UNITED STATES DEPARTMENT OF AGRICULTURE

# NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION MEETING

Georgetown University Conference Center
3800 Reservoir Road, NW
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**EXECUTIVE COURT REPORTERS, INC.**
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# A G E N D A

P R O C E E D I N G S

8:44 a.m.

Welcome

MR. GIOGLIO: Good morning.

Welcome to the Spring 2002 Meeting of the National Advisory Committee for Meat and Poultry Inspection.

My name is Charles Gioglio from FSIS. As usual, I and my staff are here to help you since you're going to helping us over the next couple of days. I hope travel was easy enough for those of you who traveled in. I think we have real nice accommodations here at the Georgetown Conference Center.

I want to mention just a couple practical things before we get started. First, as usual, we have a telephone out at the Registration Table outside. Sometimes the cell phones and pagers don't work inside these buildings. That's for the committee's use in case your offices need to get ahold of you for some reason or whatever. You may want to note that number. It's 202 784-2968. If we get a call from your office for you, one of the staff will take the message and get it to you as soon as we can.

The other thing I'd like to mention is the microphones are voice-activated and the court

reporter's here and have everything recorded. We remind you to identify yourself for the court reporter so that we have an accurate record of the proceedings. If you forget, one of us here will remind you just to identify yourself.

We have a very full agenda, I think, today and tomorrow, and basically with that, I'd like to turn the proceedings over to Ms. Linda Swacina, Associate Administrator for FSIS.

Thanks.

MS. SWACINA: Thanks, Charlie.

On behalf of USDA and FSIS, I want to welcome everybody here to the meeting and to all the other attendees.

As Charlie said, I'm Linda Swacina, Acting Associate Administrator for FSIS. This is a brand-new position for me, and I am really honored to have been selected for it. This is my first time chairing this committee but certainly not my first time attending a committee meeting. In fact, those of you who know me know that I've been around the agency for some time. We don't have to get too specific about how long it's been, but suffice it to say I've been around long enough to have advocated both sides of many issues over and over again.

In fact, my exposure to the agency began long before I started working here and that was through my father Doug Swacina who I know some of you know. He became a veterinarian with FSIS when I was 10 years old, and he took me to my very first poultry plant about that time. It was very traumatic for me having previously had a chicken as a pet but I'm okay now, and I regularly review slaughter tapes while eating lunch. So, I think I've gotten used to it.

I started out in FSIS as a GS-11 employee, and in fact, one of my first jobs was preparing press releases for recalls. Those are still going on aslong are USDA and the taxpayer required to continue holding the hand of these plants and helping them meet the requirements? So, that's Part 1 of my question.

Part 2 is, now, if a plant fails the Salmonella test, you send an inspector -- a review team, an in-depth verification team in to review their processes. Is there any limit on how long that IDV will stay in there before a plant is told you're just not making it, folks? You've got a deadline by which time you have to act. I don't know if you can answer both those, but I'd like somebody to.

MS. SWACINA: Let me ask Bill Smith to come up and address that, if he would, please. Again, Bill

is the Deputy Administrator for Field Operations.

MR. SMITH: What we do is, in an IDV, is we have a process where we look at all the food safety systems in the plant and then there is a report, and at the end of that report, that is sent to the district manager, and then a determination is made if there's issues of regulatory non-compliance, and we would follow our Rules of Practice at that point.

So, usually it's at the conclusion -- within a number of days after the report because the team goes back, puts together all their findings, checks again to make sure that the group's in agreement on the scientific and regulatory findings, and once that's done, then they have options of, if there is non-compliance, then the Notice of Intent of Enforcement would be issued. If there's questions about the science that we -- or the validity of what they're doing, a letter is sent to the plant to clarify that with the time line to respond to that. At the end of that time line, which is usually 30 days, then again we make the decision whether if we have non-compliance, then we would enact our Rules of Practice.

MS. FOREMAN: But you have a directive out now that says don't run a third Salmonella test until you're sure the plant can comply and meet the standard

of the Salmonella test. How long can you wait between the second and third test while a plant does that?

MR. SMITH: What we do, the instructions to our folks are, is that in that scenario, the regulation, I believe, requires the plant to reassess its HACCP plan. At the end of reassessment, there is usually modification. Modification then, the plant is modified. Then there's validation of those modifications, and so what we look at is what has been done and if it's structural or facility-wide, that may take longer. What is the validation, the science behind the validation test to validate that the modification has been effective, and then at that decision, when we're done with that, again we make a decision to go forward with the sampling or, if we question the science behind the modifications or those things are not going, then we have our Rules of Practice that we implement and that's been our history. We make that decision.

MS. FOREMAN: And how long might that process go on?

MR. SMITH: The process is dictated by the scientific design of the validation effort.

MS. FOREMAN: A year? Two years?

MR. SMITH: I'm not aware that that has been

a typical --

MS. FOREMAN: No.

MR. SMITH: -- response.

MS. FOREMAN: Are there plants that have taken a year or two years?

MR. SMITH: Again, I'm not aware where we've had extended periods of time where something has not been done. Again, if you --

MS. FOREMAN: No. I'm talking about so they can pass the test.

MR. SMITH: If you modify these programs and then you find out in your validation effort that your modifications are not getting where you exactly want to be and that starts that process over again. There have been some cases where there's been a number of months time involved, a year in one case I know of because a plant completely reconstructed their facility. That is not the norm.

Usually what we look at is in the regulations, when we have a new plant or a new process is brought on line, there's a new HACCP plan, 90 days is established in the regulations for them to validate and modify, and we try and use that as our barometer.

MS. FOREMAN: So, a plant that has an inadequate HACCP plan then gets a minimum of 90 days to

establish a new HACCPogies are getting communicated between the companies a lot differently than they were in the past when for a little while people thought that, you know, food safety was going to be a marketing tool and so those -- that group has come to an agreement to share those technologies.

An example of that is the Listeria training. We're actually -- you know, the larger member companies have trained the smaller member companies, introduced equipment, sanitation practices, standard operating procedures, training films, all kinds of technologies that you can think of. So, it's a really good point, and I think that effort is there.

Just two other points. One is, one thing that really facilitates buy-in by the local inspection personnel is very dependent on what kind of relationship you have with them already, and those guys like to be able to flex their technical muscles once in awhile and so if they can be involved pretty early in the stages of implementation of the technology, we found that to be pretty effective, then they have some input, and then they're not blindsided with something coming back to them from the D.C.-type level.

But I do have one question as far as local implementation, and that is whether or not the

revisions to the directive will give some type of instruction on when new technologies should be incorporated into HACCP plans? In other words, when do they come out of testing mode, and what's sort of the time in which you can collect data to determine monitoring frequencies, verification frequencies, sufficient validation studies? When does that come out of test mode, and when would we be expected to incorporate that into regulatory plans, such as HACCP?

MR. BURKE: I guess I was talking before, basically when that -- when the company makes -- and the company takes responsibility of the technology. So, once they basically -- we get the no objection letter, it's up to the company basically to incorporate the technology, if it needs to, into their HACCP plan. We're leaving that all up to them.

MS. KASTER: But there has to be some time when it's running in a field, in a production setting in which to generate the data, and we have some IICs and some inspectors who expect some new process to immediately show up in the HACCP plan before you even know if you're going to permanently adopt it, and it is no small feat to revise a HACCP plan, get it signed, have people go through it, and so I guess I'd like to see some stronger definition of when that would

transition.

MR. BURKE: I think --

MS. KASTER: I don't think it's been left up to the company to decide. I think some inspectors have dictated that and some have not.

MS. RIGGINS: I think --

MS. KASTER: Sometimes it works like you're saying.

MS. RIGGINS: I think that your suggestion is a good one, and we will formulate some set of guidance to our IICs so that they will understand the new environment that we are hoping to create in introducing new technologies and what their role in it will be. I understand what you're saying, that we aren't always communicating as well as we could. The Tech Service is the primary unit within FSIS that's responsible for conveying that information to our field employees, but I think that in the Office of Policy, we can do a better job of explaining it, spelling it out, so that everyone in the agency will understand that we have a better set of guidance for our field employees.

MS. SWACINA: Okay. Was that it? Okay.

Ms. Eskin, yes?

