their ability a two-barrel system during the course of this project. We wanted to make sure that all of the birds that we looked at in our condemned sampling were USDA condemnation decisions.

At a number of plants they don't typically use a two barrel system. That is they'll have a single barrel system where all the birds go into barrels, and you can think of it as kind of a combined reject and condemnation barrel.

What we tried to get in place and enforce, and I think we did pretty successfully is a two barrel system so only birds that were USDA condemnation decisions went into

the condemned barrel.

I would also mention it doesn't shown this chart, but overall during the course of this project in the 16 plants that we worked in, we estimate that the condemnation rate was approximately 0.7 percent. That is we estimate that about three-quarters of one percent of the birds that were being slaughtered went into the condemned barrel.

I'd like to turn now to the microbial data collection. This will go a little more quickly, then we'll open for questions.

Again, this is a slide that shows in overview fashion the work we did and how we did it in these 16 young chicken plants.

For doing our microbial data collection we essentially followed FSIS sampling protocols. We used USDA supplied materials to do our sampling. USDA supplied bags, plastic bags for doing the chicken rinses, the rinse solutions themselves, and basically the materials that we needed to use. And I wanted to thank Robin Johnson who was our contact at the USDA laboratory in Athens for all of her

material support.

Essentially the way that the data collection worked is each day that we were doing baseline data collection over a period of six weeks in each plant, we would sample ten carcasses a day five days a week for six weeks. So we did sampling on 600 carcasses at each plant.

Essentially we were examining or we were testing birds for two different types of bacteria. For generic E-Coli and for salmonella.

We did all of our sample collecting after the chiller process which is as required by pathogen reduction testing, so all of our testing was post chill. And again at each plant we did a total of 600 analyses, but 300 of these analyses were for salmonella and the other 300 hundred were for generic E-Coli.

Once again, in these 16 plants where data, where processing occurs on two shifts as it did at most of these plants, we collected data when possible from both shifts.

Now we didn't want to collect microbial data and let it sit for too many hours even under refrigeration before

sending it to Silliker Laboratories for testing, so we were sometimes confined in our ability to work across shifts by Federal Express or other types of overnight pickup. But I think in most of these plants we were pretty successful at collecting a fairly even balance of birds from both shifts in fact, and again, when there were multiple lines or I should really say when there were multiple chiller systems in a plant, we randomly selected birds from all two, three or four chillers as appropriate.

After the birds are rinsed, and I'll show a picture of that in a moment. After the birds are rinsed we send samples of our solution to Silliker Laboratories where they test the samples that they receive for generic E-Coli or for salmonella as we direct them.

When Silliker Laboratories received samples that we shipped them each day, they checked the condition and the temperature of the incoming samples. They were under strict orders by us to call us and to discard any samples they received that were off condition. This is something that occurred not infrequently. In fact we had to discard, or

Silliker at our request, discarded somewhere around 420 samples during the course of the project. If they received the samples and they were not the proper temperature or the specimen cup maybe had leaked some and there wasn't enough solution in there to test, they would discard it, they would call us the next day, and we would have to schedule additional data collection to make sure that we got the proper number of samples.

In the months of July and August we lost a number of days of samples, but we addressed that by using additional quantities of blue ice and basically procedures like that to limit that as much as possible.

We occasionally would also lose some Friday sampling. We typically sampled Monday through Friday at a plant. Friday's samples were marked to arrive at Silliker Laboratories on Saturday, to be tested on Saturday. Typically they would, but sometimes they didn't. Sometimes they wouldn't arrive until Monday.

If a Friday sample didn't arrive until Monday they discarded it and we had to collect more samples.

So we think we maintained pretty well the integrity of the samples.

I want to show again two photographs of microbial data collection at a plant.

I would like to thank Laurie Tinker and the management at Goldkist for this particular photo. Again, this is not a photo that actually occurred or this is not a photo that actually took place during baseline data collection, but during the models phase at Goldkist. No more than about a week ago. We thought it would be nice to have a couple of photos of our microbial data collector in action so you could essentially see what they do.

So this photograph is of Tawanda Maples who is one of our repeat microbial technicians doing sampling, as I say at Goldkist. Tawanda Maples also did actual baseline data collection in two of the 16 plants. She collected microbial data at Claxton Poultry and she also collected data at Kagles in Pine Mountain, Georgia. This is a photograph that looks like of Tawanda with a young chicken in a plastic bag and she's pouring rinse into it to prepare to shake it for the

test.

This appears to be a photograph of her it looks like pouring the solution into the specimen cup. I know these photographs are not great, but hopefully they give you some idea of what it looks like and how it works.

The next two and last two slides I have are the microbial results from the 16 young chicken plants. First, the salmonella results. If we had done exactly ten samples a day, five days a week for six weeks, we would have done a total of 4800 analyses. We actually ended up with 4872 analyses. Again, some days as time allowed we would do an extra sample or two to make sure that we got the total sample size of 4800 or really what we were targeting is 300 per plant.

So you see that we actually collected a few extra samples.

The arithmetic mean, that is the simple mean positive salmonella rate from these 16 plants is 6.1 percent. That's well below the performance standard for salmonella for young chickens.

The arithmetic mean was 6.1 percent. The median was actually closer to three percent. That is of the 16 plants, eight plants had salmonella rates that were below about three percent; and eight plants had salmonella rates that were above three percent.

We had at least one plant, maybe just one plant, Shawn could clarify this later maybe, that we actually had a zero rate. And we had one plant that actually had a salmonella rate that was up close to the performance standard. But you see that the salmonella rate overall, whether you look at the median or the mean, is well below the performance standard for young chickens that has been set by the agency.

These are the E-Coli results from 4884 carcasses that we sampled. Again, the generic E-Coli is measured in colony forming units per milliliter, that's CFU per milliliter and the detection limit for the test that's used which is consistent with FSIS requirements is 10 CFUs per milliliter, so that's the detection limit.

And one thing you will see is that the median, that

is the middle kind of result for these carcasses was 20 CFUs per milliliter which is just a little above the detection limit.

One thing that might help understand these numbers or put them into some perspective, is to remind everybody that there are several ranges that USDA talks about in its final rule for young chickens for giving plants guidance on E-Coli results.

E-Coli, generic E-Coli counts of under 100 CFUs per milliliter are considered acceptable. Counts between 100 and 1,000 CFUs are considered marginal. And counts of over 1,000 CFUs are considered unacceptable.

One thing you'll notice is that the median result is 20. That is half of the samples we collected were fewer than 20, and in fact what we call the upper quartile or the 75th percentile of this distribution is 90. What that means is that at least, you can see from this slide that since the 75th percentile is 90 CFUs and since the top of the range for an acceptable level of E-Coli is 100, you see that at least three-quarters, and in fact 78 percent of the samples that we

took were in the acceptable range, and 18 percent of the samples that we took or looked at were in the marginal range. Only four percent of the samples that we tested were in the unacceptable range.

I can't speak with authority about the E-Coli ranges, but essentially there's a moving window calculation, and this was not part of the project, it's not something I understand very well. But it's not unusual, in fact it's expected to have some marginal results I think in these testing windows. So again, this shows the distribution of E-Coli in the samples we collected was I think actually fairly impressive.

If there are any questions, I'm going to ask Sheri and Pat to come to the front and we'll try to answer them.

MS. JOHNSON: Alice Johnson, the National Turkey Federation. I have two questions. One is more clarification.

I do want to compliment the agency on the way they have collected baseline, looking at organoleptic as well as micro. I think this is the third party, I think this is a

great way to go about the project.

I do think that we maybe need some clarification on localized conditions and the way they're considered under the current inspection system and as an explanation for why the lesions are on the sheet.

It's my understanding that airsacculitis, just in the nature of the disease and the name of the disease itself, is limited to the air sac. And the agency has called that a localized condition. And under current inspection procedures plants had the ability to remove the affected tissue.

It's when, a food safety is when the carcass is showing systemic changes and is showing a different type of carcass, but may or may not be related to the air sac. But airsac in itself is considered localized.

And I'm probably not asking that very well, Bill James, but the localized condition is not considered food safety. Other consumer protection. Is that correct?

DR. JAMES: We do not considered localized airsacculitis, airsacculitis which is confined to the air sacs, is not classified as a food safety hazard. That is

considered a localized lesion which can be removed and the unaffected portions of the carcass may be passed. That is correct.

If airsacculitis has resulted in a carcass which exhibits septicemia, the carcass is condemned.

MS. JOHNSON: For the septicemia.

DR. JAMES: Correct.

MS. JOHNSON: That's where you're getting the food safety concerns.

DR. JAMES: Yeah.

I'm sorry, Karen just corrected me. There is a, she reminded me that there is a category on the current inspection condemnation form for airsacculitis condemnation. It is a specific cause of a septicemia and on that form it is identified as an airsacculitis.

MS. GLAVIN: But Bill, is it not correct that under the current system we don't make a distinction between food safety and other consumer protection. That distinction is something that is growing out of the experimentation with the new system.

DR. JAMES: That is correct, Maggie.

MS. JOHNSON: And Bill, also, and maybe Dr. Henderson as well, on the localized conditions, generally under the current system localized conditions, if a plant chooses to do so there are special procedures in which the plant can remove the affected tissue in most, I won't say all, I'll say most of the localized conditions.

DR. HENDERSON: Alice, you're correct.

DR. LaFONTAINE: I'd like to go back to the very last slide, is that possible? It's on the generic E-Coli.

(Pause)

DR. LaFONTAINE: Maybe I'm the only one but I have a hard time understanding this slide.

Tell me what maximum means in 45,000.

DR. ANDERSON: I'll be glad to. That means that of the 4884 samples that we did, the sample that had the highest generic E-Coli count had a count of 45,000 CFUs per milliliter. That's what that means. And I apologize if it is --

DR. LaFONTAINE: So that 45,000 is colony forming

units.

DR. ANDERSON: It is.

DR. LaFONTAINE: Not 45,000 birds.

DR. ANDERSON: That's right.

DR. LaFONTAINE: Well, it couldn't be 45 because -- Okay. I understand.

VOICE: How many birds --

DR. ANDERSON: For the maximum it would be one. That is the highest single observation.

For the minimum, you'll notice that the abbreviation ND which is non-detectable shows up for the minimum, the 10th percentile and even the lower quartile.

What that means is that 25 percent of the samples, approximately 1200 of the samples, had non-detectable levels of generic E-Coli. And in fact the median means that half of the samples, approximately half of the samples had 20 CFUs per milliliter or less of generic E-Coli.

DR. LaFONTAINE: In the reverse, looking at the 90th percentile, 10 percent or less were at the 280 colony forming units, is that correct?

DR. ANDERSON: 280 or higher. Ten percent had 280 or higher. That is correct.

I'm just trying with this to give some idea what the distribution was rather than just the average.

MR. BYRD: Ken Byrd of Pilgrim's Pride.

You said that on the zero tolerance birds, the birds you found with fecal contamination post wash, you had 306. I was wondering if you had any data to compare the location of the defect inside versus outside the bird?

DR. ANDERSON: No, we did not record the location of the contamination on the carcass, whether it was inside or out.

MR. BYRD: Did these plants have on-line reprocessing? Or were all the birds to be, they were contaminated internally to be removed and sent to a wash-out station?

DR. ANDERSON: I'm not sure I understand your question.

MR. BYRD: The on-line reprocessing with an anti-microbial treatment. Did any of these plants

have --

DR. ANDERSON: Some of these plants do have TSP or other anti-microbial treatments. When we did our sampling, I call it post wash. We did our sampling -- excuse me. The microbial sampling is post chill. But yes, there are some of these plants that have TSP or another anti-microbial treatment, if that answers your question.

MR. BYRD: Thank you.

MS. NESTOR: Felicia Nestor, Government Accountability Project.

The 2,000 samples that you took, do you know approximately what percentage of the total production that was in the time that you took those samples?

DR. ANDERSON: No, I don't. We didn't calculate that. That would be calculable, but the design of the project was for us to sample 2,000 carcasses by looking at 80 per day over the duration of the project. That sampling rate was the same in a plant with two lines and one shift, or with four lines and two shifts. It was the same number of samples that were pulled, 2,000 carcasses.

MS. NESTOR: But you could go back and determine that?

DR. ANDERSON: I'm a little reluctant to say that I could because we did not, when we set up our data collection procedures we did not set it up with an eye towards ever making that calculation. But in general we know the line speeds and the lines.

MS. NESTOR: So what you're saying is that RTI did not determine to take 2,000 samples.

DR. ANDERSON: That's true. We didn't.

MS. NESTOR: On the antemortem, when you determined that antemortem had been done a certain percentage of the time, the method that you used to determine that was to ask the person that was supposed to have done the antemortem?

DR. ANDERSON: It's strictly an interview process. It is.

MS. NESTOR: The issue about the condemned barrels, can you clarify how many of the plants had strictly an FSIS condemned barrel so that none of the condemned birds were being put in by the company?

DR. ANDERSON: Maybe Pat or somebody can clarify better, but I believe that most if not all of these 16 plants we had a condemned barrel system in place.

Now we, during our site visits when we met with the plant and we talked to the food inspectors and the ICCs, we told them that we would be or the plant would be setting up a separate condemned barrel system, separate from a reject barrel system. And we asked the food inspectors to notify the ICC if they observed plant employees inadvertently throwing birds into the condemned barrel, and every now and then we would get a report of that and then we would call and we would get that corrected.

But I think at the majority if not all of the plants there was a separate condemned barrel system in place.

MS. NESTOR: Okay.

MR. BILLY: Don, just one. I assume what we ought to keep in mind in terms of the data system that you put in place and the data that you've collected is it's designed for the purpose of making a comparison between the traditional system and the pilot system. so in a sense, it's reasonable

to assume that the production volumes will relatively be the same during the two data collection periods.

What this is about is being able to make the before and after comparison that I mentioned earlier.

DR. ANDERSON: That is true, and kind of in a more backward looking sense in fact, when we worked with the agency to schedule our data collection, we made a point of selecting a five or six week period for data collection when they believed, that is when plant management believed they would be operating a fairly normal schedule and a normal rate of production.