MS. ESKIN: I have two questions. The first one is, the experience to date, do you have, in

addition to plants coming forward and saying we want to use these new technologies, do the companies that actually develop the new technologies come forward? How does that work? Is there --

MR. BURKE: Yeah. There's been -- well, basically the same kind of procedure. We've gotten such where we had specific companies come, major companies within the meat and poultry industry, and then we've had other companies -- we normally call these establishments, where basically then they come with a proposal and stuff and basically and then they need to go out and find somebody to run their in-plant trials in, so they normally then go contact and work a partnership with some other -- with basically a meat and poultry company. We've had both incidences come to us.

MS. ESKIN: All right. And you've addressed the issue of what type of data and evidence an establishment needs to come to you with in order to get a treatment, for example, approved. Looking at, let's say, an antimicrobial treatment, to what degree does an establishment or company have to show that that treatment does not have any adverse effect on human health, for example?

MR. BURKE: Oh, yeah. That includes our --

of course, like we said, one of the incidences basically, we want to make sure that the -- as you talk about the environmental in-plants, yes. One of the things, especially if they're using any kind of a chemical, basically one of the things we look for, we send it -- we have a safety organization in FSIS, and we also send a copy of the proposal to them. They give us our recommendation, like some incidents we've had industrial hygienists go in there with their sniffers, checking the atmosphere, checking to see if any excess compounds are basically is in the air. We do check that.

MS. ESKIN: Not only environment but perhaps again it may not have occurred to date, but any residue.

MR. BURKE: Correct.

MS. ESKIN: I'm thinking back years ago. Critics of TSP, for example, are saying this stuff is paint thinner. Can you imagine if people wind up consuming it? So, that is something also that's --

MR. BURKE: We check, right.

MS. ESKIN: -- correct?

MR. BURKE: Right. There's not supposed to be any residue of, say, an antimicrobial on it.

MS. SWACINA: Ms. Johnson?

DR. JOHNSON: Just to piggyback a little bit on what Collette said, there's a lot of sharing with the industry at various meetings to talk about the technology that's working, how it works, and some of the bumps you have to go through to implement some of the technologies as far as equipment flaws, things like that, and it may well be that FSIS could provide some venue there to allow the companies as well as the technology providers kind of an open forum to talk about what might work and what might not.

Getting back to the IIC and particularly in the smaller facilities, if you have a technology provider coming to a company, some of the smaller companies don't really understand how to go about some of the procedures. So, I think it's real important that the IICs don't shut it down before you even get started because the first thing somebody's going to do is walk up to their IIC and go, so, have you heard anything about this type of technology? What do you think? Does it work? Does it not? And if the IIC isn't aware of it or feels that it violates regulations, then you may automatically get things shut down. So, I think it's very important that you get information once technologies are out there to the local IICs, the circuits, down through the chain so

that when a company comes and specifically asks a question to the IIC, the IIC, first of all, isn't taken aback and goes I don't know anything about this or doesn't immediately shut it down just because they think it's not going to work.

Thanks.

MS. SWACINA: Mr. Denton? Mr. Denton? Did you have your -- no? Okay. Mr. Link, yes?

MR. LINK: Charles Link. Patrick, could you just comment on how the memorandum of understanding between FSIS and FDA is supposed to work and how it actually works with regards to new technology and antimicrobials and things of that sort?

MS. RIGGINS: Let me answer that. The Food and Drug Administration has a responsibility to approve all additives to food. When -- under our current MOU and our current regulation, when FDA receives a petition for food additive, they work with us to include all the questions that need to be addressed with respect to use of that additive in meat, poultry or egg products.

So that, at the end of the process, at the end of FDA's review process, those questions have been addressed and their approval does include the provisions that would cover meat, poultry and egg

products, and we then act on that decision of FDA, and in instances where there are unanswered or unfulfilled information that FDA needs, we then work with them to gather that information to answer those unanswered questions, so that we can make sure that the review is a complete review.

MR. LINK: When that's completed, does that information --

MS. RIGGINS: FDA under its current regulations publishes a regulation which spells out all of the provisions, all of the conditions, under which that additive can be used in a food and that will -- that regulation includes those conditions for its use in meat, poultry and egg products, and we then -- we then administer that provision of FDA.

MS. SWACINA: All right. We'll take a break till 10:30 and then start back on Farm Bill Issues.

(Whereupon, a recess was taken.)

MS. SWACINA: Okay. Dr. Morse is on the phone and apparently will be awhile. So, let's go ahead and get started again.

We had talked about what would be a time to be able to discuss the directive on Salmonella, and I think what we've worked out is we want to try and fit it in tomorrow morning after the Standing Committee

Reports, and we'll make the break shorter and we'll play it by ear. If that doesn't work, we'll try and fit it in after lunch. So, our hope is to fit it in tomorrow morning then before lunch.

MS. FOREMAN: Thank you.

MS. SWACINA: Okay. Okay. Let's see. Next, we have a presentation on the Farm Bill Changes by Bryce Quick.

Issue - Farm Bill Changes

MR. QUICK: I'm going to stand up here so I can see you all. It's good to be with you today. It's -- I've had the privilege of working with a lot of you over the last several months. I've gotta tell you, I got an e-mail from my deputy director, Danni Shore, that was kind of humorous, and in it, she said, "Remember, you're not a lobbyist and you're not a congressional staffer." It says, "I have to be dispassionate, succinct, non-opinionated, and I have to stick to my script." So, if you see me flinch like this, Danni is pushing the electronic collar on my leg.

So, with that, I'd -- this is an issue that, as a former congressional staff, I gotta tell you, it's one of the most passionate things to be a part of, is the Farm Bill, and not from a department standpoint but from a staff point. It's an exciting process.

Our counterparts in our sister agencies would probably laugh at us because we really only have a handful of issues. They're important issues, but if you compare them to the issues that ARS or FSA or these other folks are dealing with, they're in the hundreds. So, we're lucky in that respect.

The President signed into law the Farm Bill on May 13th. Like I said, there's only a handful of provisions and we're going to go through those today really quickly, and on one, we're going to ask your advice. Some of the issues, we have country of origin labeling, overtime for veterinarians and other employees, humane methods of slaughter, a food safety commission, a presidential commission, pasteurization and irradiation, state meat and poultry inspection systems.

Country of origin labeling is one that my staff, when they were putting together the original talking points on this to explain to the agency what had happened, the acronym for this, as you can see, is COOL, and I've deleted that from the presentation because if you're AMS, it's anything but cool. It's going to be extremely difficult to implement and you've seen and read this in news accounts. It will require retailers of beef, lamb, pork, farm-raised fish, wild

fish, perishable ag commodities, peanuts, to inform customers at the point of retail the country of origin of these commodities, and this will be during a two-year voluntary period followed by in 2004 when it becomes mandatory.

For us, particularly, it will be an issue but AMS has got to deal with that first. Ground beef is one of the things that will be particularly problematic and challenging for the agency.

Some of the other things that I think are challenges for us will be trace back authority, verifying and enforcing country of origin, and there is basically no clarification in the bill as to how mixed origin products are to be treated, and it really does not address enforcement and oversight. Lastly, there's really no evidence to suggest that country of origin presents any kind of benefit to food safety or public health.

The next provision in the Farm Bill is that of overtime and holiday pay rates. As an agency, we've kind of got mixed emotions about this. The personnel that benefit from this were probably pretty thrilled with it. It presents budgetary challenges for the agency. The conference report directs the Secretary to -- I'm sorry. It authorizes the Secretary to pay

overtime rates to our employees and it basically balances out the Federal Meat Inspection Act with the Poultry Products Inspection Act and allows her to pay that overtime when she deems appropriate.

We audit -- I'm sorry. I keep skipping around here. Prior to this authority, the Secretary was limited in the rate that she could pay her employees in the federal establishments.

The next issue is humane methods of slaughter. This is an issue that was debated at great length in the committee, in the conference rather, and what we came away with is a non-binding sense of the Congress amendment that the Secretary should fully enforce the Humane Methods of Slaughter Act and as the proponents -- as the Department folks and ourselves explained to the conference committee, this is something that we take very, very seriously, and that we are keeping track of in our plants. Our vets and our inspection force has very clear direction on this, but they do direct us to continue tracking the number of humane methods of slaughter violations, and the Secretary's expected to include a report of the violations in our report to Congress.

We -- to show -- we also let them know that we had a 117 documented violations since October 1 when

we started keeping track again of these violations and let them know that this is one of our highest priorities.

The agency is very pleased about the establishment of a food safety commission. It is a 15-member, 14 plus the chairman, member committee, and it is presidentially appointed. It will be comprised of individuals from a cross section of food scientists, the industry, consumer groups, and others and will be helpful to identify new ways to enhance food safety and protect the public's health.

Specifically, the commission is tasked with developing recommendations to enhance the food safety system, improve public health and help create a harmonized framework for federal food safety programs.

Pasteurization and irradiation provisions ended up in the bill at the very end, and we are very pleased with what the Congress decided to do with this. The bill directs the Secretary and the Department of Health and Human Services to publish a rule to revise the current regulation governing the labeling of foods that have been treated by radioactive isotope, electronic beam or x-ray to reduce pest infestation or the prevalence of pathogens.

The conference report also instructs the

Secretary of Agriculture to conduct an education program regarding the availability and safety of processes and treatment that eliminate or substantially reduce the levels of pathogens on meat, meat food products, poultry and poultry products.

Like I said, we're very happy with this. It does present opportunities and challenges for the agency. Once again, budgetary challenges because the authorization was put out there but, of course, no appropriation followed. So, we will be anxious to see what the Appropriations Committee and the rest of the Congress does for us in terms of education money because we are anxious to do this. The bill directs us to move on this very quickly, within 30 days, to develop an education plan.

Lastly, and this is one of the issues that we need your guidance on somewhat, the conference report includes language directing the Secretary to review state meat and poultry inspection systems and report the findings to the Congress. In the report, they are asking us to get the guidance for the state systems should the prohibition on interstate shipment be removed. We audit state inspection programs on a three-to-five-year rotational basis with six-day programs under review each year.

Some of our concerns are that we secure the right funding and the staffing necessary to actually pull this off. Reviewing 27 inspection systems within this abbreviated time frame will be extremely challenging, and without the appropriation, we as an agency need to figure out how we prioritize this because we will need to cover the costs and hopefully we will be able to do this without sacrificing other programs and resources.

With this said, as we are charged with overseeing state meat and poultry inspection programs, we're concerned about how best to respond to this within -- to this congressional directive within available resources, and some of the questions that we'd like to have the committee give us guidance on would be, firstly, how can we best use the limited food safety resources to meet this mandate? What kind of guidance would be useful to the states in advance of legislation authorizing the interstate shipment of state-inspected product? And lastly, this committee met in 1997 and discussed this issue. Do you have any further concerns or advice on this issue before it is upon us?

That said, any questions?

MS. FOREMAN: Could we -- when we last

considered this, we developed a paper. The subcommittees met endlessly on it, and the committee met endlessly, and there was a paper developed. Would you arrange, please, to have that made available to us this afternoon? It would certainly be helpful in anticipation of tonight's meetings.

What do you think --

MS. RIGGINS: Can you clarify? You're talking about the interstate shipment?

MS. FOREMAN: Yeah. Yeah.

MS. RIGGINS: Okay. All right.

MS. FOREMAN: Yeah. I'm sorry. I don't think we've ever discussed the other issues. We may have had one or two of them, but this is the one that we've spent lots of time on.

What do you think they mean by a full review? What do you think? What will FSIS look at in conducting a full review?

MR. QUICK: Well, I can tell you in the first -- in the Senate-passed language, they specified a review of all 27 states and in talking to them, looking at your HACCP plan, I think maybe Bill Leese, Dr. Leese could probably answer this.

DR. LEESE: Well, I think that's part of the function for the committee to try to come up with some

recommendations with regard to that. We saw that the Senate's version was rather specific in doing a full comprehensive review of each state program. I'm not quite what the Senate considers a comprehensive review to constitute, but certainly I would perceive that to include reviews of each of the programs from the in-plant and the compliance standpoint, in-plant compliance enforcement-type programs.

Now, the language has become more general, and I don't know that we can predict what they had in mind, other than to look at the process and come up with options as to how to do that. The most severe and cost-expensive, the most expensive way to go would be to have a process of doing a review in the field of each state program, and of course, there's no funding to provide that, and we're doing about six to eight states per year right now. So, it would be an extreme hardship right now to try to find the personnel and the funding in order to do that, but, of course, that would be one of the options.

Short of that, it's talking in terms of the report to Congress. Now, each year in the report to Congress, there's information regarding the state programs. At this time, it includes primarily tables of information, number of states and what have you that

have programs and that type of thing, plus maybe two-three-sentence paragraph defining the fact that there are 27 states.

Now, going from there, it's a long stretch from there all the way up to the report to Congress that includes a comprehensive review of each state. So, there are many things that could be added to the information in the report to Congress beyond the bare bones material that's there right now that would have to do with the state programs.

MS. FOREMAN: As I recall, the legislation that was sent to the Congress earlier on this issue, when USDA supported the legislation, required an initial federal audit of each state to ascertain that their system was in fact equal to.

DR. LEESE: Yes.

MS. FOREMAN: Do you remember? Am I correct about that?

DR. LEESE: Yes, and then there would be, once the program came into place, then there would be an annual review of each state program and also funding provisions were involved with that as well.

MS. FOREMAN: Is there any way that you can offer guidance to states about what would be expected of them if they were to ship interstate without doing

an individual audit?

DR. LEESE: Well, without doing -- as far as what would be required in order to ship interstate, it would depend upon what legislation came forward and what that legislation demanded. So, we could only generalize on that because we don't know. We know that the legislation has already been provided states clearly that there would be the comprehensive review of each state program. It got into references to testing and other factors. It would only be conjecture to say that that would be how it would come about the second time.

As far as states preparing for interstate shipment, conceptually, they should be prepared for interstate shipment anyway from the standpoint of how the program operates with regard to inspection. Now, getting into other aspects of how they would interact with other states, what kind of a seal of inspection should be on the product in order to facilitate this, how this product could or could not be distinguished from federal product that was produced in a federal plant, how this would impact with exports, all of these items, of course, are not necessarily food safety issues but they are things that relate to the overall process of going interstate.

So, I would say that those type of issues would be of more consequence as far as what extra they would have to do than would be the actual process of inspection in the plants because the -- while the programs are required to be at least equal to, basically it just wouldn't be feasible for each state to try to reinvent a type of inspection program that could be equal to when they could tap into the process as it's performed by the federal.

MS. FOREMAN: I'm not sure I understand you.

DR. LEESE: I'm saying basically they adopt federal requirements anyway. The -- so that there -- and they're not adopting our law directly. They adopt -- in the main, they have adopted our regulations and in most respects would have adopted our directives that expound upon how to implement the regulations.

MS. FOREMAN: But while some states have very fine state inspection systems, my bow to the gentleman down here from Iowa, there are some that clearly don't. OIG and GAO have both put out reports detailing the fact that state inspection being equal to is often just a myth, and my own experience is that when asked, how do you know they are equal to, the answer would be we wouldn't be allowing them to operate if they weren't and that's as specific as the definition could get.

Everybody knows that many of the state programs are not equal to. It's a given. It's the reason that this thing has been such a fight over the years. If you were actually equal to, you'd be inspected by the Feds, and where some states run very fine programs, some states, we know from history, do not.

So, I don't believe the fact that you are now -- that 27 states have these state inspection programs means that you would assume they could qualify under new legislation. I don't believe Congress meant that when they said tell them what would be expected of them. I think that kind of presumes that they know that there's some states out there that have to make a change. The legislation before required a federal audit. This committee was assuming that some states would have to make changes in order to come under the -- to ship their product interstate.

So, I think there's some issues there that would have to be addressed. Maybe the Department should seek some money to do this study the right way.

MS. SWACINA: We certainly made that point during the Farm Bill discussions.

MS. FOREMAN: Are you going to -- that -- the House hasn't marked up its bill yet. OMB going to let

you ask for any extra money?

MS. SWACINA: They haven't -- we haven't approached them on that.

MS. FOREMAN: Okay. So, we should assume it isn't going to happen.

MS. SWACINA: I couldn't answer that at this point. It's not happening at the moment.

MS. FOREMAN: Okay. How many -- given the tight budget constraints that many states are under now, most of them, I guess, all of them have balanced budget requirements, how many states have been in communication with the Department about the potential that they would now give up their state inspection because of those budget requirements?

DR. LEESE: Well, there's all manner of degrees as to how far a state would be concerned that they would lose their program, and to my knowledge, there are no states that are going to lose the program and the majority of states being concerned about their budgets.

MS. FOREMAN: But any of them been in communication with FSIS about this being a possibility?

DR. LEESE: Possibility of losing the program?

MS. FOREMAN: Of having to give it up.

Traditionally, when states get into a bind, some states say hey, that's one place where we can save some money, and they give it up. Traditionally states have gone out and come back in.