We avoided, in a few instances we rescheduled or delayed data collection because maybe they were going to do an equipment changeout during a period of time that we thought we might need data collection. We didn't want to collect data when there was anything like that going on that might disrupt production.

MS. NESTOR: Can I ask a question about that?

DR. ANDERSON: Sure.

MS. NESTOR: Under the traditional system there are

maximum line speeds, and if I'm not mistaken, under HIMP there is no limit on the line speeds, isn't that the case? So how could the production volume be the same if the plant can increase its line speed?

MR. BILLY: I think the point is what Don just made, that the effort was to try to collect a set of data under the traditional system that would be typical of a normal operation, not involving periods where there was unusual situations in the plant or whatever. As sort of the foundation or the basis to compare to the pilot system which may involve different line speeds, higher or lower; it may involve moving equipment, it may involve other changes, but it's a comparison between the traditional inspection system and the results of that to the pilot approach.

MS. NESTOR: You were just saying that it would be typical of the traditional and then typical of the new.

MR. BILLY: It will be the new, whatever it is, and it may vary somewhat among the plants.

MS. NESTOR: I have one more question if I could, and we probably will have to discuss this later but I just

wanted to ask the question now in case we should discuss part of the question now.

In using the baseline data to devise performance standards, it sounded like what you were saying is that when you analyze defects, it's different from the say FSIS analyzes a defect, for instance for feathers or something like that. I'm wondering if FSIS when it developed its performance standards, whether that was taken into account.

MS. SCHOR: Why don't we hold that because I think this afternoon the data, or the information presentations will help to put a context around that question. But please do ask it again.

MS. DeWAAL: I have two questions.

The first is for the condemned carcasses, you collected them eight times a day, but for the pass carcasses, you collected ten carcasses eight times a day whereas for the pass carcasses you just collected a batch of 80. How did you do that --

DR. ANDERSON: I'm sorry. I did not mean to give that impression.

We collected our passed samples in essentially the same way as our condemned samples. That is eight times a shift we would randomly select ten birds and examine them.

What we typically did at a two-shift plant is we would work a week on the night shift followed by a week on the day shift, back to the night shift. So we alternated shift work by week. But it was eight throughout, 80 birds selected throughout an eight hour shift.

MS. DeWAAL: Okay.

My second question has to do with the data you don't have.

DR. ANDERSON: I won't be able to answer questions about that.

(Laughter)

MS. DeWAAL: I know, but I need to get this on the record.

Did you run any tests on campylobacter?

DR. ANDERSON: No.

MS. DeWAAL: Why didn't you run any tests on campylobacter seeing that you were running all the tests on

salmonella and E-Coli?

DR. ANDERSON: The good thing about being a contractor is I can say we weren't asked to. That's the simple answer. I would let somebody else answer that question.

MS. DeWAAL: Do you have any of the, did you discard all the solutions?

DR. ANDERSON: Yes.

MS. DeWAAL: So we have absolutely no data from this dataset telling us what the baseline numbers for campylobacter were going into this project.

DR. ANDERSON: That's correct.

MS. DeWAAL: And are you aware that campylobacter can be present on as many as 90 percent of chickens coming out of the processing plant?

DR. ANDERSON: I read the papers.

(Laughter)

MS. DeWAAL: And there's just no data that RTI has from this project dealing with the campylobacter dates --

DR. ANDERSON: There is no campylobacter, and I

don't mean to, sorry about my attitude.

We did no campylobacter testing. The salmonella testing that we did was a simple positive/negative salmonella test. We're not reporting the types of the salmonella. I'm not a microbiologist. I understand that some types of salmonella are pathogenic and some aren't, that's my understanding as a lay person. But we did a simple prevalence test that looks for the presence of one or many strains or types of salmonella.

Again, the generic E-Coli was a simple generic test.

MS. DeWAAL: Thank you.

MR. BILLY: I'd like to just mention that during the same time period the agency has conducted a nationwide baseline survey for campylobacter that includes both determining the presence and the quantification of the numbers. So we will be making available in the near future the report of that baseline study. There will be data and it is based on the traditional system. So the type of information that Caroline was referring to will be available

but through a separate means.

One other point is that we're provided a certain amount of funds to do our work, and we have to manage this project in a way that is consistent with what funds area available to us. So we've been very careful to try to do that. I think these data are very significant in the context of the current regulatory requirements. And we have a wealth of data from our own salmonella sampling to make comparisons and as well as the data that the plants are collecting on a daily basis for generic E-Coli. So there's a lot of data that will be available to make comparisons of all types related to those two bacteria areas or categories.

MS. DeWAAL: May I simply note, though, that your baseline data collection that provided the basis for the salmonella standards in the HACCP pathogen reduction regulation, also that data set also contains campylobacter data.

MR. BILLY: Yes.

MS. DeWAAL: So you have already prevalent data on campylobacter in chickens, turkeys, beef, swine. So we

already have the data, a large body of data dealing with campylobacter which could have been used as a tool to compare this dataset.

MR. BILLY: One of the important things we will be able to do is to in fact make a comparison between our two baseline datasets as it relates to campylobacter. So that type of information will be coming forward in the next few months.

MS. DeWAAL: But what we can't do with the dataset that RTI has provided now through this study is to make comparisons on how the inspection models project will impact one of the largest pathogenic concerns on these products which is campylobacter on chickens. We will not have the data to tell us how changes in the inspection program will impact campylobacter contamination rates.

MR. BILLY: Perhaps you've forgotten, but this subject was discussed at length in the meat and poultry advisory committee --

MS. DeWAAL: I remember.

MR. BILLY: -- and the agency has made a commitment

to collect that type of data for plants that are under the HIMP type system once we get that well enough established. So there will be data collected that will enable us to compare the results of the traditional system to the new system.

But obviously we're just now swinging into this pilot phase and it's a little premature to do that.

I think it was important that we get additional baseline data that's not based on 16 plants, but based on the plants nationwide, geographically distributed, representative of the production the marketplace, so we have done that.

MR. VOGEL: Lyle Vogel at AVMA.

I'd like to go to the chart on the organoleptic results for condemned samples. You made a comment that 12 percent of the condition -- I don't know that you need to pull it up, but the chart shows that 12 percent of the samples showed no abnormal conditions.

A point of clarification, when you pulled those samples were the viscera attached or were they not?

DR. ANDERSON: I think that depends on, we looked

at the carcasses as they were in the barrel. Pat, maybe you can give us some idea from your time that you spent in the plant.

MR. VOGEL: I guess my basic question is, is it possible that those 12 percent or a portion of that could have been condemned based on lesions in the viscera, but yet the viscera was not there to confirm that?

DR. BROWN: I would say yes, that is a possibility. There were some of the birds that didn't have viscera. At what point they were put in there, I don't know, whether the viscera just broke away. But I would say there may be a small percentage of that 12 percent that may have been condemned correctly with respect to what was seen in the viscera. But it would be a very small percentage. Most of them did have the viscera attached. At least when I was in the plant, and I visited all of these plants at least once and possibly twice for some of them.

DR. LaFONTAINE: I have a question on the same chart. A question/comment.

Something, I believe I'm correct in this and it

needs to be brought out somewhat in defense of my colleagues in the USDA.

When we get into this chart and it shows essentially 50 percent that were not generalized conditions, 38 percent and 12 percent, the inspector on the line has, I would guess, about three seconds per bird to make a decision with a line that's running at 90, 93, with three inspectors on a line.

The RCI veterinarian is taking a look at these birds with essentially unlimited time and so all I want to do is, if that's a correct statement, make it for the record that there's a tremendous difference in the amount of time to make that disposition.

DR. ANDERSON: I agree with that correctly. Again, though, I think that is exactly right for the record. But I would also like to point out again that, understand the purpose of the project is primarily to establish the current performance of the system so that we can relate it to the model's performance of the plant. We're not here to really judge the current inspection system, but rather to establish

what's occurring under the current inspection system using, as you correctly point out, a much closer eye. So that we can compare that to the performance in the models phase.

DR. LaFONTAINE: Please understand this is not intended as a criticism of RTI, it's just that looking at this chart without that explanation could really be detrimental to interpreting what FSIS is doing. That's the only reason I bring it up.

DR. ANDERSON: I think that's a fair comment. And I would also point out that that same comment, even though you brought it up in the context of the condemned sample, the same comment applies and is appropriate for our examination of the passed sample as well.

Our data collectors had a lot of time, not unlimited, but they had minutes rather than seconds or fractions of seconds to observe these defects. That's true. So that's a very good point and I think a necessary clarification.

DR. HENDERSON: I would just like to add to Dr. LaFontaine's comment that the industry is allowed to

recondition product that does not have systemic conditions if at any time whether there are too many birds with airsacculitis or too many birds with whatever condition that they cannot keep up with their off-line salvage or their on-line trim, the industry often makes a decision that we're not going to recondition this product.

We are therefore in a position where that product must be condemned and go into the barrel even though it may have a localized condition.

MR. SEWELL: Alvin Sewell with the National Joint Council of Food Inspection Locals.

I'd like to discuss a couple of issues here and amplify on some comments that were made earlier.

Dr. LaFontaine's comment that the time elapsed under the normal conditions is in all cases less than two seconds per bird for the federal inspector, and this may involve in some cases as many as 12 separate decisions to be made during that time period contingent upon the number of off-line salvage or reprocessing procedures that are present.

So when we start talking about inspection error

rate, I think it's important to keep that in mind.

And Ms. Johnson pointed out the localized condition option of the plants to recondition or remove localized conditions, and on your chart that identifies the 38 percent localized conditions, I wish to address the issue with the RTI data gathering in cases, and there is a signed affidavit on file with the American Federation of Government Employees that identified that during that baseline data collection that the plant would from time to time, actually on an almost daily basis, institute or suspend that off-line salvage and reprocessing procedure, at which time there was no change in the data collection from the condemned carcasses from the barrels that were identified as carcasses condemned by inspection.

What I'm saying is that during this data collection the inspector's decisionmaking process may have changed as a result of the plant's option to suspend or apply an off-line reprocessing or salvage procedure, and why wasn't that taken into account in the error rate that was calculated for carcasses that were condemned in error in this 50 percent?

DR. ANDERSON: I guess one thing I'd like to point out is I haven't used the term "condemned in error", and you'll notice that I haven't used terms like "properly condemned" or "improperly condemned".

For one thing, again, the criteria are not necessarily the same that we're always following. We looked for the presence or absence of generalized or localized conditions. Whether they were properly or improperly condemned is not what we're claiming, and I didn't mean to imply that although I can see that maybe it gives that impression. But we don't mean for it to have that impression. I don't think we're maintaining here that half the carcasses were improperly condemned

MR. SEWELL: Having said that, what is the purpose of that data?

DR. ANDERSON: The purpose of the data is to, I guess to give us some idea of what the condemnation rate was and some idea of what the conditions of the birds were in the condemned barrels. Again, this was part of the project, and maybe I would defer to somebody on the committee or at the

agency to explain better what they can get out of this data.

MR. GRASSO: I'd like to comment on that. That was an actual request that was made at the December 1998 public meeting to add that on to the project, and one of the reasons that we wanted to take a look at it was the types of conditions for these young animals, why they are being condemned.

The other thing I'd like to make a statement on, it has, is, and always will be the right of the establishment to decide whether the salvage operation is on or off. Before the models, during the models, and after the models. In fact, not all plants have a salvage operation.

MR. BILLY: Can you identify yourself please?

MR. GRASSO: My name is Mike Grasso.

VOICE: Could you identify who made that request in 1998 at the December meeting?

MR. GRASSO: We can go back and look at the records.

MS. DeWAAL: On this point, and I don't remember who made the request and I'll be interested to find out, but

the bottom line, and I'm only making this comment because of the discussion we've been having.

When I look at the two charts for passed samples and for condemned samples together, it confirms for me that the bias in the current system of government federal inspections is that we condemn maybe more birds than necessary in order to protect consumers. So the bias in the traditional inspection system seems to be towards consumer protection when you look at those two charts together. So I think that that information is valuable to this project.

MR. BEHRENS: I would like to raise a concern on the passed samples where it says one percent there have zero tolerance for fecal contamination. That one percent, that's all fecal contamination? Is that what it is? Or is it a combination of --

DR. ANDERSON: Yes. That one percent is fecal contamination.

MR. BEHRENS: I certainly concur with the zero tolerance for fecal contamination. It's important that this not be misleading that this means that only one percent of

carcasses have been fecally contaminated and that only one percent presumably then would have any foodborne pathogens on them.

That means that this is an examination for visible fecal contamination and it's done after the carcasses have been washed which will have removed the visibility of the contamination but would not be construed to have removed the pathogenic organisms.

I think we need to be very careful in presenting this as to what this means. This means that after that final wash, that's all that was visible. But the invisible is still there, as is evidenced in the fact that you got six percent of carcasses that in the chill still showed salmonella. And we don't know what percent would have shown campylobacter if it had been cultured for that.

So I would like to raise this as an issue as we move to human foodborne pathogens as being the significant aspect of food safety, and that we not mislead by having hidden it by washing.

MR. BILLY: I understand your point. If you could

put that chart back up, Don.

One thing that might be helpful is for someone to explain what the significance of the word "passed" is in this slide.

DR. ANDERSON: I'm sorry, I didn't understand the very last part of --

MR. BILLY: What is the significance of the word "passed" --

DR. ANDERSON: Oh, passed.

When we say that we examined passed carcasses, what we mean is the carcass has been through the entire slaughter line part of the process up to but not including the chiller system. So this is after the carcasses have passed all of the organoleptic checks that the agency's going to make on them.

What that means, if I understand correctly, is that at the point that we're looking at these carcasses, what we're calling passed carcasses, these carcasses are not going to be examined after this point again by USDA inspectors. They're going into the chiller and then they're going into

packaging or processing or whatever.

Again, we did our bacterial checks, our microbial detection was done after the chiller because that again is required by the PR final rule. But these are passed carcasses. They've essentially, after the final wash, these carcasses have been deemed proper to enter the food chain. They're not completely done with the process because they're going into another very significant treatment process in some sense because they're about to go into the chiller, but these exams were done after the last point in the slaughter line where USDA inspectors examined them.

MR. BILLY: Thank you.

I wanted to draw that out because it's very relevant to this afternoon's discussion and one of the key features of the HIMP-type system is that it's designed to provide us an opportunity to intensify our food safety checks. This is a particular area of focus. So it creates the opportunity to see improvement in terms of the safety of the products, at least, George, in the context of what's visible and what can be done in that context.

So I take your point that there can be pathogens present and the data supports that, even though you only see a certain number of birds that have exhibited visible fecal contamination.

I'd like to make a more general point as well, which is that I think it's important that all of us keep in perspective that the poultry and in fact our overall inspection system is recognized and accepted around the world. It was said earlier and it bears repeating that while our system's good, it is not perfect. This whole project is about getting documentation, getting information about the strengths and the weaknesses of the current system for the purpose of identifying opportunities where we can make improvement, and I believe that when we get into the discussion this afternoon and you see what we're attempting to do and then when we're able to share the data with you from the HIMP phase where we're actually in the pilot phase with the models being tested, it will allow us to make those kinds of comparisons very directly and then put us in a position to make judgments about whether we should move

forward to formally change our inspection system based on that comparison.

Other questions?

MS. FINELLI: Mary Finelli with United Poultry Concerns.

It seems pretty much common knowledge that cross contamination is greatest in the chiller when these birds are put into a communal bath, so I don't really understand why the, and if they are finding fecal contamination in this organoleptic testing, why isn't this being done after the chiller?

MR. BILLY: Because the way the chillers work, it would tend to remove this visible evidence of that contamination as part of that process. So it's an attempt to make that observation before that would occur. So it's after we've completed our on-line inspection effort but before it would go into a chiller-type system.

It was a strategy to try to get a good documentation of what's occurring at that point in the process.

MS. FINELLI: It seems like if the same number of samples are being taken both through the traditional system and with the new system but it's not the same number of birds going through, I don't really understand how that could be statistically significant. It seems like you would want to do it proportionately the same. And if you're testing a greater sampling with one system than with the other, I don't see how this can be really comparatively analyzed.

DR. ANDERSON: I'm not a statistician but I've been doing this a long time and it's basically the power of statistics.

The sampling rate, the sample size that you take does not need to be proportional to the population. In election times as we're in now, you wake up in the paper, the Washington Post, and you read who's ahead in the election. They're looking at a statistical estimate, a statistically valid estimate of over 100 million voters and they're usually dealing with sample sizes under 2,000. A statistically valid sample is usually in the range of 1,000 or 100. So a sample size of 2,000 is actually quite large.

MS. FINELLI: But if you're comparing two different systems, I don't see how that can work. You're getting a different percentage between the two.

DR. ANDERSON: It's irrelevant. It doesn't matter. Again, this is where, I'm not the statistician, and there may be a USDA statistician here, but it's not a very relevant consideration.

MR. BILLY: One other point is that you're making an assumption. The assumption you're making is that the production rates will be different. That may not necessarily be the case, or it may not be the case during the testing period. It's up to the plant in terms of what their production rates are going to be based on the type of approach they want to take.

So we need to wait and see what the rates are. We'll keep an eye on your concern, we appreciate your raising it, and as we move forward we'll look at the data. But Don's comment is well taken in terms of the power of the numbers and the statistics that will be used.

So it's an important point and we'll keep an eye on

it.

MS. FINELLI: I'd just like to add that I think a way to make it more accurate would just be to do a percentage of the birds being processed rather than a set sampling size, the number of birds being processed.

MR. BILLY: I learned a long time ago that I'm not a statistician either, and I'm going to rely on statisticians to help us make sure that we've got a good basis for comparison. So that will be part of our focus.

Alice?

MS. JOHNSON: Alice Johnson, National Turkey Federation.

I'd like to go on record as saying that the chiller water now, there are studies that say that prevalence actually goes down through the chiller. The chiller at one time may have been something totally different from what it is now. Poultry plants currently are looking at a lot of ways to improve the actions of the chiller. In fact in most poultry plants now the chiller actually is an anti-microbial intervention. Not only does it help to start getting the

temperature down on the birds, but there are anti-microbial treatments that actually show a reduction after the birds come out of the chiller as before going in the chiller. So I did want to be sure that statement was put on record.

Also I want to say that there are plants currently in the models phase that have implemented the models that actually have decreased their line speeds. Line speed is dependent on the number of birds you can handle through your chilling system, the number of birds you can handle through your boning and whatever further processing, so there are plants in this room that have actually decreased line speeds as they have implemented the models.

VOICE: Could you specify which plants?

(Laughter)

MS. JOHNSON: Yes, but not publicly. I'll let the agency do that, if they care to do so.

MR. BILLY: No.

MS. HAUTER: Wenonah Hauter, Public Citizen.

I had a question about the last chart. Doesn't this mean that 50 percent of the birds that were tested had

fecal matter but there's just a certain amount of fecal matter that's permitted by USDA? The baseline microbial results for generic E-Coli.

(Getting chart)

DR. ANDERSON: If you'll ask the question again I'll attempt to answer it.

MS. HAUTER: This is a very confusing chart.

Fifty percent of the birds that you tested I understand from looking at this had some kind of fecal contamination even if USDA permits some E-Coli to be present.

DR. ANDERSON: I certainly don't mean to give that impression whatsoever. These are generic E-Coli tests that are done by rinsing birds after they've been through the chiller. Somebody's already pointed out that the presence of fecal contamination may or may not correlate with E-Coli or salmonella or anything else. So this does not say -- The word fecal contamination isn't on here, I didn't mean to say that it was.

This does not indicate anything about the number or the percentage of birds after the chiller that are

contaminated with fecal matter.

DR. JAMES: Maybe I can clear that up just a little bit. Bill James, FSIS.

Chickens are an animal that are processed, and at that point at which they are sampled here they have the skin on them. So it is quite likely that we will find some E-Coli, generic E-Coli, which is a typical environmental bacterial on these chicken carcasses.

So the presence of the E-Coli does not necessarily indicate that there was fecal contamination on that carcass, it just means there were E-Coli on that carcass.

We use it as a measure of process control, but it is not necessarily correlated with the presence of feces. After all, the animal has worn that skin his whole life.

DR. ANDERSON: I apologize for the confusion that apparently this chart has caused several people, and I mean that sincerely. Maybe we can figure out a better way to present that information.

MS. NESTOR: Felicia Nestor, Government Accountability Project.

I want to make a brief comment and then ask a question.

At the last couple of public meetings consumer groups have asked for an independent peer review of the sampling protocol. On June 28th I got a copy of a sampling review done by a Dr. Phil Kaat with National Agricultural Statistics Service.

GAP wants to reiterate that we still think that consumers have a right to understand an explanation in English whether the sampling program is adequate that RTI is doing to compare the two systems, and whether the verification sampling is adequate under the models project. And like I said, I think we need it in English, this doesn't explain it to me.

But I have some other concerns about this.

We asked for an independent review, and I don't have any bone to pick with Dr. Kaat, but he works for the same agency that's devising this models project.

VOICE: Not FSIS, however.

MS. NESTOR: So that to me calls into question how

independent he can be.

Also the last couple of comments in the end sort of strengthen that concern that I have. He offers to help FSIS develop a test because he's pointing out the problems you have with how you're going to be doing these comparisons. And he gives FSIS advice in how to present this data so that it looks good. At least that's what I'm reading here.

So those are my concerns.

And I called Mike Grasso and was asking whether we could have someone here that could explain this to us. So I'm wondering, is there anyone here? I'm not a statistician. Everybody else here that I've heard so far is not a statistician. Is there a statistician that can explain the sampling review to us?

MR. BILLY: We appreciate your concerns. We've noted them. Obviously we've followed up on the concerns that were raised earlier. It would be fair to you to assume that as we move forward we will be providing a more detailed statistical explanation of the study, both the design and the results. But we don't intend to do it today.

MS. NESTOR: Okay. I have one question based on a sentence in this sampling review. And I'll read the beginning of the paragraph because I'm not sure whether my question will then make sense.

But he says, "I focused my remarks on the analysis of a single slaughter plant".

MR. BILLY: I just stated that we're not going to address that today. We'd appreciate it, if you'd like you can provide us your questions in writing and we'll respond in writing. As I said, we will be providing a much more detailed statistical explanation of both the design and the results at a future public meeting, and clearly if we move forward in terms of a more formal action to change the regulations that will be a necessity if we're going to move forward.

Are there other questions?

MS. FINELLI: It just seems to me that I know this has been addressed. You say that past concerns have been addressed, but the sampling size continues to come up as a problem. It seems like we're going to refuse to talk about

it and what, then we'll find out that all these results are really skewed and unusable and we're right back at step one? I think we really need to examine this as soon as possible if not beforehand. It should have been figured out beforehand.

MR. BILLY: I appreciate your view. We have taken it into account and we are addressing it and we will in fact, as I said already, provide a much more detailed explanation.

So I think you're going to have to bear with us. This is a step-wise process. We have asked a separate agency to look at it. They've given us comments and advice. We're responding positively to that. That will be reflected in the project as we move forward and in terms of our analysis of the results.

I think that's what we're prepared to say about it today, and as we move forward we look forward to an opportunity where you can ask all the questions you want about this area.

Other questions?

MS. SCHOR: Okay, we're getting an early lunch

since we didn't have a morning break. So I would ask people to return as scheduled, at 12:30.

(Luncheon recess taken)

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

12:35 p.m.

MR. McCUTCHEON: If you all could get in your seats, we can get started this afternoon.

We have a very active agenda this afternoon. There will be six speakers covering different aspects of the HACCP-based young chicken inspection system which is what we're going to be focusing on. It's also known as, the overall system is known as HIMP as Tom Billy mentioned earlier today. But we will, because of the fact that we're further along in the young chicken area, are going to be focusing on that.

The handouts that Maggie mentioned are copies of the overhead slides that we have here, that are out on the table there, so there are copies that you can take with you.

First of all, let me then start by saying good afternoon. We have covered the topic this morning, was the current system, and as Tom mentioned earlier, we are continuously seeking improvements in the inspection process.

We're extending HACCP to the slaughter line and we want to build on the achievements thus far. Under the model

projects, FSIS is maintaining a strong inspector presence.

Furthermore, no changes will be made until all the data are in and that the data supports such a change.

The goals of the HIMP system are first, to extend HACCP into the on-line slaughter activities, as I have already mentioned. Therefore industry will be extending their interest into assuming responsibility for their products in this area of the plant. It allows FSIS to focus on food safety. It also allows FSIS to shift its focus to system performance in complying with the regulations.

What this means is that when we have had the fixed locations as was mentioned this morning for the inspectors, they have been looking at, if you will, on a product-by-product basis. So instead of just doing product-by-product examination they are also now responsible for evaluating the overall performance of the system.

It's fundamental to what we're doing with the HIMP model system that we're maintaining the accomplishments of the current inspection system. That I think has been issued and stated in just about every publication and every public

hearing that we've had.

What is HIMP inspection? The role of the inspection team is really to cover three activities -- continuous oversight inspection, and I'm going to cover these topics very quickly because we have five panelists who are sitting to my left, to your right, that will be giving detailed explanations of the topics that I'm mentioning very briefly now, so I won't go into a definition of continuous oversight. Many people probably are already aware of the term.

On a regular basis there's scheduled verification that has been included. We also have unscheduled verification that the oversight inspector can call for when necessary.

In conjunction with that, we are operating the system against performance standards, some of which discussion has started to take place this morning as relative to the baseline that was discussed. Dr. Henderson this morning also discussed the issues about finished product standards. He gave us some information on how the current

system operates.

In two ways, the system for HIMP has been designed where they are stricter, our performance standards are stricter than the Finished Product Standards system has been, and I think if you remember from this morning's discussion you may have heard terms like bruises of one-half inch, so many feathers before you had to score the process, and Dr. Henderson went through a description of how that process operated.

In this case our definition of a defect is if it exists at all it gets scored and the scoring system then determined based upon the baseline, what was going to be established as our performance standards.

Our performance standards have also been designed with a second improvement over the current system. Improved performance over traditional measurements.

Traditional measurements we were discussing this morning, also known as the baseline. We are using the baseline data, but we're using the 75th percentile as the standard, based our standards on the 75th percentile, or if

we have a total of 16 plants, which is the number of poultry plants we have, it's the performance of the 12th plant, if you will, if you look at the plant's performance on a continuum from say the worst plant to the best plant. We didn't take the worst plant performance, although that plant is producing product today. By worst it doesn't necessarily mean it's bad, it just means what the numbers represented.

In preparing our staff for performance in the HIMP system, FSIS training, and the question of training came up this morning also, has been modified to incorporate the needs that we have so that our workforce is properly prepared to perform in the HIMP plans.

For supervisor training we cover topics such as the role of the inspector in charge as being the team leader, and what is expected of the team leader in working with the people inside the plant, with the plant personnel, and with the Washington staff, meaning the technical consultants. They were trained in the HIMP system in terms of what was oversight or what is oversight inspection and verification inspection. They were also trained in statistical process

control.

As you can see, we are moving further and further along into a quantitative system that is determining the measurements of the performance of the systems than we've ever had the pleasure of having from prior times.

Inspector training, the inspectors received the same HACCP training that was given to inspectors in the other HACCP plants. The on-line inspectors were not incorporated into the HACCP training at that time, so we did that before we started a HIMP plant.

They also received computer training because a lot of our records now are being put into the computer for ease of maintaining the data and further and more important, for the ability to do some analysis on the information. They were also trained in the HIMP system.