DR. LEESE: Well, this -- every year, every state has to -- I don't --

MS. FOREMAN: But nobody --

MR. NEAL: The head of the program of every state having to defend to their legislature on an annual basis whether or not to continue the program, but as far as the degree to which any state program was in such dire straits that they could almost guarantee that they were going to lose their program and then it's a matter of a day-to-day thing as they work with their legislature how far it's going to go, and I really can't say that there's any of them that -- I can't predict. I mean, I can't get into the heads of the legislatures.

MS. FOREMAN: No, none of us can do that.

DR. LEESE: So, I don't have an answer to that.

MS. FOREMAN: But in the past, before a state gave up its program, frequently there would be some communication from the state saying look, you need to be prepared because they wouldn't want to leave their

small plants without any coverage, and they would say from time -- sometimes there's a good chance you're going to have to -- that we're going to turn our program back to you.

DR. LEESE: Well, Florida, for example, it was a long period of change as Florida worked with us as to what conceivable options might be available in order to maintain the program or a portion of the program, and of course, they concluded that they did not have the resources to continue, and they gave a date which was about midways through their fiscal year at which point they would no longer have funds and the program would stop.

If there states that -- one of the state programs in dire straits right now that would relate to that new fiscal year starting in July, there would be no lead time.

MS. FOREMAN: But you haven't had any communications?

DR. LEESE: I haven't had any of that kind of a panic.

MS. FOREMAN: Okay. Are you working with any states to help them decide what kind of -- what part of their program they might be able to maintain?

DR. LEESE: No.

MS. FOREMAN: Okay. All right. Thanks.

MS. SWACINA: Okay. Ms. Johnson?

DR. JOHNSON: Thanks, Bryce, for the presentation. I have a couple questions related to what's going on right now with state reviews.

You said you're doing six states or you're trying to get six state reviews in a year?

DR. LEESE: Well, it's based on the cycle that's generated over time with the reviews in the states usually being every three years, maximum being every five years and possibly down as much as once every year and that in itself shakes the system out to the point where that's about how many reviews it takes to continue the cycles.

DR. JOHNSON: All right. Dr. Leese, I was trying to figure out if you looked at the reviews that you'd done since 2000, when the small category of plants came in under HACCP and SSOPs, I mean, is there a substantial number of state reviews that have been done since -- that you could say done 2000, 2001 and that would be done during 2002?

DR. LEESE: Yes.

DR. JOHNSON: Okay. Do you have a number? I mean, is it --

DR. LEESE: Not off the top of my head. I

probably could come up with something wrong, but it would be -- but I would suspect that would be close to have of them.

DR. JOHNSON: All right. So, there has been some reviews going on since HACCP and SSOP?

DR. LEESE: Oh, yes, every year.

DR. JOHNSON: Yeah.

DR. LEESE: There's been reviews and usually it's around seven. In a year or so, that'd be well over half the states.

DR. JOHNSON: Is there -- and all states now require HAACP and SSOPs as well as the -- use the same NR, non-compliance report, that federal plants are using?

DR. LEESE: All the states are required to have HACCP and SSOPs. That came through on the same time frame as the federal program.

DR. JOHNSON: And they are using NRs to document state inspectors using NRs, is that fair to say?

DR. LEESE: Yes.

DR. JOHNSON: And I'm on the subcommittee which is why I'm kind of interested in some of the ways to figure out how to do this, if you're not going to go and try to get additional money.

Do the state programs have systems that the federal plants do as far as looking at number of NRs, number of tasks and that type thing that's already in place?

DR. LEESE: You mean like the PBIS-type?

DR. JOHNSON: Yeah. The PBIS.

DR. LEESE: Almost all states have adopted the PBIS system.

DR. JOHNSON: Okay. And just one more question. I've talked to a couple of the state guys over the last couple of days to be sure I kind of understood what was going on, and they were telling me that a lot of states, and you just mentioned it, adopt by reference the FSIS regulatory requirements directives notices, the whole thing, and others have to do it through legislation.

Do you know how many states do the adopt by reference of FS -- just automatically the FSIS requirements?

DR. LEESE: Well, the two things go together a little bit differently than just as you mentioned because in the majority of states that adopt, they adopt a specific time frame and then as the federal regulations change and their legislature meets, they adopt a more recent version.

There's some states that adopt as amended. Very few adopt as amended, meaning that they can just set back, relax and automatically they've come under the new federal regulations as they are written. Now, the states that don't -- that -- the states that adopt at a given time frame and then have to go back and reinstitute that process, ordinarily they're following through anyway with the new procedures, but they don't have the sound backing that they would have if they had passed it as far as their own legislation.

DR. JOHNSON: Okay. One more question and this may be a Bill question. On your food safety system correlations, are they -- they go into a district and poll so many plants. Are they including any state plants in that correlation?

DR. LEESE: No.

DR. JOHNSON: Okay. Thanks.

MS. SWACINA: Thank you.

Mr. Govro?

MR. GOVRO: Thank you. My question concerns country of label origin -- country of origin labeling, and if you'd rather finish with the interstate, the state programs, I'd be glad to defer till later.

MS. SWACINA: Okay. We'll come back to you then. We have John Neal.

MR. NEAL: Yeah. Dr. Leese, it seems like this bill is going in the direction that it's going to affect smaller plants statewide than it will larger plants under inspection providing interstate shipment. This is the take I get on it.

It's hard to say that the state would have enough personnel at this time or, you know, even in the near future to implement a major program in major processing facilities, and I may be off base here but just tell me if I am, and I think it has a lot of merit. I see where it would save the USDA a lot of money if the states, you know, were up to par and the ones that adopted the program in 27 states, but what I see is that it would also absorb small plants that say we're currently under USDA inspection, but let's say we're a low-risk based, and you would probably do a risk assessment, and they would put them under a state guidance because basically a lot of small plants are only federally inspected in states that are for one reason because they ship interstate.

I see that the USDA would be losing these small plants, but in isolated areas, such as the area that I'm from, you have basically people who patrol those areas and go from one small plant to the other which would free them up to be more available for

larger plants and that type work and the better use of personnel, such as workforce, and I think that's one of our issues here.

Do you feel like I'm on base on that? I'm saying that it's going to affect small plants as much as any, you know. I mean, the ones that are currently under state inspection, you know, in the states, you know, like Texas is really hard, I'd say that's going to -- there will be some bigger plants, but I think you're going to lose some plants out of the federal system and it'll drop right into the state system, even though it's the same process.

MS. SWACINA: You're talking about interstate shipment as a whole, not the --

MR. NEAL: Yes, as a whole, yes.

MS. SWACINA: Okay.

DR. LEESE: Well, it would be conjecture on my part to try to make any kind of a guess as to whether there would be plants going from the federal system to the state system as a result of the interstate. It's conceivable that it could, but there's certainly no requirement that they would have to go over to the state program. Of course, they'd be able to go interstate. So, whether they would have reason to want to transfer over, that would be their

option.

As far as larger plants, traditionally there haven't been much more than the so-called very small plants that are involved with the state program at this point in time, and clearly I think it's -- it would seem accurate to say that if there was a flood of plants going to state programs, that it would seriously interfere with the capability of the state program to do it, but I have no way of knowing if that would even happen.

Even if you're looking at the issue from the standpoint of marketing, is it good for their business to be able to say we are state inspected and we are the state and we're proud of ourselves or to say we got federal inspection, we got the Feds that are looking at us, which one is -- it depends on the individual perspective.

MR. NEAL: Well, that's true, that comes back to the education part of your bill that you're going to educate the consumer. I think you make the states more -- it's just that there's certain areas more accountable if they know that that's their plant.

The reason I say this, in small plants, you will find -- that do any interstate shipment all, and we're talking small and very small plants, you will

find that -- I'll use mine as an example. It's the best one that I can relate to. You have the retail-exempt area which is retail across the counter right there every day. All right? Everything else, even though I have a section of my cooler that is marked off specifically for retail, everything is done under federal inspection, but at the same time, once I put it up front and it comes back from the front to the back, it goes back into retail exempt once it's removed from there.

What I'm saying is that I have two inspections, you know, I have a retail inspection from the state, then I have federal where I process the meat and storage and all the other aspects that go along with that.

So, what I'm saying is that I think it's going to affect small plants a tremendous amount if they want to do interstate shipment and that is the key element here. I'm for this. I think it'll work, whatever works the best for the government, as long as we don't compromise any safety procedures, and I don't think this bill's intended to do that.

I understood what Carol was saying a minute ago. I think one reason the states -- it may seem like at times that the state doesn't do as good a program,

but also I don't think they've had to for anything to do other than local state programs. I mean, I don't think the challenge has been put out there for them, and I think any state programs I've been around are just as equal or superior and a lot of times, it's just some of the personnel doing the job and you find those at any level.

DR. LEESE: I'd like to comment. With regard to whether the programs are as good, if we can use that term, I think we've got to look at two parts of the program. One would be the substance of the program, how it's defined, what it is that they are supposed to be doing, and the other would be the implementation of the program. They are two parts of the same thing, and together they make up the program, but at the same time, they are both somewhat independent of each other as well.

MS. SWACINA: Okay. Ms. Donley?

MS. DONLEY: I would add that there's a third component to that and that's enforcement of the program.

Let me -- the situation today, real time today, is that any state can ship interstate if they're under federal inspection.

MS. SWACINA: Any plant.

MS. DONLEY: In plant.

MS. SWACINA: Any plant.

MS. DONLEY: Any plant.

MS. SWACINA: Not in plant.

MS. DONLEY: Any plant. So, any plant can request a federal inspection so that they can ship interstate.

MS. SWACINA: Right.

MS. DONLEY: So, no plant is prohibited from shipping interstate.

MS. SWACINA: Unless they're under state inspection.

MS. DONLEY: Correct. What's stopping them from requesting federal inspection, getting it, complying with the program as it exists and going about their merry way doing the business as they want to do it?

MS. SWACINA: Million dollar question.

MS. DONLEY: So, where does this whole issue that's been going on for 25 years come from? Because no company, no plant is being discriminated against from doing whatever it is that they want to do as long as they follow the program and follow the rules. So, I think this issue is just absolutely ludicrous. I thought it was ludicrous before when we visited this

back in 1997. I've seen some erosion of some areas of concern that it makes this whole thing even more concerning with what's happened with the Salmonella performance standard, and if this is just something that is for the benefit of the agency that's going to free up some resources from the agency, I say that's hogwash.

If it's not going to be something -- if it's going to perhaps impact public health and safety and I challenge the agency to say, listen, we are the Food Safety and Inspection Service, public health and safety is our Number 1 mandate, our Number 1 priority, so Congress, give us the money and so that we can do our jobs.

I'm just totally baffled by where this is all coming from and, I guess, the politics behind it, and I'm sure there's a lot, and I am definitely not a political animal. So, if someone can, you know, clue in this clueless person, I would be really grateful.

MS. SWACINA: Conveniently, Mr. Mamminga is next on the list.

MR. MAMMINGA: I am Mike Mamminga. I'll try to answer your question for you.

I've been at this too long, over 30 years, and I'm becoming a dinosaur, but before I quit, I would

like to give you a perspective of why these plants do that, why they want to keep state inspection and why some of them would like to have interstate commerce.

If you look at the discussion we had this morning about the new technologies and what we do in inspection and you listened to the discussion and the sharing back and forth of the challenges introducing new technologies, you can also look at the implementation of SSOPs, E.coli testing in the slaughter plants, you can look at all of the issues that this committee takes up twice a year into the night, and then you go to a person that operates a small plant and you say now, would you like to buy into that, and if they are working with their Department of Agriculture, if they are properly upgrading and doing their job the regulations require, most of them will say no, I think I'd rather stay here because I can call Mike Mamminga in the morning and he answers his phone and he's the administrator of the program. You know, if I call the county executive director's office, he might be there, and I can get in the car, and in two hours, I can go to the government. I can sit down and deal with what's going to happen in my plant.

Interstate commerce is not the burning issue. Carry out the policy. I don't make it. And so, there

should be an industry incentive based on what they perceive is in their best interests.

(Inaudible) The fact of the matter is when you look at the challenges we face in implementing these rules and regulations, the Iowa Program has for its entire existence, we have very few experts on the departmental administrative rules other than the adoption of the federal regulations. But we look at people, we say to ourselves as the state person, we have some capability to provide some guidance as well as regulations, to team up with our Iowa State Land Grant Universities, our Iowa Department of Economic Development, our Iowa legislature, to provide funds to create programs that guide people in the regulatory framework and the training of our people with the industry people, and we train over 400 people at Iowa State University in actual SSOP and HACCP programs and implementation through verification and validation of their programs, and then we look at this whole system as something that is very, very challenging for very, very small plants to get in there, and maybe they're not important. The Congress will decide that. This committee will provide some information along those lines.

But when you look at where we buy our food

and the ability to buy a diversified menu of food, we can see ourselves quickly becoming a country where a few producers will produce all of what we eat, and we would like to see that we maintain a healthy supply of independent processors out there as long as they abide by the same rules that everybody abides by.

So, we're not asking for anything any different. In fact, at one time, I asked USDA to consider the state programs with the same consideration they give foreign countries. Put us under those standards then for interstate commerce. Let us do what they do in Australia or New Zealand or Mexico. If we can't fit into the FSIS program, treat us as good as you treat foreign countries. Make us apply to those standards.

Most of the states that are willing and very anxious about interstate commerce have indicated many times that they will do almost anything to comply. Set the standard and we'll comply with it or we can't have it. The challenge is, is to get the policy to the road. So, that's my best two cents worth on that matter.

The Iowa Program has no secrets. I think Dr. Leese will tell you that. I don't -- we operate. Are there problems? What are we doing here today with

FSIS? Trying to workout the challenges. Well, that's what we do every day and that's all we ask, to be treated with the same thoughts as you treat any of your other constituents. Put the standard up there and then tell us meet it or get out of the business.

Thank you.

MS. SWACINA: Thank you.

It's very clear why this issue has been around forever and ever and that's one of the issues that I mentioned this morning. I've had to advocate on all sides of this issue, so as everybody takes different positions.

I do just want to remind everyone that the issue before us is not necessarily whether or not there should be interstate shipment, although clearly that is where this might head with Congress, but again to focus on providing advice to us on how to conduct these reviews that are directed in the Farm Bill Conference Report.

With that said, and we're over time, and I wanted to circle back with Mr. Govro to talk about country of origin labeling, too. So.

MR. GOVRO: Thank you. I have a question and a comment afterwards.

You mentioned that the country of origin

labeling would be required at the retail level, and I was wondering which agency would be responsible for the inspection and gaining compliance with those requirements.

MR. QUICK: The lead agency will be the Agricultural Marketing Service, AMS. There is an Agriculture Department-wide implementation, Farm Bill Implementation Working Group that -- this is on their agenda, but AMS will be leading the charge on that. That's one of the many, many challenges they'll face.

MR. GOVRO: Okay. In light of all of the efforts that have been undertaken in recent years to create national integrated food safety system, I would recommend that USDA look at leveraging its resources to include state and local agencies who already do the inspection work at retail level.

I can assure you that if you do not do that, there will be a considerable outcry from both the industry and the regulators in those states and in those facilities if another inspector comes in and begins enforcing a new set of requirements when that work could be done by the local inspectors who are already there.

MS. SWACINA: Thank you.

Ms. Foreman?

MS. FOREMAN: Yeah. I'm gonna forego the longer statement because I realize we already are over time. I do think that the review has to include -- one thing. The reason that the exemption is in the law is that there were some very small plants back in 1967 that clearly couldn't meet the facility's requirements that were being put in as part of federal law, and this was the bargain that was struck to get enough votes to get the bill through the Congress on both sides of the issue.

And today, it's being sought because small producers think that somehow they'll stay in business if they have other companies that they can market their meat to. The Economic Research Service has said that that effect is likely to be very small. They said maybe a total of $6 million a year additional. So, we're spending a lot of time as is the Congress on something that's not likely to have at least in economic terms a big impact.

I think there are two things that do have to be considered in the review. The first is since the last time we talked about this, we now have the threat of bioterrorism. We learned with anthrax, you don't have to make very many people sick before you can create a public panic, and state-inspected plants, I

think, might be somewhat more susceptible to somebody who wanted to intentionally contaminate meat with a dangerous substance.

The other one is one that somebody from the industry, in fact from the biotech industry, raised with me and I think it is a big concern across the board. As you have more and more companies developing transgenic animals, there is a question of what happens to the animals after you've harvested whatever product you want. These are the PH farming animals. Some of them grown for kidneys or livers, so on and so forth, and the companies have struck an arrangement, I believe, with FSIS that the animals could go into rendering but not into the food supply.