The status of the young chicken plants. We have 15 plants that are waiting to get into the project. That means that we have 16 plants that have done the complete data collection. At this point seven of the 16 are operating under the new model and two of the 16, data is being

collected under the models. Remember there was the baseline phase, then the models phase, after they finished, everybody finished with the transition and the system was operating such that they're prepared for the second set of data collection. So two plants have reached that.

You do have a handout that lists this information along with the swine information and the turkey information that was on the table this morning.

I wanted to particularly mention that we took extra caution during the transition, before a plant actually started making a change in the process. It's already come up this morning about four times the number of food safety checks versus the traditional checks. We have two food safety categories, and I might mention that the agency started with recommending six verifications per line per shift and in consultation with the National Joint Council, one of the topics that came up was let's be extra careful and we agreed with that, and did raise the number to four times or eight checks per shift per line.

So we have data on doing the checks six times per

shift, and now we have it at eight times. We did agree with that suggestion and did institute that as a policy.

Our staffing policy in the plants has been liberal in that we have worked out a staffing policy that we feel gives our inspectors and our inspector in charge ample opportunity to perform the functions that have been done. We wanted to be, again, conservative in how we introduced the system.

We also have the technical consultants who are our staff officers either in Omaha, in the technical center, or on the Washington staff that have been assigned to all of the plants. They work together with the in-plant inspection team, answer questions, provide information that's needed, and in other ways support the project.

There will be five presentations this afternoon starting with Dr. James on the food safety and other consumer protection conditions, followed by Dr. Dan Engeljohn who will discuss performance standards, followed by Dr. Harry Walker who will discuss the HACCP and the process control plants and the process that we have for reviewing those plans before a

plant starts its operation. The fourth presenter will be Dr. Hany Sidrak who will discuss the role of the inspector performing oversight and verification. Finally, Ken Peterson will talk about the in-plant control systems that are in place to be used in the model plants.

We will not be taking questions between each of the individuals here this afternoon. If you would, please make a note of any questions that come up. I think the best way to get through the process is to go through the whole process and then the panel of six will be available. We'll have a break as soon as the presentations are finished, and then the panel will be available to answer any questions that have come up during the course of the afternoon.

With that as an overview I'd like to introduce Dr. Bill James to talk about food safety and other consumer protections.

DR. JAMES: Good afternoon.

One of my favorite things to do after a meal is talk about food safety, so let's to it, shall we?

(Laughter)

One step in the development of the inspection models is that of distinguishing it antemortem and postmortem, animal diseases and conditions that are food safety hazards from diseases and conditions that are objectionable for other consumer protection reasons.

We published a Federal Register notice in July 1998 which announced the availability of our paper entitled "Diseases and Conditions Observable in Meat and Poultry". We have also discussed this issue at two previous meetings on the HACCP-based Inspection Models Project.

Now we are not aware of any pre-harvest program which is capable of producing young chickens that are free of all food safety diseases and conditions. Accordingly, we believe one or more food safety related diseases are reasonably likely to occur in all slaughter production facilities. Therefore, volunteer plants in the HACCP-based Inspection Models Project must have a HACCP plan to address food safety hazards.

The other consumer protection diseases and conditions are addressed in an establishment process control

plan.

Volunteer plants will modify their HACCP and other process control plans to address young chicken diseases and conditions that can be identified at antemortem, and verification of antemortem will be conducted as determined by the IIC.

Now young chicken diseases and conditions identified at postmortem are categorized according to their food safety or other consumer protection significance. We have classified certain diseases and conditions as food safety related because they are reasonably likely to one, contain infectious agents that can cause the product to be unsafe for human consumption; and two, be transmitted through a foodborne route.

Now diseases and conditions having other consumer protection significance are those that rarely or never present a direct foodborne risk, but are unacceptable components of poultry products.

The food safety or other consumer protection distinctions are based on current agency regulations and

clinical or epidemiologic literature. Diseases and conditions in both categories are to be removed from the human food supply.

In young chickens FSIS has identified to general postmortem food safety categories -- infectious conditions and fecal contamination.

Now infectious conditions basically have two categories. One we discussed for a moment this morning, septicemia which we will identify for our purposes as systemic or a generalized disease associated with the presence of pathogenic organisms in the blood stream; and toxemia which is systemic or generalized disease associated with bacterial products, toxins, in the blood stream. Birds exhibiting these conditions are condemned.

The second category is fecal material. fecal material must be removed from a carcass according to agency requirements or the carcass must be condemned. This standard has not changed.

Other consumer protection or OCP diseases and conditions adulterate products but are not food safety

hazards. We have developed five OCP categories for our current use. Examples that I'm about to review within each category have been presented in previous public meetings as examples of OCP diseases and conditions.

The first category we'll review is that of animal diseases. Some of the listed animal diseases and conditions are caused by infectious agents. These infections agents, however, are primarily or only animal specific pathogens that are not reasonably like to cause human foodborne illness. Now if this disease is localized the lesions can be removed and the unaffected portions of the carcass can be passed. If it is a generalized condition the carcass is condemned.

You can see some examples up here on the screen. They include conditions such as airsacculitis, tumors, and synovitis. Conditions exhibiting a septicemia or toxemia, I repeat, are considered food safety hazards and they are condemned.

Another category is one of superficial conditions. If they are localized, again, they can be removed and the unaffected carcass portions are passed. If they are

extensively, however, the carcass may be condemned.

Examples here include items such as breast blisters and bruises.

A third category is contamination with digestive content. This is handled in accordance with current regulatory provisions. Examples are up on the screen -- crop contents and ingesta.

Category four is dressing defects of a miscellaneous sort. We try to characterize these or lump into these categories defects which are of a like nature. This is something of a catchall category, however.

Examples of these miscellaneous dressing defects are feathers, lungs, and oil glands.

Then our final OCP category are dressing defects which contain digestive track tissue. Again, these defects can be removed and the unaffected carcass portions may be passed. Examples here include things such as crop, esophagus, and intestine.

In conclusion, we have made a distinction between diseases and conditions related to food safety and those that

are objectionable for other consumer protection reasons. These classifications are subject to change as new scientific information becomes available.

This distinction helps us to focus our inspection efforts. The following speakers will provide more information on this point.

Our next speaker will be Dr. Dan Engeljohn talking about how the performance standards were established.

DR. ENGELJOHN: Thank you. Good afternoon.

The significant aspects of the performance standard development for the HACCP-based Inspection Models Project are as follows:

The standards will focus on organoleptic factors. The microbiological performance standards currently in place are not intended to be changed at this time.

Organoleptic factors relate to the visible defects such as feathers, bruises, and scar tissue as just mentioned by Dr. James which when they're not reasonably controlled they contribute to adulteration determinations.

The organoleptic factors were grouped into common

categories. First, they were separated into the food safety versus the OCP or other consumer protection, different groups. Then they were further divided within those groups into more specific categories. Under food safety they were separated into an infection condition versus contamination. Under OCP the categories included those for contamination versus dressing defects and versus other condition aspects.

Right now we do have five categories. I would add that one of those categories relates specifically to ingesta because we do have an interest in looking at that at this time, so we did separate that category, particularly for evaluation during this project.

For the 16 participating plants, each plant's performance or the outcome data for each of the food safety and OCP categories was independently assessed. That is the data was not pooled or averaged across the plants. So that we will have 16 separate data points to be establishing the performance standard and I will go through that in a step-wise manner in the following slides.

The performance standards were designed to reflect

the current processing capability of the industry under the current inspection procedure. The agency's goal regarding these particular performance standards as well as all the performance standards that we are currently working on, is to tighten them as conditions change, as the industry is able to meet the standards, or as conditions exist such that the agency wants to tighten the standard to force improvement.

On this slide I want to talk about how we actually segregated the 16 data points and developed the standard.

Values up to and including the 12th plant which are the dark colored columns on the left side of this graph, represent the 75th percentile, meaning that 75 percent of the plants -- that's 12 out of 16 plants -- are represented by those dark columns. The other four plants are represented in yellow on the right side.

I also would like to explain that the numbers at the bottom of the graph are arranged left to right reflecting the best to the worst performance during the five week baseline study conducted by RTI for each of the participating plants.

The actual plant designated by the plant number on the bottom axis of the graph may be different for each of the OCP categories. That is plant X may be identified in the plant 15 position for OCP-1, but plant X may be in the third position for OCP-5. So again, we separated the data, determined the performance standard on an individual plant basis. We didn't identify the plants specifically, but we kept the data segregated.

For purposes of this discussion, the black columns represent plants one through 12 and they also represent the top 75 percent performance. That is these plants had the best performance for a particular OCP category.

The yellow columns, they appear in white on the handout that you have, represent the worst performing plants, and that would be four out of 16 plants.

I'd also like to point out that when I talk about percent of carcasses with OCP-1 or OCP-2 what that means is this represents the number of carcasses out of the 32,075 carcasses that were collected for each of the plants. So it's a percent carcass found with defects within a category.

Regarding the selection of the 75th percentile, this represents a tightening in terms of the current inspection system capability. We could have selected at the 100 percentile which would have been the 16 plants' data. That plant, as you will recall from this morning, was producing product that passed the current inspection system. So all these data points represent product that passed the current inspection system.

We selected the 75th percentile because it's a nice way to segregate the data. We could have gone with the 80th percentile or the 50th percentile or the 25th percentile, but we took into consideration current capacity to be able to meet the standard.

We also need to be considerate of the impact that the standard will have in terms of production as well as inspection, and those will be issues that we will welcome input from the stakeholders as we move forward with this project.

I'd like to point out that the performance standard represents the agency's current thinking. We do intend to

publish this project as a proposed rule this summer and would welcome comment on any aspect of the project, and particularly the performance standard.

On this next slide I'd like to explain a little bit about what we have here. Again, we separated this into the outcome of the 12th plant, which represents the top 75 performers out of the 16 plants versus the outcome of the 16th plant which is what we will call the 100th percentile.

For food safety defects, and it's listed here again as percentages, we've identified that for food safety one, and that would be the infectious conditions category, the performance standard or the data that was represented by the RTI sampling, showed a 0.1 percent for the 7th percentile or the 12th plant, and it shows 1.6 percent of the carcasses with food safety one in the worst performing plant.

For FS-2, it was 1.5 for the worst plant, 3.3.

For the other consumer protection categories, OCP-1 is at 1.7 for the 12th plant versus 6.4, and so on down the list.

Again, we separated the defects that were found or

recorded by RTI into the two food safety categories and the five OCP categories.

On this slide I'm presenting the actual performance standards for the HIMP plant, and this represents the maximum percentage of carcasses with defects within a category.

I want to particularly point out that for the food safety category we have the actual data which for food safety one was 0.1 and for food safety two it's 1.5. We adjusted the performance standard for both what the plant has to meet as well as what FSIS verification will check against to zero percent. There is a zero tolerance for both the food safety categories.

For the other protection OCP categories, we left the performance standards as represented by the 12th plant. Again, that's the 75th percentile or the top 75 percent of the performance of the 16 plants. Again I remind you that OCP-1 deals with animal disease. OCP-2 deals with conditions such as sores. OCP-3 with ingesta. OCP-4 with dressing such as feathers. And OCP-5 with intestinal tissue.

Again, I'd like to point out that we at this time

do have two food safety categories. I don't expect that we will be revising that, but certainly based on comment that we get with the proposed rule, there may be reasons to reconsider that. But for the OCP categories I can say that there is an interest in collapsing the categories down to fewer categories, but we would do that with looking at the data to see how it impacts on the performance and the product that would result from collapsing the number of categories. But at this time there will be five categories that we will evaluate.

This next slide presents some information that I'll go through, and I'll walk you through some information that's not on this slide but in the handout materials that you received you have a number of pieces of paper that walk you through the differences between the current FPS or Finished Product Standards system versus the new HIMP-based system. But just so that you can look at this and get a little bit of idea of what I'm talking about I pulled out the OCP-5 category specifically to make the comparison.

Within the Finished Product Standards group we have

the individual defects listed separately. They're not combined into categories. So for instance for intestinal material, the maximum percentage of birds with defects is 60 percent. For the esophagus it's 100 percent. The crop which has partial, it's partial crop with mucosa, is 100 percent.

In lumping these categories into one OCP category in the HIMP project, what we were able to identify was the number of carcasses with these defects resulted in a performance standard of 20.8 percent as opposed to the individuals for the defects allowable on maximum number of birds.

I'll just walk you through a few of the differences between the two systems which again are noted on the handouts that you do have.

In the traditional system, tests are conducted for each line hourly by the plants as well as hourly in the HIMP system. So there's no difference there.

In the traditional system, tests are conducted two times per line per shift on a ten bird sample by FSIS.

In the HIMP system, and this will be discussed at a

later presentation by Dr. Ken Peterson, tests are conducted eight times for the food safety categories, and they're conducted six times for the OCP categories -- two of which are on the birds themselves, on ten carcass samples. There will be two individual ones per line in the operation, so there will be two hands-on tests and then four records review under the HIMP system.

In the traditional system defects are grouped into categories as they are in the HIMP system. In the traditional system there are 19 processing defects and 14 pathology defect categories.

In the HIMP system at this time there are two food safety categories and five OCP categories.

In the traditional system different defects represent different or separate categories.

Within the HIMP system different defects are collected within a category.

In the traditional system, the sum of the defects are calculated against a standard.

In the HIMP system the sum of the birds, as opposed

to the defects, are calculated against a standard.

The way we've looked at the information from the two systems, when you sum the defects in the Finished Product Standards system, the importance of each defect is minimized, it's diluted. But in the HIMP system by calculating the number of birds against a standard, we believe that this enhances the importance of each defect.

On this slide I'm pointing out the FSIS verification activity that will occur. Again, the food safety verification will be handled through the HACCP system so I'm going to concentrate on the OCP activity.

There is an 85 percent criteria that was used in terms of determining the performance standard which means that a plant operating at the performance standard -- for example, for OCP-5 the performance standard is 20.8. If a plant is operating at that performance level we would expect the plant to fail 15 percent of the time. So by adding the 85 percent criterion into the performance standard and the verification activities, it adds an increased tightness to the process control that the plant would have to have, so

they certainly would have to take that into account in designing their process control system.