I believe that state-inspected plants are a likely target for people who decide that they would rather have that -- all of their takes and no takes or their takes after they've been harvested, put into the food supply and taking them to be slaughtered or processed at a small facility with less oversight is definitely a risk. As I say, it was raised with me by someone who's in the industry and fears that this may happen and in fact undercut the economic viability of what he's trying to do.

I think that somehow you're going to have to

deal with guidance to small plants, federal and state, about what you do with that.

MS. SWACINA: Okay. Thank you.

DR. Johnson?

DR. JOHNSON: Just one more question on what we're doing on reviews right now. When you go in and do reviews of the state programs now, is there one team that does the review, and do you have checklists that's used for that review, and is there anything that's currently used in federal plants that equates to that checklist? Do you use any parts of the IDV or any of the checklists that are being used in the federal plants?

DR. LEESE: Well, when you're speaking in regard to the in-plant review, excuse me, component of the comprehensive review, the Technical Service Center's the one that performs that review, the same people who would be involved working with the federal system and in the foreign reviews, and they have a basic format that's the same for whether it's the state review or whether it's a foreign review, and if it were going to be used for conventional-type review in a federal plant, I presume it would be used as well.

Of course, that's different than one of these more complex type of in-depth reviews which is a little

bit different than either of what I've been mentioning.

DR. JOHNSON: Thank you.

DR. LEESE: But some of it relates and some of it's tied together, yes. Among other things, it includes the grouping of worksheets that are involved in our current material for FSIS as to what components have to be accomplished with regard to the SSOP and the HACCP plan and the E.coli and so on.

DR. JOHNSON: But you do the checklist that's used for the state programs are also used for federal. So, it's not something totally different for each different --

DR. LEESE: It's a checklist that's used in those cases where there's going to be a conventional type of field review.

DR. JOHNSON: Okay.

DR. LEESE: But the federal program primarily at this time is involved in very specialized-type reviews.

DR. JOHNSON: Thank you.

MS. SWACINA: Thank you.

Okay. We'll move on to the presentation by Bill Smith, and the topic of the FSIS Field Workforce Roles and Structure, and the issue paper on that is under Tab 6 in your notebooks.

Issue - FSIS Field Workforce Roles and Structure

MR. SMITH: Thank you.

We would like to discuss FSIS Workforce Roles and Structures. Specifically, we are very interested in gaining input from all our constituents, the consumers, the states and the industry, to make verifications of food safety requirements, wholesomeness standards, and labeling provisions more effective and efficient.

Last Spring, we initiated a program called our Food Safety System Correlation and Review Teams to have a new approach at looking at how to -- the type of inspection we're doing, how we're verifying HACCP pathogen reduction requirements and how the plants are implementing the HACCP pathogen reduction requirements, and what's unique about this is after we do that assessment, then we come back to those areas and we meet with industry and the inspection team and share our findings, and so what we would like to see is recommendations from this group on how we can maximize the benefits from that program.

What I'd like to do is turn it over to Ms. Cheryl Hicks, who's our program manager in Field Operations here at Headquarters and she wants to give you -- walk you through the Food Safety Correlation

System process and then identify some specific issues we'd like the group to discuss tonight.

So, I'll turn it over to Cheryl.

MS. HICKS: Thank you, Bill.

Good morning. I'll give you a little background on myself, too, as others at the table have. I've been with FSIS for 14 years and had a lot of jobs in those 14 years. I started in Human Resources, worked in Review and Assessment in the Administrator's Office. I was the director of an information-related staff that reports to the Administrator, the Freedom of Information Officer, and we had executive correspondence and other functions, and I spent three months in Dr. Murano's office when she first arrived showing her the ropes with the administrative processes, and finally, after all that time, in January, I joined Field Operations where the rubber meets the road and happy to be there.

As Bill said, for those of you that don't know this, Standing Subcommittee is a new one, was just established this year on Field Workforce Roles and Structures, and I'd just like to go over the charge of this subcommittee for those that might not be familiar with what it is.

FSIS established a Standing Subcommittee of

the National Advisory Committee on Meat and Poultry Inspection to deal specifically with issues concerning FSIS field workforce roles and structures. The agency intends to use the subcommittee and full committee's expertise on an on-going basis to consider changes that we plan to make in our workforce. The subcommittee's role will be to provide advice on these changes and on how best to implement them over time as the food safety system evolves.

As Bill mentioned, the issue that we want to present for deliberation this evening by the subcommittee is how may FSIS further use the findings from its Food Safety System Correlation Reviews to enhance effectiveness of its field workforce.

Now, I know that in November, Bobby Palisano of the Technical Service Center gave you all a briefing on what these reviews are and what they're not, and I'll go over some of that same material again as a refresher. You also have an issue paper in your binders that goes over some of the same material and presents the questions we want you to answer and there's a copy of our agency directive on the FSSC reviews as well.

So, first of all, what are they? They're, as many of you know, they're reviews that are conducted by

our Technical Service personnel, district-by-district, and the review activity consists of two parts. It's in-plant data gathering by the staff officers from the Technical Service Center along with participation from the in-plant people, and there's follow-up correlation activities with both in-plant instruction personnel from the district and industry and state representatives from the area.

What they do is gather information about the food safety systems focusing on two things. First of all, the range of inspection practices within the districts and, secondly, the approaches employed by industry. What the objectives of these reviews are is to assess effectiveness of inspection verification activities of industry food safety systems, and the primary objective being to facilitate learning through correlation with in-plant personnel and industry representatives in each district following the reviews in that district.

More specifically, the feedback to inspection personnel is to enhance and improve the effectiveness and consistent application of inspection activities related to food safety and the feedback to industry is to improve the quality of HACCP and SSOP plans and the industry's understanding of our regulatory requirements

related to these.

Why did we decide to conduct these reviews? Based on our experience after HACCP implementation and feedback we've gotten from our own IDVs and in-depth verification reviews and audit findings, we realized that we needed to start focusing more of our resources on scientific and technical bases for HACCP plans and SSOPs, and while the purpose of these reviews is to improve our capability and effectiveness in verifying compliance with HACCP PR requirements and increase industry awareness, there are a number of things that the reviews are not and that is, they are not to give a report card on any individual plant or a report card on any individual employee or inspection team.

As I mentioned earlier, the reviews are conducted by Technical Service Center personnel along with the circuit supervisor, the IIC and often a district office representative.

What is the protocol for conducting them? There's a sampling of plants taken and it's either 10 percent of the plants in that district or 40 plants, and none of the plants that are selected are -- any of them have had IDVs or have current enforcement activity.

The teams gather information on the range of

practices within the districts. Weaknesses identified are discussed informally with the inspection personnel and plant officials at the time of the review, and then once the visits are completed in the district, formal correlation sessions are scheduled after that, after the information is summarized, and there are separate sessions for the industry people and our employees. Our Grade 8s and above attend the session for the agency, and then industry and state representatives are invited to sessions as well.

What are our time frames? We started this in fiscal year 2001, and by the end of this fiscal year, which is September 30th, we'll have completed these reviews in nine districts, and we expect to have all of the districts completed by the end of fiscal year 2003.

What are some of the common findings? Primarily the findings relate to HACCP plan design and supporting data and documentation. Findings indicate that inspection personnel often do not recognize non-compliance with regulatory requirements relating to the supporting documentation for HACCP plans. Plant personnel, while they're maintaining the required records, are not necessarily reviewing the records to determine the effectiveness of their food safety systems. Likewise, our inspection personnel are not

always reviewing the records to determine if they indicate non-compliance.

Some specific practices identified include weakness in identifying preventive measures relative to SSOPs, the use of standard operating procedures or GMPs in lieu of CCPs, lack of scientific support for critical limits, inadequate support for monitoring procedures and frequencies, and flow charts, hazard analyses and process steps that don't match.

What have we been doing with these findings thus far? Thus far, they've been used for the correlation meetings in each district. As I said, the findings are summarized by district for correlation in that district. However, common findings among districts that -- from previous district reviews are used in the correlation sessions for the following reviews.

By the end of the fiscal year, as I said, we'll have completed these reviews in more than half of our districts. Therefore, we've convened a group to begin looking at the findings from these reviews and to determine what our next steps are for the findings and for these correlation reviews themselves. Therefore, the timing is perfect for us to bring this to the subcommittee for input as we are beginning this

process.