The FSIS verification samples can be accumulated throughout the day if necessary to provide a minimum size to evaluate. And we've determined that a minimum size is 50 birds. We built in some flexibility into the system to allow the IIC, the inspector in charge, to make some determinations as to whether or not the sample size can be increased, and we've developed criteria that reflects from a minimum of 50 bird sample sizes up to 100.

Again, this provides some flexibility but it also continues to define the performance level that the plant would have to meet and it maintains the 85 percent criterion.

I'd like to point out that for OCP-1 which there was quite a bit of discussion about airsac, airsac would fall into the OCP-1 category.

We've added an additional criteria to address a process that's inadequately controlled.

During the RTI baseline collection period, the maximum or the greatest individual number of defective birds

founds was 15 percent. Remember that the performance standard for OCP-1 was set at 1.7 percent. that was at the 12th plant.

So what we've done is if any time during the production 10 or more birds which are sampled and in accumulating those samples up to the sample size of 50 or 60, if at any time there are 10 or more birds found with OCP-1, then there are additional actions that the plant would have to follow up with to address this particular issue which we would deem to be out of control.

One of those would be following up with a 60 bird post-chill sampling, and I think Dr. Peterson will deal with that in more detail later in terms of how we handle verification by FSIS.

On this last slide I'd like to just point out some of the concepts of the verification activities that do occur, and I have two different activities up here, one being lot acceptance and the other being SPC or statistical process control.

Traditionally acceptance sampling has been used by

both the plants and by FSIS for a variety of processes. For the plants, acceptance sampling does not provide meaningful measures for process improvement. Each lot of product is independent of the next, and there is no indicator of processing variability from one lot to the next.

For FSIS, however, acceptance sampling has been an effective means of verification because it allows the agency to address acceptability of a lot at any given time.

If the plant does not have control over its own processing variability the chances of a plant passing FSIS verification is significantly reduced.

We built in what we would hope and encourage all plants to use during this model phase, statistical process control, and we're certainly intending to propose this as a requirement in the proposed rule.

Statistical process control is a means of characterizing the variability within a process and then controlling that variability so that the chances of passing the FSIS verification is significantly improved.

Again, we're considering making this a mandatory

requirement of the proposed rule, and we're encouraging the plants to take advantage of statistical process control during this models project phase because it is one way for them to be able to address continual improvement in their processing capability.

I put up some terms up here related to stable processes and capable processes. These are terms associated with statistical process which are measures to define if a plant is actually performing at the level they're capable of and if they're able to maintain it. So in the proposed rule we certainly will add additional information about that.

But in closing my discussion on performance standards, I'd like to again address the issue that we've established the standard tighter than what we believe the current system is, considerably tighter by setting it at the 75th percentile. We've built in the concept that we're interested in process system capability, and controlling the system as opposed to reacting to individual ten bird samples. So as a consequence we will be pulling samples throughout the day, and in fact be looking into ways of increasing the

sampling timeframe so that it can go beyond one day to more days, but those would be issues that we would bring up in the proposed rule.

Again, you should expect that we will be proposing this yet this summer.

Now you'll hear from Dr. Harry Walker. Thank you.

DR. WALKER: Thanks, Dan. Good afternoon everyone.

Today I'll be discussing the agency review of HACCP plans and process control plans or PC plans.

An important element in the review process of HACCP plans and PC plans is to ensure that a plant is ready to start the transition phase of the models project. If we determine a plan is not adequate, then we communicate this to the establishment and require that the plan be corrected. We retain the right to postpone the startup of transition if adjustments cannot be made in a timely manner.

Of course in order to review a plan, the establishment must first develop one and submit it for review. Their HACCP plan must address food safety issues and their PC plan must address other consumer protections.

The plan must be specific on how it will deal with food safety and OCP issues.

To let establishments know what we're looking for, we send guidelines for preparing industry HACCP and PC plans for FSIS review. I'll be discussing this a little bit more in a few moments.

Then we address the two basic components of the plan. The HACCP plan has to be consistent with regulation 417. Then we make recommendations to the PC plan.

Just to let people know, it takes 12 to 15 working days for FSIS to review the plan.

An outline of preparing a HACCP plan and a PC plan for FSIS review includes the guideline to industry. And in this what we try to have is a stand-alone document. In a few minutes this will be explained, each one individually, why we need the stand-alone document.

The next one is the elements necessary by regulation to constitute a HACCP plan and what we're looking for in the PC plan to include statistical process control.

Then just a few comments on the overall format.

I need to explain a little what I mean by a stand-alone document. What we're looking for really is a document that the inspector can sit down and read and be able to understand the plan with what's in front of him at that time. If there's any supplemental documents to the plan we ask that those be included so that the inspector can review it.

We feel this is to everyone's advantage, and an easy to understand plan is going to be less plan for the establishment explaining how the plan works and it's going to be less time for the inspector understanding the plan. I think that's to everyone's advantage.

On the PC plan, what we're looking for first is the regulatory requirements of 417. At a minimum it must have a hazard analysis, a flow diagram, the CCP locations, control measures, corrective actions, the frequency of monitoring, and verification procedures. One non-regulatory thing that we're looking for also is the performance standards for food safety conditions.

On the process control plan, again we provide guidance on the PC plan and it should contain at a minimum

the basic elements of the guideline draft 31899, process control based inspection in models plants. I'll go into this again in just a few moments.

And it should also have a listing of the performance standards for other consumer protection conditions.

The elements of the PC plan that we're looking for that I just mentioned are control charts. Of course control charts enable the establishment to track trends.

Sampling refers to how often carcasses are checked and the number of carcasses in the sample size. This of course should be based on the size of the lot being examined.

The upper limit should be at or below the performance standard. Documentation of process adjustments addresses significant changes in the process, and of course we'd like to know what type of recordkeeping is occurring and who the designated officials are. In case there's a problem who do we go talk to?

On statistical process control the only thing we're really asking is, we're telling the plants that we strongly

encourage the use of statistical process control because it predicts trends. Dan explained a little earlier the importance of that.

Just a few comments on the overall format. When there's a review team reviewing this over the phone in several different locations it really helps to have a table of contents that references the page numbers. And of course when we talk to the plant the same problem occurs, we can't communicate where the problems are.

It's also helpful to identify the appropriate parts of the HACCP and PC plan that address antemortem and postmortem.

So the ongoing process, that's the final step. When the establishment starts a transition phase, a technical consultant from headquarters is present to ensure that the actual plant practices conform to the submitted plans. So when we receive a plan, we review it, make sure it conforms to regulatory requirements of HACCP for food safety conditions, make recommendations on the PC plan for other consumer protection issues, and inform the establishment of

our findings.

When the establishment starts transition, a technical consultant is present to ensure that the actual practices match the written plan.

The next speaker will be Dr. Hany Sidrak.

DR. SIDRAK: Thank you, Harry.

I'll be talking about oversight and verification inspection procedures under HIMP.

A HIMP establishment slaughter inspection consists of two types of procedures -- oversight inspection and verification inspection. FSIS inspectors are trained to perform both types of inspection procedures.

The inspector in charge, IIC,has the responsibility to determine how to allocate inspection resources in the plant.

Unlike the traditional slaughter inspection system where inspectors are assigned to fixed points along the slaughter line, inspectors in a HIMP establishment may be assigned to perform oversight inspection at any point in the evisceration process. HIMP inspection activities are

designed to fit the individual establishment's HACCP and process control Pc systems.

Oversight inspection consists of inspectors continuously observing slaughtered carcasses and plant employees conducting sorting and other on-line activities. Every carcass receives oversight inspection.

Under oversight slaughter inspection, inspectors make expert and informed observations of the establishment's HACCP and PC systems. For example, inspectors may perform oversight inspection at places where plant employees are monitoring critical control points and at points where critical equipment such as poultry eviscerating machines are operating.

Inspectors conducting oversight activities are equipped with modern technological devices to rapidly report to the IIC any observations of potential process deviation. For example, the eviscerating equipment in a poultry plant may not be perfectly aligned for the size birds that arrived that morning. As a result, an unusual percentage of carcasses may be contaminated. The oversight inspector

rapidly communicates excess contamination to the IIC who decides how to respond.

Verification inspection consists of inspectors taking samples of product and carefully examining them to ensure regulatory compliance. Inspectors examine all establishment records including HACCP records. Inspectors also review and determine the adequacy of corrective actions taken when deviations occur.

Verification inspection procedures are carried out by inspectors after the establishment's HACCP and PC systems have been completed. HACCP systems address food safety concerns and PC systems address other consumer protection concerns.

Verification inspections are conducted at two frequencies. The first frequency is a routine or steady state frequency designed to confirm the establishment's regulatory compliance and the second frequency the IIC may choose to assign verification inspection procedures in response to oversight inspection findings reported to him or her. This strategic assignment of verification inspection

enhances the capacity of the regulatory system to hold establishments accountable for the continuing successful operation of their process control system.

In this slide it shows that unlike the traditional inspection where an inspector is assigned to a fixed location, here inspectors can move up and down the eviscerating line to conduct oversight inspection.

Another slide here is showing an inspector conducting postmortem oversight procedure and she is using a quick communication device to report findings to the inspector in charge.

I have a couple more slides regarding verification inspection. In this one the inspector is conducting antemortem inspection.

Another example of verification inspection is inspector performing a fecal zero tolerance verification check. That is done eight times per shift per line.

FSIS is able to quadruple the number of food safety checks and conduct two OCP procedures in addition to four examinations of establishment sample records per line per

shift.

That's another example for a verification check on the anti-microbial chemical level.

My final slide is an example of how HIMP made possible for industry to use modern technology. Showing is an establishment employee using a technologically advanced carcass disposition recording system. By pressing the appropriate position on the key pad, data such as carcass postmortem disposition and product performance standard testing enters directly into the computer system, allowing for continuous monitoring by establishment management.

I'd like to point out that this data is also available for FSIS verification at all times.

Next is Dr. Kenneth Peterson.

DR. PETERSON: Now we're going to look at what are our in-plant regulatory controls. These activities are based on basically everything that we've heard so far this afternoon.

The next two slides are going to provide us just an overview of what we do and then we'll look at each of them a

little bit more closely.

We conduct continuous oversight inspection of the plant implementing their HACCP and process control plans. We've heard about how we review their plans, now we're looking to see that they're actually doing what they told us they were going to do.

We conduct scheduled verification at antemortem; scheduled verification of product for food safety hazard; scheduled verification of product for other consumer protection defects; scheduled verification of the HACCP and PC plan records. Again, we just heard some of the elements that are in their plan which includes documentation, so again, are they doing what they said they were going to do?

We have the opportunity to conduct unscheduled verification of products or records should the need arise.

We document our findings and we retain our regulatory authorities.

It's becoming a popular slide.

(Laughter)

This is an example of an FSIS inspector, in this

case the veterinarian in charge, conducting a scheduled antemortem.

Currently in a traditional plant, antemortem is really a random activity that we do basically when we get to it. And those activities are infrequently documented.

We've changed that to become a scheduled activity to include scheduled record checks of what the plant is observing when they do their antemortem.

Verification of food safety hazards. We look at ten birds at the pre-chill location eight times per line per shift. So 80 birds per line.

As far as scheduling this activity, it is four times more frequent than we do under the traditional system.

We do the verification for food safety hazards for the two food safety categories that we've had mentioned earlier.

The first one is the so-called FS-1 category. We check to see that birds do not exhibit septicemic or toxemic conditions. This is a new food safety verification that we do not have in the traditional plants, so plants under the

HIMP system now are subject to this food safety hazard.

The verifications for zero tolerance are basically conducted the same way we do in traditional plants, except with the increased frequencies.

Should we find a failure, our response in these plants is the same as it is in a traditional plant that's under HACCP. A non-compliance record or NR is written by the inspection service and the plant must initiate corrective and preventive actions. Except in the HIMP plants they're subject to that for these two food safety hazards instead of just one.

Verification of the OCPs. We verify each of the five OCP categories that we've had mentioned earlier. This activity is done six times per line per shift. Fourth of those six are records checks. Again, is the plant doing and documenting what they said they would do?

Two of those six are ten-bird verifications per line, for each of the five OCP categories. However, with the increased staffing flexibility that we're now afforded because we're not at fixed locations, the IIC, should the

need arise, can shift some of the scheduled sampling, bias it if you will, away from lines that he or she believes are under control towards lines that he or she has questions about control. So we can shift our sampling as the need arises.

As we've just seen for the oversight inspection, we can conduct unscheduled sampling. The oversight inspector identifies a particular problem, we can react to it, verify it with unscheduled sampling.

So for each of the five OCPs the plants are expected to meet the performance standards on a per shift basis. The IIC documents these daily results. So how do we do this?

For the OCP categories, we expect the plants to maintain continuous process control. To monitor this we evaluate it over a 25 day period. We'll look at an example.

Let's presume we have a typical three line young chicken plant. We would routinely check 60 carcasses for each of the five OCPs in that plant per shift. So 20 carcasses per line routinely.

If we take the OCP-5 example which Dr. Engeljohn mentioned earlier, again this category includes things such as pieces of crop, cloaca, those kinds of things.

From the 16 plant data we found that the maximum allowable, which is the expression of the performance standard, is 15 out of 60 carcasses.

Also what we found from the 16 plant data is that under the current system if we apply this new standard, the current system would have failed this standard five out of 25 days. The 25 days is, you'll recall, the organoleptic sampling period that we had in these plants.

So that's the accomplishment of the current system.

How do we track it in the HIMP plants? Well, as I said, each day we'll take the OCP-5 example, we monitor the carcasses to see if they have fewer than these 15 out of 60 defects. If they exceed the 15 at any time during the day then we notify the plant. If they exceed it three days from now, we notify them again. We expect that as we get incrementally closer to the five days, we would expect a plant to react to that and look at their process. Why are we

going out based on the inspection results? Is it an equipment problem, a training problem? What is it? So they can start to deal with it.

If, however, they don't control it and they exceed the five out of 25 days, then they must reassess their PC plan to include detailing new preventive and corrective actions. We do a similar activity for each of the other four OCPs. So we track them over time.

As was mentioned in Dr. Engeljohn's presentation, for the OCP-1, which is the animal diseases, we do an additional OCP verification. Animal diseases are not processing defects. We expect them to be controlled a little more closely. They're subject to what was previously referred to as the maximum limit. So for OCP-1, the maximum limit, again using this three line example is nine carcasses at any time during the shift.

If the plant exceeds that they've exceeded the maximum limit and that again arises from the baseline data. If they exceed it at any time, then they must go to the post-chill location because that's where the represented product

is, and begin testing for this category. If they fail, then they are subject to reworking that product to bring it back into compliance for this category.

They must continue that post-chill testing until they reestablish the process as being under control at the pre-chill location.

So what do we have? We have now two food safety performance standards. We look at them more frequently. We have the same regulatory authorities. We do continuous oversight at any location. We track all of the OCP categories over time. However, for the one category, we'll look at them a little more closely. And we have the flexibility to verify that the process is in control, flexibility through unscheduled sampling or biasing our sampling towards different lines to monitor the process.

I believe John McCutcheon has some good news.

MR. McCUTCHEON: To give you time to properly prepare your questions I propose that we take a 15 minute break and that we reconvene at about five minutes of 2:00.

(Recess taken)

MR. McCUTCHEON: If we can get started with the questions and answers.

There's a page that looks like this that you may remember from Dr. Engeljohn's presentation. We have tried to put copies of that out at all the places. Unfortunately, it was left out of the hard copy that you picked up at the front desk. So if you would, you can just add that to your package.

We're open for questions. If you would remember to identify yourselves for the purpose of the record, and if you would identify which panelist your question is directed to, that would be helpful.

MR. POCIUS: Joe Pocius with Wampler Foods.

I guess the question is for Dr. Walker, and it has to do with the review process and the approval of the plan.

Could you walk us through a little bit of what the steering committee's role is and how this whole approval process takes place? I'm not sure I'm clear from your handout here.

DR. WALKER: In the review process the steering

committee oversees what we do and makes comments and recommendations. If something comes up that I don't understand as the coordinator for the technical consultants I take this to my Mike Grasso and he will then either answer for me or take it to the steering committee.

I'm not quite sure if that answers your question. I may not totally have understood it.

MR. GRASSO: The process that we use is that the establishment submits not for approval but for review and feedback on both the HACCP plan and the process control plan.

The steering committee does not review those plans. Dr. Walker heads up a technical team from the Office of Public Health and Science, OPPD&E in Washington and the technical center, Omaha, Nebraska, and then they review the document and we provide verbal feedback to the establishment on both plans.

Does that help?

MR. POCIUS: Yeah.

MR. GRASSO: We actually have a conference call with the plant after the review and then if any changes have

to be made, those changes are made, the IIC is involved with the conference call and the changes that are made between the plant and the IIC.

MR. POCIUS: Is the difference between a review and approval a subtle word?

MR. GRASSO: It's a major word.

MR. POCIUS: If a plan is submitted and goes through a review, comes back with recommendations. Those recommendations will be taken and put into play where they can be, but some may not be if it's not possible. How then would the plan -- What's the future of that particular plan?

DR. WALKER: If I could answer that here, if it's dealing with food safety issues it must comply with the current regulations 417. There are some things in food safety that we are recommending. As I mentioned earlier, the performance standards for food safety, for example.

The other things that we make comments on are in the process control portion of the plan. And those we make recommendations on.

Once we get through with this process of making recommendations, it is then between, I can't say totally, but pretty much between the IIC and plant management to come to terms on whether the plan is going to work the way it should.

MR. POCIUS: Let me ask another question that may play into this, it may not.

Earlier we were talking about the OCP and if the OCPs, any one of them, were failed five out of 25 times, you go into post-chill check and you continue to post-chill check until you gain control up front.

Let's for instance say that maybe it's feathers. Let's say we can't gain control up front. We just decide okay, we're going to do post-chill checks. How long do we go and do that? What's the action?

Is it the intention of the agency over time to shut a line down for feathers, for instance?

MR. McCUTCHEON: Ken, does that get into your area?

DR. PETERSON: The performance standards as of now, and we'll take the example you're talking about, feathers, are to be met where we collected the baseline data, and

that's at the pre-chill location. For the example you gave, we don't do any post-chill activities related to these OCP activities other than OCP-1. Those post-chill activities I mentioned are limited to that category.

So we expect them to be met, as I said, consistently over time.

I think during the actual models phase, I'm not aware of any plants that are having repetitive problems, cycling in and out of this 25 day period.

If we get into that situation then it is a pilot and we have some leeway on exactly how we want to approach that.

Once we get to a rulemaking activity I think our enforcement actions related to that would be more clearly described. So we're in a pilot phase. We have some flexibility that once we get into a rulemaking mode would be more open for everyone.

MR. BYRD: Ken Byrd with Pilgrim's Pride.

I had a couple of questions. I was wondering on the slide of the veterinarian doing the antemortem, I wonder

if he changed his coat before he went back out to --

(Laughter)

DR. PETERSON: We checked, and he definitely did.

MR. BYRD: Did a zero tolerance check on him.

Something a little more on the serious side. Dr. Sidrak, in your presentation you were giving the example of the oversight inspection that an inspector observing an eviscerater out of line that was causing a higher than normal number of contaminated carcasses.

My question is, what is the standard that that inspector would use to make that determination? Is there a standard for this? Is there some guidelines? Is it an opinion? What standard would they use to say okay, you've got too many contaminated carcasses? And is there a possibility that this over a period of time could get off course and get back into command and control type inspection?

DR. SIDRAK: What I wanted to come across in that slide, if the inspector observes more contaminated carcasses as compared to what they're usually used to seeing. Remember they have used also the terms that these people, meaning our

inspectors, are trained expert individuals and looking at the process. That's a very important point to bring up here. That's not just a casual observation. These people are used to seeing, for instance, let's say a two percent contamination in all day scattered.

When you have a situation as I described, you're seeing more frequent contaminated birds, and at that point in time they cannot leave the oversight activity and go perform something else. They are merely conveying that observation to the inspector in charge who might choose to react in different ways. One of them is to instruct another inspector to conduct a verification activity, meaning going to at the end of the line after the final wash, before the chill, and conduct a zero tolerance check, for instance. That might reveal that the process is in control and that's it.

So I don't think this will bring us back to command control, per se. We're just saying that there is more flexibility for us to make sure that the compliance is met.

MR. McCUTCHEON: I might add there are really two ways we see that being used. One is the inspector in charge,

let's say in the morning if he knows that an above average, weight wise, a lot of birds coming in, may request that additional unscheduled verification checks could be made to be sure that the equipment is in fact adjusted properly before it gets started. So the IIC could use it with whatever other additional knowledge he has to do that on a regular basis.

In addition, the unscheduled verifications are done by the, requested by the oversight inspector when they see something going down the line. And we think that's a way of designing a responsiveness into the system to use professional judgment. And if in fact everything is "okay" then the additional check should show that it's okay and there shouldn't be a problem.

MR. MINA: Can I add something to that response from a practical standpoint. If every bird that's coming down the line or every other bird is contaminated, that obviously is excessive, and we're going to take whatever action to correct that situation including stopping the line, asking you to slow the line down. Those are the actions we

have taken traditionally. And HIMP would not change that.

MR. BYRD: Where I was coming from were the borderline questionable. Not the wholesale every bird coming down is contaminated, but some of the in-between type instances where well, it may be a little more than what we might see, but it's not too awful much either or some of those in-between gray areas.

MR. McCUTCHEON: Was there a question over here?

MS. DeWAAL: Caroline Smith DeWaal, Center for Science in the Public Interest.

I want to get back to the questions on airsacculitis. And essentially how this -- This program was premised on the idea that there are very low disease rates among these poultry products, and yet some recent news reports have indicated that in fact in some of these plants the amount of diseased poultry may be much higher than we thought.

Can you give us a sense of what the disease rates are for airsac? And then I have some followup questions.

MR. McCUTCHEON: I'll call on Bill James for that.

DR. JAMES: The agency keeps statistics on condemnations of young chickens and we report them each year. The levels of condemnation in young chickens, I'm pulling this out of my memory, was .6 or .8 percent, a very small number of young chickens.

So when we say this project is designed for young uniform healthy animals, young chickens as a class of animal meets that. That's a very low condemnation rate.

We are aware, though, that when disease presents itself, it is not necessarily in a uniform manner. So reports of high levels of airsac in some areas of the country during some seasons is not news. We believe this process that we're developing will be able to control that. This will be tested.

MS. DeWAAL: But reports on highly contaminated meat products being produce out of airsac lesions, I guess, seems to be news, so I think we need to deal with that.

What percent of the airsac poultry is not condemned? You were saying earlier based on questions I was asking that the airsac can lead to a septicemia but

frequently it leads to lesions.

DR. JAMES: That is a statistic that I don't think we would know. Most birds that come into the plant with airsacculitis are handled in such a manner that the carcass need not be condemned if there is not a septicemic condition. But which proportion of birds have airsac and then are passed is not a statistic the agency keeps.

MS. DeWAAL: On Dan Engeljohn's presentation he said that airsac would be treated as an OCP-1 and yet the condition sores, which the lesions seem to be described as sores, is treated under OCP-2. Can you tell me where airsac is being -- What it's being counted as right now?

DR. ENGELJOHN: Airsacculitis is included in OCP-1 and sores is in OCP-2.

MS. DeWAAL: So septicemic birds would be treated as one and --

DR. ENGELJOHN: No, septicemic would be treated as a food safety in FS-1 which is an infectious situation. So once they reach that point they're a food safety issue.

MS. DeWAAL: But the lesions from airsacculitis are

treated under which category?

MS. GLAVIN: OCP-1.

The reason I jumped in is, you referred to some recent press accounts, and I just wanted to reiterate that following those press accounts both the agency and the Department's Office of Inspector General went into those plants and did an investigation and found no evidence of adulterated product being shipped or of other violations of the law.

MS. DeWAAL: And adulterated in this instance includes unwholesome product?

MS. GLAVIN: Yes.

MS. DeWAAL: And finally, one more question just on the same page and then I'll turn it back over to someone else because I have more I'll ask later.

On OCP-2 and on OCP-4, you seem to be permitting rates as high as 52 percent of product under these, the HIMP plants can have sores and 80 percent can have feathers. For the feathers, why have a standard at all if 80 percent of the birds can have them?

But is that standard for sores really sufficient? I think consumers would like to see that standard much lower.

DR. ENGELJOHN: I'll just the issue again, we were taking the data that was compiled by RTI which was actually collected on the individual defects. We categorized them into categories that has multiple defects within a category for the most part. So for instance for OCP-2 where sores are included it includes a number of other things that are there, so it's not the only thing within that category that counts towards that number.

But again, the numbers that we have, referring to OCP-2, again at the 75th percentile where 12 out of 16 plants were actually performing, that establishes a level of 52.5 percent of the carcasses that would have any number of defects within OCP-2. Whereas the worst plant participating in this project we found 86.9 percent in the 16th plant.

So this, in terms of process capability and what may in fact be happening within the industry today and getting to the system we currently have, the worst plant in this particular project showed 86.9 percent for that same OCP

category.

So can we tighten that standard down because we don't believe we should be setting the standard at the worst case for this particular project because we do have the goal of process improvement and performance standards. So we established a standard lower than what the process is currently achieving under the current inspection system.

MR. McCUTCHEON: And I'd like to add to what Dan just said, too. That's the starting point and the logic of how we got to that starting point, but as Tom pointed out before, this is a starting point and the intention is as time goes by that we would be improving those standards.

MR. SEWELL: Alvin Sewell with the National Joint Council of Food Inspectors.

I've got several questions starting with issues of food safety. We discussed earlier the performance standard for food safety and we have one plant in the pilot project that before implementation of HIMP had five, over ten weeks time had five zero tolerance failures, food safety failures. After HIMP the same plant had 40 failures. The rate of

testing for food safety was increased, that's true, and this has been discussed before. The rate of testing increased by four times, correct?

MR. McCUTCHEON: It depends upon the period. Either three times or four times.

MR. SEWELL: Then the rate of failure increased by eight times in this scenario. And this clearly would demonstrate -- and these failures were not concentrated in a couple of weeks or whatever, this was spread across two months time. This to me clearly exhibits a failure of the plant's HACCP plan concerning a food safety hazard.

Why then is this situation tolerated and as of yet no enforcement action's taken place in this case, and the failures in that facility have continued as recently as yesterday.

So my question is, why is that allowed under HIMP when it's not allowed under the law of HACCP?

MR. McCUTCHEON: Without the actual information I don't want to respond to a particular situation in a plant. If you have some data we need to look at or a situation to

look at we'd be glad to do that.

I think Dr. Peterson did point out that we do have a process in place. We did have, although you're referring to, if you're referring to food safety issues we did make a change and have improved the process on OCPs over the course of the experiment such that we have a much improved system with the three layers of the ten bird samples, the daily samples, the 25 day sample situation that is there so we can get a good system's view of the plant.

MR. SEWELL: That's for OCP. I'm talking about food safety.

MR. McCUTCHEON: In the food safety area, we just have to take a look at what plant you're talking about, what information you're responding to. Because without that information, I can't respond specifically to --

MR. SEWELL: I discussed that with the agency on two occasions, as a matter of fact, in the month of February.

Another issue on food safety issues, and we touched on this before, in which Bill James commented that the presence of the visceral organs was an integral part of the

disposition on septicemia and toxemia, yet the verification process in the HIMP model which would make the decision as to whether the process control plan or in this case the HACCP plan is functioning properly, is done without the viscera. There's a lab report, and I'm quoting the lab report, concerning in a HIMP plant where a carcass that was affected with a septicemia/toxemia condition was sent to the lab. The lab report was returned saying that this requires examination of tissues with gross lesions as well as tissues comprising the major organ systems -- cardiopulmonary, urinary, lymphoid, intestinal, et cetera.