The specific questions that we'd like the subcommittee to answer are the following. What ideas does the committee have on how we can further disseminate our common findings to our field force, industry, the states and other stakeholders so we can work towards ways to address common problems? What suggestions does the committee have for additional ways we can utilize the findings of the FSSC reviews to enhance the effectiveness of our field workforce? And what does the committee believe the findings of these reviews may tell us about the make-up of our field workforce?

Does anyone have any questions? Keeping in mind that I've only been in Field Operations since January.

MS. SWACINA: Nancy?

MS. DONLEY: Nancy Donley from STOP. I found it very interesting that the reviews, as you mentioned, Cheryl, say that thus far indicate that the primary shortcomings relate to HACCP plan design and supporting data and/or documentation, and I'm just wondering, what is the agency doing about this problem? What's in the planning stages to correct this?

MR. SMITH: There's a couple things. First,

we are when we publish our regulations like we did with the stabilization regs, are publishing ways for plants to achieve these through appendices, cooking standards and chilling standards, like we did with that. So, we're sharing any information we already know and making available for scientific basis why they're doing what they're doing.

We're also -- that's where we have designed this, what we call our 30-day reassessment letter, that if we don't understand how the plants arrived at conclusions based on their science, we're going back and asking them formally to identify to us and at that point, we can get them to then relook and either provide more information or reassess their plan. So, those are two of the major things we've been doing.

Also, with our Consumer Safety Officers, we're again working with the plants, directing them to a lot of resources that are available to help them again substantiate the science or the reason why they're doing what they're doing in their plants.

MS. DONLEY: I'd just like to follow up and say that, you know, kind of looking at this, and I think it's an excellent idea to have this type of program going on, it's just -- it just kind of leaps out at me, and we advocated from the very beginning of

-- during the whole rulemaking process for HACCP, that there has to be -- we argued for FSIS-validated HACCP plans, but what it is here is I see this as being something that -- where doing correlation studies to see how well ineffective plans are being implemented, how well they're being -- what type of inspection is being -- is in the inspection on these incomplete and invalid plans being done effectively.

It's just kind of ludicrous to me that we're -- we need to attack the base problem and that is, and I think this is very interesting to see that the Number 1 problem is, and this -- the whole idea of the PR HACCP legislation was to further protect government -- further protect public health and safety, and that we're finding here as the Number 1 -- the primary problem is that the plans are no good and that's --

MR. SMITH: No, no. Well, that would be -- that's not what we said. What we're saying is that in a number of cases, the supporting documentation for the decisions that they made. So, let's say somebody is cooking a ready-to-eat product to 160 degrees. Well, we do not have concerns with a 160 degrees for delivering lethality, let's say, to a ready product. Many times, the plant will not have the documents that say why a 160 degrees -- why a 6.5 log reduction in

Salmonella achieves the elimination of the organism. That is different than saying that they don't have the control in place.

So, what we're finding more often is that past practices of the regs, let's say cooking to a 160, is in -- is the critical control point in these plans. What we're saying is sometimes we don't -- they don't have the scientific documentation that says why a 160's important.

So, we've made -- I just want to make it very clear. We expect and have been, if our people have any concerns about critical control point, critical limits from a safety standpoint, they are to act on that and that's what we did initially, and coming back in the reviews is what we're trying to make sure that everybody has the documentation that supports why a 160 does this in this situation or why this critical limit does this in this situation. What's usually a requirement of the HACCP plan doesn't mean that it's been ineffective.

MS. DONLEY: If I can just follow up with one last question, and that is, on the last page of your -- the FSIS Notice that you included is dated October 11th, 2001. It just -- the Question 7 -- 12, I guess, never been very good with Roman Numerals, is who can

attend the correlation meetings, and it says, "FSIS inspection program personnel and industry representatives are encouraged to attend the correlation meetings."

My question is, where are these meetings held, and why can't all stakeholders attend this who want to? Why aren't all stakeholders invited to attend?

MR. SMITH: Well, again, we're hoping that we'll get guidance from this committee that if it should be expanded, that we get that kind of guidance.

MS. DONLEY: Okay. Thank you.

MS. SWACINA: Thank you.

Mr. Govro, yes?

MR. GOVRO: Thank you. Cheryl, at the last meeting of this committee, we listened to a presentation -- which was before you were here. We listened to a presentation about an effort that USDA is undertaking to evaluate the effectiveness and understandability of the directives that it issues to the field, and we also heard a little bit on this subject, and the committee recommended that perhaps those two groups should talk.

It didn't appear that there was a real effective way of actually evaluating whether the

requirements of the directives were being followed by personnel in the field, and we made that recommendation, and I just wondered if that was being followed through with.

MS. RIGGINS: We are following through on that. Jane Roth, I believe, is here and is actively in the throes of evaluating our directives.

Jane, do you want to kind of give a thumbnail sketch of the process that you're undergoing and the interaction that you have with the Tech Center and others in Field Operations?

MS. ROTH: We have one staff person who devotes a large portion of her time to getting feedback on the directives that are identified as major objectives -- major directives. We just finished an evaluation of the Animal ID Directive and we're writing that final report, and as a result of that, the Regs Office makes revisions and they send out revisions that amend any of the issues that arise, and also we've started to publish the reports on the website. We have a new website, and so those reports will be going up there, and they'll be available for the field as well as for industry.

MS. RIGGINS: And in addition, we intend to use the results from the evaluations to improve our

training. One of the things that we have instituted is to include personnel from the Training staff, what we are now calling our Center for Learning staff, in each of the groups that are developing policy for regulations and for directives and to make sure that they are fully involved and engaged in the discussion of the issues so that when we issue the directive along with the regulations or guidance with the regulations or just simply a directive by itself that they will have an understanding of the thinking that went into the rationale of the directive and will have a better opportunity to develop training with us that is meaningful to our employees, so that we're doing a better job of communicating with them using the information that Jane's folks are feeding back to us to make improvements in our communications.

MR. GOVRO: Just a little bit more on that. It says here that these reviews are about finding areas on which Inspection personnel and industry officials need further information and awareness to improve the effectiveness of FSIS verification activities and the quality of industry SSOP and HACCP plans, and it appears that you're very much directing this toward dissemination of information which is fine, but I'm wondering if some of the data that you gather in these

correlation activities indicates that perhaps the problem is not one of understanding but of other issues and what you do with that information if and when you find it.

MS. HICKS: When you say other issues, what do you mean? Just execution?

MR. GOVRO: Well, there may -- yeah. There may well be a full understanding of what the rules are. They may be choosing not to follow them for some reason or another.

MS. HICKS: Another way in which we're using the information we got from these reviews is this Summer, we'll be training all of our supervisors of in-plant personnel on a new system that they're to use to look at what Inspection personnel are doing, to visit them and with them and look at how they're carrying out their inspection activities. It's a much more structured and consistent approach than we've had in the past, and it'll be implemented at the end of the fiscal year. We'll be training this summer, and what we plan to do is -- I mean, it covers everything that they're responsible for, but we plan to use what we've found in these reviews and disseminate that information to the supervisors so they can make sure that they target those areas in which we've -- that were

highlighted by these findings. I don't know if that answers your question.

MR. GOVRO: Yes, thank you.

MS. SWACINA: Okay. Thank you.

Mr. Neal?

MR. NEAL: I'll let Collette go. She had her card up, and I think she's going to say the same thing I did. She's a better speaker than I am anyways.

MS. KASTER: I don't know that I disagree -- agree with that. That was Freudian.

MR. NEAL: Don't blow it.

MS. KASTER: But I think, you know, we have both a strong reaction to, Nancy, to your comment, and, you know, we've been through the correlations. We've been through CSO visits and it shouldn't come as any surprise to anybody familiar with the concept of HACCP, and I wish Dr. Pearson was here, that it's in a state of continuous improvement. Any type of process improvement plan like that, quality improvement program, one of the cornerstones of it is continuous improvement.

Most of the things that have been identified are even more housekeeping detailed than what Bill indicated. They're things like should we calibrate a thermometer that we're going to check 45-degree

temperatures one time or 20 times per day? We have spent hundreds of man hours since this has happened just going back through dotting Is, crossing Ts. I'm not saying that that isn't something that everybody should have done, but certainly I just kind of feel very strongly that, wow, it's resulted in a strengthening of the programs and, you know, you can argue timing and that kind of thing, but I think there's been an awful lot of effort there.