Trimming away and removal of gross lesions and major organs without the benefit of examination is equivalent to the loss of crucial evidence in making your determination. How then can we make a determination on food safety in a verification process that has no viscera?

DR. JAMES: Bill James, FSIS.

The question you bring up was considered when the design of verification of the process was drawn up. It is true, I said that viscera are currently used and always have

been since this poultry inspection was implemented in determining whole carcass dispositions.

The decision was that there would be less of an impact on the normal process if birds were evaluated at the end of the line than if we tried to insert ourselves right at the point at which the dispositions were being made. We did not want to impact the normal process by our presence.

The viscera are used on occasion to help us make a whole carcass disposition, but it was the, I believe it was a unanimous decision of all the veterinarians of great experience involved in that decision both in headquarters and the field, that experienced veterinarians, veterinarians who have been trained, can make a fairly accurate disposition without that viscera.

The viscera is the ideal, an ideal component to have in making a whole carcass disposition, but if you have a veterinarian there with some degree of training, a good decision can be made without it. We'd rather have it, but we can get by without it especially for purposes of this project and trying not to impact normal process.

MR. SEWELL: I'll finish up and then I'll let you off the hook on this.

With regard to the OCP checks for, four being records checks, two being actual hands-on checks. We've recently looked at the data from a HIMP plant in the models project, and the red line on this chart indicates the rate of failure of FSIS testing and the blue line on this chart indicates the rate of failure -- I'm talking percentage of tests that result in failure -- that result in failure on the plant's part. These two lines are clearly out of correlation.

This indicates a testing inaccuracy on the plant's part, yet four out of the six tests during the day rely on those records or that process control chart to indicate process control in our process of verification. And the National Joint Council has a specific concern about the discrepancy in this data and the reliance upon recordkeeping as a measure of process control.

It would seem to me that part of the correlation process with any plant under any inspection system previous,

current or in the future should involve a correlation that brings the testing standard of FSIS and the industry in general agreement, in something better than the correlation discrepancy that we're seeing here. So that's a specific concern.

Now one more issue I'd like to talk about, John is this issue of staffing in which you said there was a liberal staffing policy for the HIMP plants during this phase, yet we've got a HIMP plant in the models project that is short staffed most of the time, at least by one inspector or more, and in the previous material you discussed the need for employee training, employee supervision, computer training, this direct, the supervisory component of this process. But the supervisor not only was in an oversight capacity during the short staffing scenarios -- this isn't an intermittent situation, this is a chronic situation -- and I've since learned that this is a district policy that says that that short staffing situation is going to be tolerated up until the point that it causes down time for the industry. That's not in keeping with what we're seeing in terms of your

material presented concerning the staffing levels, the training intensity, the correlations, the computer training and this kind of thing.

Not only did the IIC wind up in the oversight function which took him out of the supervisory function and the ability to move amongst all his subordinate inspectors and overseeing their activity, did you not tell this group that oversight was to be continuous?

MR. McCUTCHEON: I did tell this group that oversight is to be continuous, and that is the policy and that is what is being practiced in the plants. My comment was relative to the staffing patterns that we agreed to.

Now on a daily basis in any individual plant there can be shortages that show up. And in the staffing that we had, we have a relief inspector that is assigned to all the plants.

Now on occasion, you do have situations where you don't have all the staff that was projected to be in the plant. However, the line will not operate without proper oversight inspection being given, and that is the policy of

the agency.

So you're saying that oversight was given. Now in that case it was maybe given by the IIC, but it's not unknown for IICs to go on the line to give breaks and so forth in traditional plants too, when necessary. It's not desirable, and as we go further into the models project and we have more plants in the model situation and we can share some resources from plant to plant, individual spot situations like that will change.

My comments related to the staffing pattern itself and not to a day-to-day type of issue. But in no case will oversight not be conducted.

MR. SEWELL: I beg to differ. The IIC was in the oversight capacity, and I have four statements that are signed by inspectors that witnessed this supervisor in this oversight capacity who left the oversight function for a total of 55 minutes, and that line received no oversight.

MR. BILLY: Alvin, I think I'm going to intercede here. For the record I think it's important that everyone in the room recognize that the union has filed suit to prevent

the agency from pursuing this pilot and obviously trying to achieve the improvements in food safety and other consumer protections that we've talked about today.

So you need to be clear to everyone what's behind your effort and your motivation.

Secondly, our experience in the past has shown us that your assertions and the assertions of the president of your union, when checked out almost always don't check out and the facts aren't as you report them to be.

What I'd like to suggest is that given the fact that you now are appealing the case that you lost in federal court, that you submit this data and this information to us and we'd be happy to respond in writing to each and every one of your assertions and the concerns that you've raised.

MR. SEWELL: May I respond to that? You're talking about a lawsuit. I'm not talking about a lawsuit. I'm talking about a condition that exists within the plant now. I'm not even talking about something that's already been settled. And your assertion suggests that this information is less than truthful or less than of honest motivation and I

reject that.

And I will say this to you and I've said it before and I'll say it to everybody here. I've been personally involved in the HIMP training of the inspectors in this project, and we have told these inspectors in earnest that this is the new system. Interface with the new system, learn the new system, move into the future.

So I reject that we have some sort of motivation to discredit this system.

We have specific issues, Mr. Billy, that I think we need to address, and I think at the end of this process hopefully we will have a system that's functioning better than it is right now, and that's the intention of my comments.

MR. BILLY: Then I strongly encourage you to provide all of that information that you've just referenced and do it formally in writing so that we can respond in kind.

MS. BEERS: I'm Allison Beers with Food Chemical News.

I just wanted to follow up with a little bit of

what Alvin was saying about the zero tolerance data, and I know you said you didn't want to comment on it, John, until you have a chance to look at it and I'll definitely follow up next week.

But one thing that I think would be helpful, if you all are prepared to discuss it at this time. I know the agency committed to taking daily salmonella tests in the model plants during the transition phase as they're moving into the model before RTI goes in to collect the model data.

Can you all give us a little bit of information about what that salmonella data looks like? Does it correlate at all with this zero tolerance data that Alvin's come up with? Have any of the plants failed the salmonella standard during that time?

DR. PETERSON: Yes, we did initiate salmonella compliance in these plants as they've entered into the transition phase. That's been our policy.

As each new calendar year comes along we tend to reinitiate testing in most of the plants kind of in synch. So what I'm getting to is this year when we have models

plants coming on line, some of them have recently started a salmonella set so there is some overlap there, but they're still under the compliance mechanism.

I'm not aware of any of these models plants that have failed a sample set while they're under the project, however, I'll certainly look at that more closely and follow up.

Regarding the correlation between fecal and salmonella, in fact in the literature there is a very poor correlation. When you look at correlations between E-Coli counts with salmonella, it's just not there. So salmonella is something that we've seen in our own agency data that was initially in 20 percent of the carcasses. That's our performance standards. It's coming down under HACCP. But there's no direct correlation between zero tolerance failures and salmonella rates in these plants.

MS. BEERS: Thank you.

DR. LaFONTAINE: Dan LaFontaine, American Veterinary Medical Association.

I have more of a statement than a question at this

point. I do have some questions later.

First of all, I wanted to state for the record that the AVMA has from the beginning supported exploring this concept of turning this responsibility over to the industry provided there is adequate government oversight and verification, and we continue that today based upon what we know and what we've seen.

In addition to that statement I wanted to comment on food safety versus OCP-1. That is the birds that are septicemic and toxemic as opposed to those that are sick with airsacculitis or any of the other disease entities.

Many of you heard me say this before, but disease processes are a continuum. A sick bird today tomorrow may be toxemic or septicemic. It's a very fine line between those. So we're really talking about a very fine line between a sick bird that is unwholesome and a bird that's been overwhelmed by the infectious process and clearly has the virus or the bacteria throughout its system and needs to be condemned for a food safety reason. It's a degree of pathology.

What I'm leading up to, and this may sound parochial, but I mean it with all sincerity. There is a need for veterinarians with the proper skills, both industry veterinarians and FSIS veterinarians to in these slaughter plants, to make sure proper dispositions are being made and that in fact those birds that are septicemic or toxemic are being clearly and consistently eliminated from the marketplace.

I'll just stop there, but I wanted to make sure that point was made for the record.

I'll have some questions later.

MS. NESTOR: Felicia Nestor, Government Accountability Project. I'll try to get a few things out of the way real quick.

Based on the chart that Alvin showed with the company records versus not correlating with the plant's records, I'm wondering if FSIS would consider reporting to us at the next public meeting or at the following public meeting on -- I know you want to blind the data because you don't want any of the single plants data out there. Would FSIS

consider reporting to us what the plants are reporting for these conditions versus what FSIS is reporting? Because if I'm not mistaken, enforcement of OCP is based on twice as many company records as government records. So consumers will be heavily reliant on company records.

I'm not saying we need to know any particular plant's records, but just some sort of comparison.

MS. GLAVIN: I think we'll be glad to take that under consideration and look at whether that's doable.

MS. NESTOR: Thank you.

MR. McCUTCHEON: I just would like to make one comment, because the issue of correlation has come up.

It is a very key part of our operation in the plants that correlation between the plant management and the FSIS inspection team take place on a regular basis. And that is something that we do take a look at. We focus certainly on the food safety aspects of that most thoroughly. But it is of concern to us to see that in fact we are on the same page and we do follow upon that on the individual plant basis.

DR. HENDERSON: May I respond to that also?

MR. McCUTCHEON: Sure.

DR. HENDERSON: For the OCP-1, we are taking all of the samples for the day. In a three line plant that would be 60 samples. And those are added together to determine whether or not the performance standard hard been exceeded.

If a plant is not being up front in some way with their data, there is no way that they are going to be passing those 60 bird tests.

MS. NESTOR: Are you saying I was wrong that the 60 bird sample does not include four company samples?

DR. HENDERSON: No, the 60 bird test does not include any company samples that we are doing at the end of the day. Those are all FSIS samples that are taken across the line for that entire shift. Those are added together, and that is where we get the performance standards where we had two out of 60. They have to be able to meet that at the end of the day. If their figures are not correct, there is no way that they're able to meet that performance standard on a daily basis.

MS. NESTOR: Okay, I'll look again. I was quoting from the BNA reprint supposedly of FSIS' enforcement policy on OCP and it said that it would be two government samples and four --

DR. HENDERSON: There are two per line. So if you have three lines -- You're adding them up over the day. We're adding all of the FSIS samples over the day.

MS. NESTOR: Okay. I'll look again at that.

MR. McCUTCHEON: All the regulatory decisions that Ken Peterson talked about are based upon only FSIS samples.

MS. NESTOR: Okay.

MR. GRASSO: There may be a misunderstanding with the pulled records check, but the plant indicates to us in their plan how many samples they're going to take per day per shift. And part of our records check is to number one look at the documentation or the results of their direct bird examination, which has nothing to do with our direct bird examination.

In addition to that, to observe the establishment and number one, the selection of those carcasses and number

two, the evaluation of those carcasses. That complete record check is done four times a day.

To follow up what John said, in our instructions to our inspection personnel, the second paragraph speaks to the importance of ongoing correlation activity between FSIS inspection personnel and the establishment so that the data collected by the two sides on their direct bird examination gets closer together.

MS. NESTOR: Okay.

I have a question about the IIC being pulled to the line. You're saying that happens in typical, traditional plants, and that it may happen under this system.

If I remember from your description of oversight at one of the last public meetings, I thought that the IIC had to be available because the oversight inspectors on the other lines, if they come up with a problem, they are supposed to radio the IIC to come and take care of that problem. So if the IIC is pulled to the line, how is that going to happen?

MR. McCUTCHEON: I'm saying that on an individual plant basis occasionally there may be a staffing situation

that develops due to a shortage, but that we will provide, the policy is that we will provide oversight inspection for any line to be able to operate.

MS. NESTOR: That doesn't answer my question. What would an oversight inspector do on the line if there were no IIC available to come and assist that person?

MR. McCUTCHEON: No, the IIC doesn't come and assist the person. This is where we're --

MS. NESTOR: Reacts to a problem that the oversight inspector sees.

MR. McCUTCHEON: What the IIC has to do, and that's why we have a communication system, so that we all can be in communication with each other in the plant on a continuing basis. So the IIC could be called upon to make a decision if there's a verification check that's going to be needed in another part of the plant to agree to have a verifying inspector go ahead and do that verification check. So he wouldn't have to leave the line to go do that. That's why we have the communication systems in the plants.

MS. NESTOR: So that's the only thing the IIC does,

really, is decide whether a verification inspection should be done?

MR. McCUTCHEON: The IIC has a large, complicated job. He doesn't do all the things -- He also have to evaluate the 25 day samples, et cetera, but he doesn't do all of those all the time. They get done during the course of the day, but it's not a continuous operation.

MS. NESTOR: Okay

One more question on OCP.

Whoever gave the presentation on OCP said that if you fail, for instance, OCP-5 five times in a 25 day window that the window gets restarted again, right? They failed the -- right? And you said the plant must meet this. Must or else what? Do you shut the plant down if they fail six times in 25 days?

DR. PETERSON: No.

MS. NESTOR: Do you write an NR?

DR. PETERSON: No. WE document that on official records.

MS. NESTOR: So a record would be made.

DR. PETERSON: We inform the plant of those results. If they fail, the example you're giving, six out of 25 days, that tells me that their plan is not able to control the process for that OCP even though they've been advised of that along the way.

So they must then revise their plan to decide what they need to do to make it work. So we start a new 25 day cycle. And that really gets to I think the earlier question here.

We're in the pilot phase. If we get in a repetitive failure mode what is our response? I'm not aware of that occurring to this point, but these are volunteers. The actual long term enforcement strategy for that would be part of the rulemaking process.

MS. NESTOR: So at this point there is no enforcement action that consumers can be assured you're going to take if the plant restarts the window every sixth day.

DR. PETERSON: The enforcement action is that we're documenting that failure.

MS. NESTOR: But all that product is still going

out.

DR. PETERSON: We have a history, are building a history of repetitive deficiencies. And in the pilot phase if it was an egregious thing where it was continuing continually, we would have to assess that plant's participation in the project. Again, that has not happened, but we have that flexibility because it is a pilot system

MR. McCUTCHEON: If we did --

MR. MINA: This is Mark Mina, FSIS.

We are not going to accept continuous failure without doing anything about it. We expect a plant when we notify them that they failed the first time, we expect the plant will take corrective and preventive action, and we evaluate the effectiveness of the corrective and preventive action. It's not just we tell them about it and they continue to fail and continue to fail.

When we would propose a regulation, we would articulate our enforcement position on these issues. This is a pilot. This is a test. And we continually make adjustments. But we definitely take action to make sure that

defective product does not leave the plant.

MS. GLAVIN: We have also made it abundantly clear to the participating pilot plants that if they cannot perform successfully they will no longer be in the pilot, we will return to traditional inspection in that plant.

As Dr. Peterson made clear, under a proposed rule we would have to lay out what would be the penalties. If we move to this as a complete system, there will be no return to traditional inspections so we'll have to make abundantly clear in our proposal what enforcement action we intend to take under that kind of system. But in the pilot, we simply can't, we've made it very clear that we will simply end the pilot in that plant if the plant is not capable of maintaining control of its system.

MS. NESTOR: Are the OCP failure records FOIA-able?

MS. GLAVIN: I'm sorry, I'm not a FOIA expert, so I simply don't know the answer to that.

MS. NESTOR: Does anyone here know whether that's a publicly available record?

MR. McCUTCHEON: No. I don't know. I know that

has come up, a question has come up and there has been a request of our FOIA staff and they've been handling that, but I don't want to speak for them.

Dan had a question a few minutes ago.

DR. LaFONTAINE: I guess this is a question for Dr. Engeljohn and Dr. Peterson because I've got a carryover to your two presentations.

I'm talking about OCP-1 which is my favorite topic today and those sick birds that I don't want to see go into the marketplace. See if you can follow me.

The performance standard in the HIMP plants for OCP-1 is what you've, it was zero but now I see that you've settled on 1.7, so I can follow that.

And on FSIS verification the maximum allowable defects are two birds out of 60, or that would equate to four percent, three percent. So that I, although I don't like to see that percentage, I guess I can say that that's real world for a chicken plant.

Here's where my concern is. In the slide that Dr. Peterson presented, additional OCP verification. It says

that for OCP-1 a maximum of nine carcasses with OCP-1 defects per shift.

Let's assume best case scenario that those nine were found in 60 birds. A little math tells you that we're allowing up to 15 percent based upon that sample size, 15 percent of the birds to be passed with OCP-1 defects.

Maybe I'm missing something, but that doesn't pass the common sense test to me when we're talking about 1.7 or maybe three or four percent. It appears a giant leap in the tolerance level for animal disease birds.

So maybe you can explain to me the logic on that. If you can't, then I'd ask you to take a hard look at that tolerance.

MR. GRASSO: If you take a look at the finished performance standards sheet that we provided to you, you can see for trimmed non-conformance table, that we would be allowed 30 percent on the finished performance standards, three out of ten birds for airsac.

And in the data that we collected of the 16 plants, the 16th position was 6.4 and one plant had a 15 percent rate

on a given day under the current system.

DR. LaFONTAINE: Let me follow up and say that what you're telling me is that you're going to allow any individual plant to perform at the worst level that any plant performed during the baseline.

MR. GRASSO: No, what that tells you, the nine in 60 tells you that if a plant ever gets to that point we will require them to be at post-chill, sample 60 birds. If they fail there, they are at rework.

DR. LaFONTAINE: But that still equates to a failure rate of 15 percent before there's any action taken.

I'm going to drop it. I feel that if you're going to have a 1.7 or a two or a three percent, let's make that the tolerance across the board and not allow it to go up to 15 percent on individual occurrences. It just doesn't pass the common sense test for birds that are unwholesome.

MR. GRASSO: From my perspective, so long as you know that the current system allows for 30 percent on a regular standard, our regular standard is two in 60 which is the 1.7.

DR. LaFONTAINE: I realize that, but you're front up saying you're going to have a tolerance of 1.7 or a maximum allowance of two birds out of 60, and all of a sudden the additional OCP verification which sounds great really is allowing 15 percent, and I can't buy that.

MR. GRASSO: No, it's not.

DR. LaFONTAINE: Yes, it is.

DR. PETERSON: Mike, let me maybe add something here.

As Mike said, the 15 percent is based on data that we gathered in the plants. That is a number that we are working with today and that would be the number we would propose in a rule. If that's a number that's not tenable to the public, then we would certainly look at that number.

But I would add two other things. When we develop a new inspection system, I think there is of course many things we need to look at but it should do at least two things.

It should enhance food safety, and I think clearly we've shown that.

I think it should also not make product less safe -- safe meaning foodborne illness. And we have this level of nine out of 60 because that's when the plant goes into a rework mode where you have additional handling of product, products diverted from the normal channels, and that additional handling may make the product less safe. So at what points do you jump from monitoring the process and putting them in a situation where you have additional handling? And that's where that number comes from.

But again, it's a number that's out there today. We'd be happy to reconsider it.

MS. HAUTER: My name is Wenonah Hauter. I'm with Public Citizen.

I am trying to understand if you can't enforce compliance with 16 plants in a pilot project, and that's not built into the project, then how could you ever hope to do it if this is a standard that's adopted by the whole industry?

MS. GLAVIN: We absolutely are enforcing compliance on a daily basis in every single plant. We are putting the mark of inspection on product, and that is done only if the

product is not adulterated.

What I'm talking about is setting compliance standards that everyone understands and knows and that has to be done through a rulemaking process. While we're in a pilot process, we simply move them out of the pilot if they cannot perform according to our standards. That has not occurred. We have not had any instances of plants even coming close to that. But should it occur, our response will be to end the pilot in that plant.

That's not an enforcement issue. That's simply making sure the product remains, that we remain convinced that the product is under control, that the system is under control. But we do enforce every day, that's why we have inspectors in plants.

MS. HAUTER: I'd like to make a comment.

MR. McCUTCHEON: It's getting very close to 3:00 o'clock which is when we said this is going to be finished, and Maggie had a wrap-up statement to make

You had a comment to follow up on that? We can take that and then we should -- go ahead.

MS. HAUTER: I just wanted to speak as a consumer a moment, and I know that most of the people in this room are technical people and that I may be breaking the orthodoxy here, but I'm really disturbed by this meeting. I think it's a real example of why the many constituencies who should be involved in this process aren't sitting here today.

This meeting has been most a dog and pony show using a lot of jargon and a lot of statistics that people can't understand. But the truth is that you can't dress up scabs, sores and tumors even if you call them OCPs and Americans, if they knew they were eating them, wouldn't want to eat them, and they'd be shocked that in this pilot project more of the stuff is going out to consumers.

It seems like the basic issue hasn't even been discussed today, and that is whether we should be privatizing meat inspection or not. I think that's a question that should be taken on the road.

I know it's naive to talk about our democracy, but the USDA should be going out and presenting this to the American people for what it really is and talking about the

real issues. And it's real clear to me why the agency has now legalized irradiation, because you're going to need it. Meat's going to get dirtier, and you're basically going to mask the problem with irradiation. The two things are very closely connected.

MS. GLAVIN: Thank you very much for that comment. I think it's real important to look around this room and recognize that my best estimate, 90 percent of the people in this room have been in this project from the beginning, have been through every public meeting, have had extensive ability to comment. This is another attempt to provide a full explanation of what is going on. It's not whitewashing anything. We're putting out the data. We're showing where our current thinking is, which way we want to move. We will go through a full notice and comment rulemaking on this project in the future, and we don't want that notice and comment rulemaking to come as a surprise to anyone. That's why we continue to put out the data, continue to put out our current thinking.

Our current thinking is just that. Where we think

this project is going at the moment based on the data we have. We will continue to provide data as it is available to make it publicly available and publicly discussed, and we will go through a rulemaking process.

I'm not aware of any constituency that needs to be in this room that hasn't been in this room or similar rooms throughout the past three years.

John do you want to see if there are a few last -- I think we can run over a little bit.

MR. McCUTCHEON: Take some more questions?

MS. GLAVIN: Yeah. I think there are some people who --

MS. FINELLI: Mary Finelli with United Poultry Concerns.

I'm wondering why ingesta and intestine tissue are considered other consumer protections not in the food safety category?

DR. JAMES: The categories that are not listed in food safety are not there because they are not considered to be reasonably likely to contribute to the bird in a foodborne

illness. Those categories have been identified and put here for the purpose of presenting to you what our current thinking is.

We believe based on the information that is available to us in the literature, at least that we've seen, that these are the appropriate categories for these items. And I will repeat what I said in my presentation, if someone has some new information available to us that they would like for us to consider, we are happy to receive it.

DR. ENGELJOHN: In my presentation I did identify that we listed ingesta as a specific category for which we collect data. The reason is that we do have a special interest in that particular category. You should expect activity related to the opportunity to deal with it on a separate issue from this proposed rule on HIMP related to ingesta sometime in the near future.

So we do have a special interest in ingesta. At this time we don't have the science to support it as being a food safety issue. So we've categorized it in a separate situation.

MS. NESTOR: Just so that I can understand, make sure that I understand how these two charts work together, let me just ask this question.

If we're looking at OCP-2, sores, what this means is that in 75 percent of the plants more than 50 percent of the carcasses have sores on them. Do I get that right?

DR. ENGELJOHN: The chart that you're referring to, the large chart that you received as a handout just now that puts all 16 data points into the situation identifies them based on rank. So that doesn't identify the percentage of defects within each of those plants. If on that large chart you look on the left hand side, this doesn't represent OCP-2 as an example, but one plant may have had two percent for that particular defect. Another one may have had three, four, five, six, on up to the 12th point. So they're ranked according to the number of defects by plant.

MS. NESTOR: But the performance standards, am I correct if the performance standard is based on a 75 percentile, am I correct that what it means for OCP-2 is that 52.5 percent of the carcasses have sores?

DR. ENGELJOHN: No. That means that that standard was set at the 12th plant. Again, rank them from plant number one has the lowest number of defects for that particular OCP category. Plant number two has a bit higher or may have the same, but it ranks up to plant number 12 which in this case has 52.5.

So the other 11 plants may have lower than that.

MS. NESTOR: I see, okay. Sorry.

MS. GLAVIN: I'm going to wrap up now, if I could.

Dan you have one last thing? Okay, go.

DR. LaFONTAINE: Thank you.

This morning I asked the introductory question about FSIS' training for their inspectors and veterinarians. That was kind of a loaded question because my followon question is related to industry.

My understanding is as far as the elements of the plan, the PC or process control plan or HACCP plan, that currently there is no requirement to address the training issue in the plans from the model plants.

I think that is a mistake.

The bedrock of any procedure or system, I don't care if it's working with the fast food industry or model HACCP or whatever is to have a baseline procedure or training so that you can accomplish the task at hand.

Now I'm not saying that there should be dictated what kind of training. I feel that the way to approach this is the following.

First of all, the plants that are now involved are volunteer plants and one could assume that they're proactive and progressive, and I've talked to some of the plant management and they in fact have training plans so they can be successful. But I'm looking beyond, that if this goes across, turns out to be successful and is allowed industry wide, that we need to have a system in place that will assure us that when they take this task at hand, that they have a part of their bedrock certain procedures in writing on how they're going to train their individuals and in turn that FSIS can verify that they're meeting what they say in their plan.

So I guess if I could summarize, I would ask that

FSIS again look at what are you going to put in place as a part of this overall system that assures that in the out years if this is successful, that you have a system that is solid and doesn't fall apart for those plants that don't accomplish training or have something very weak.

Finally, I want to mention that our friends from Canada, the Canadian Food Inspection Agency, who published their modernized poultry inspection program, it was put out for review by FSIS, have very extensive comments on this very issue. In fact a whole document that they require. And I'm not trying to say right and necessarily we're wrong, but just to read one sentence. "Establishments' operators are required to have a written training program which must include a HACCP system for each position, trained person theory," et cetera.

I won't go through all the details. But I feel very strongly that you're missing the boat if you don't take a hard look at that.

MS. GLAVIN: Thank you very much. I agree absolutely with you that a plant will not succeed if it

doesn't have a well trained workforce, and we will take your comments on suggesting that we require some training under very careful consideration as we go through this, and I thank you.

I want to thank everyone today for their sticking with this. There was a lot of information presented. This is about the third time I've seen some of these presentations and I learn something new each time I see them, because they are really packed with information.

I hope you will keep the handouts and go through them as you continue to think about this so that we will have the benefit of your added comments as you give it additional consideration.

We are planning this summer to have yet another session, so plan your summer vacation around this. We anticipate this summer that we will be in a position to share some actual models' data, not baseline data but models' data this summer. We think we'll be in a position to do that so we will have a meeting to do that, and also to cover other subjects as appropriate.

We, as I said, are committed to using the data as we go through the project, and to using the input that we receive in these meetings as we go through the project and also to go through should we move to rulemaking, to go through a notice and comment rulemaking should the data convince us that we do want to move forward with this project. That notice and comment rulemaking would include such things as how we use the data to set standards and that's been perhaps the subject of most discussion today. So that would certainly be part of any rulemaking.

Rulemaking would also include such things as enforcement strategies, et cetera.

So with that, I'd like to thank you for your attention and for your input and your active participation, and for spending your valuable time to help us as we work through this project.

I also would like to thank the presenters who have done yeo-person's work as we've gone through the day. I would also like to thank our two moderators, John and Dannie, who I think helped to illuminate some of the issues as we

went through the presentations.

Thank you very much.

(Meeting adjourned at 3:10 p.m.)

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Inspection Models Projects
Name of Hearing or Event

N/A
Docket No.

Arlington, VA
Place of Hearing

March 30, 2000
Date of Hearing

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