I think the other thing that's happening, right or wrong, I'll just point this out, is that it's resulting in a homogeneity of these plans and basically we're ending up with cookie-cutter plans across the industry where, you know, if this type of verification is being seen in one district, why isn't it being seen here, and so we're heading down the road of plans that look very similar.

MS. DONLEY: Is that a problem?

MS. KASTER: Well, it's not really consistent with what we say that HACCP is supposed to do, which is supposed to be customized and unique to each process, and in some places, yes, slaughter is slaughter is slaughter and so that may not happen, but I think that in order to train as many and inform as many personnel as we have to, that we're losing some of the ability to

customize and have these plans really be specific to the plants and businesses in which we operate. It's not a bad thing, but it's just maybe not consistent with what HACCP itself was designed to do.

MR. NEAL: She said it right. But basically, what they're not finding is they're not finding -- the critical control points are set. That's the heart of the issue. Those are set, and we're finding housekeeping. That's exactly what I was going to say, not as well, but I was going to say.

MS. SWACINA: Thank you.

Let's see. Mr. Holmes, you had your card up. Did you still want to talk? Marty?

MR. HOLMES: Actually, I had the exact same thing that Collette said, but it was just recognizing that it was relating to supporting documentation, that they're being maintained, not just reviewed. The same comment.

MS. SWACINA: Thank you.

MR. SMITH: I just wanted to add one thing to -- because I think it is very important. Our issue is not to drive things to be the same everywhere, other than that the requirements that on-going verification, that a part of that is not just verifying equipment is working, but it is looking at the results of the

inspections or results of the information being generated through monitoring and reacting to it.

That's -- because I don't want to lose the preventive message, was whether it's SSOP, there's requirement to constantly re-evaluate the effectiveness, there's a verification requirement in HACCP to constantly look at the data and make adjustments, and that's -- everybody's done an excellent job getting it implemented. So, one of the things we would like to see both from our people to focus on and with the industry is what is the data now telling us, and are we adjusting those programs based on that data? So, it's not a drive to make everybody the same, but it is a drive to meet those requirements from the standpoint of what is the information these programs are telling us, and what are we doing to these programs to adjust them based on that information?

MS. SWACINA: Ms. Eskin?

MS. ESKIN: Yes. I wanted to just focus back on that sentence we're all focusing on here where the second part of the sentence, again, the "FSSC reviews thus far indicate that the primary shortcomings found relate to", and we focus a lot on supporting data and/or documentation.

I understand the housekeeping piece of it.

What about the first part there? Again HACCP plan design. You know, what have you seen to date, and I guess there's a larger question here, is, these reviews, are they themselves either on a district basis written up, and is it something the public can have access to? Again, we don't need -- we just -- whatever it is that is produced, so that we all, to the degree we want to see it, know exactly what you are seeing when you're in there.

MS. HICKS: First thing I want to point out is that what's done in each plant in the course of these reviews is not a comprehensive review.

MS. ESKIN: I understand.

MS. HICKS: Like IDV would be. They just look at a few.

MS. ESKIN: Again, just whatever it is that you look at, you know. Again, we're talking a lot about these two things here, plant -- a plan design and supporting data, and maybe some of our questions would be answered if in fact what you said orally is somehow available. So again, I'd like you to address this issue of whether the HACCP plan design problems or issues that you've seen to date in these FSSC reviews.

MR. SMITH: Okay. A number of it -- a lot of it is that a piece of equipment that may or may not

impact the product has not been considered --

MS. ESKIN: As a --

MR. SMITH: -- in the hazard analysis. No, has not been considered in the hazard analysis. Not each and every piece needs to be -- equipment -- not each and every flow or addition of this, that or the other results in a hazard that needs to be controlled by a CCP, --

MS. ESKIN: Right.

MR. SMITH: -- but it does need to be considered in that. So, there's been -- what has been standard practice, sometimes it's taken for granted and therefore in the end probably will not have a whole lot of result on the hazard analysis and what establishes the CCP, but what we're seeing is not has been considered in the hazard analysis and those are some things we're trying to get caught up on. That would probably in my mind be most of what they're finding.

MS. ESKIN: In terms of the questions regarding plan design, but I assume --

MR. SMITH: Right.

MS. ESKIN: -- at least however number of incidences you've taken a look at, some of them which haven't included, let's say, a key piece of equipment in fact should have. It's safe to say that not --

again, you identify the issue, but I'm wondering again to what degree have you found -- maybe you can't quantify this, but I assume you have at least in some instances found that the plan design, the thing that's been left out in fact is material, something that should be included. Is that a fair --

MR. SMITH: Right, and again, when we're at the plants and we find, you know, the directive also says if we determine there's non-compliance, it will be handed off to the inspector to deal with. So, the question you have to -- let's go back to Reg. E because that's the easiest to talk about.

Even though something's been left out, the question is, will the hazard raised by that not be controlled by the critical control point or the critical limit?

MS. ESKIN: Right.

MR. SMITH: You can come to the conclusion at least right on the spot that it is not an issue because of the critical control point, then it becomes a finding that needs to be adjusted, but it's not something that's going to be unsafe and that's the decisions we're asking the teams to make while they're there.

MS. SWACINA: Okay. Let's see. Ms. Foreman?

MS. FOREMAN: Thanks. Carol Tucker Foreman with the Consumer Federation.

I think I'm back in the same area of this. If the goal is to ensure that program activities are carried out in as consistent a manner as possible throughout the country, I thought the goal was to see if plants are turning out safe product.

I happen to share some of industry's concerns about homogenizing HACCP plans and going back to command and control inspection, but if you want to not have command and control and you don't want to have homogenized HACCP plans, there's got to be some standard that products meet at the end of the line. That's why all the way through this process, we've said if you -- you've got to have some numbers that show at the end of the line that a product -- that verifies that the HACCP plan is doing what it's supposed to do.

If there were some way you could test for every pathogen out there at the end of the line in real time, I would say to you, I don't care how you get there. But if there's not going to be any standard regarding food safety at the end of the line, then we're all going to end up going back to are you doing each little thing along the line in a way that USDA finds meets some subjective standard and that's where

we're going, right back to the subjective standard, because there is no objective measure at the end of the line. It's really sad because I think we're slowly unraveling what HACCP was supposed to be.

MS. SWACINA: Okay. Mr. Link?

MR. LINK: Charles Link. Just a general comment and just based on my own experience. On this HACCP plan design issue, I think it's back to what Collette said. It's almost a housekeeping situation more than anything else. I mean, we've had the CSO come through and say, well, this part of your program really ought to be in the raw ground or raw not grounds or in the slaughter, pick a spot and put it in there and make it fit. Therefore, our plan design was inaccurate.

I think Bill made a comment. Even for years and years, we've done 10-bird inspections. That's just what we've done, and it's been ingrained in our heads, but now we've got to support the 10 birds is actually the appropriate number. So, those are the kind of things that kind of get overlooked as you're building these programs, and I support the concern that we had, you know. I've seen this down the road. You gotta have it in your plan, too. If you don't get it in your plan, we're going to give you 30 days to make it right

which gets back to this homogenizing thing which is a bit of a problem.

But as far as what these guys have been finding through these district reviews, I've seen with the checklists, the 10-part checklist, kind of a summary of the types of things under each checklist that they're finding. It might be beneficial to have that, and I guess it's in here somehow, to actually have that kind of laid out for the group to be able to look at and see under SSOPs what types of things we're finding. Is it we forgot to do the preventive measure piece or just what it was? So, it would help to kind of work through this and what they're seeing.

MS. SWACINA: Okay. Thank you.

I guess we are ready to break for lunch. So, we'll be back in an hour, and hopefully we'll be right on time because I know this afternoon, it'll be an interesting session.

MS. FOREMAN: Do we have the HIMP documents here so we can review them over lunch?

MS. SWACINA: I believe that's what she has right behind you.

(Whereupon, at 12:06 p.m., the meeting was recessed, to reconvene this same day, Wednesday, June 5th, 2002, at 1:00 p.m.)

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

1:17 p.m.

MS. SWACINA: Okay. Welcome back.

This afternoon, we are going to be talking about the HACCP-Based Inspection Models or HIMP, and we will start with -- I hope everyone got the materials. Is there anybody who didn't get the materials on the committee?

(No response)

MS. SWACINA: Okay. Okay. I'm going to turn it over to Phil Derfler, who is the Deputy Administrator for Office of Policy, Program Development and Evaluation.

MR. DERFLER: Hi, and welcome, everybody, to this afternoon's session of this advisory committee.

We intend this afternoon to spend the afternoon making an important presentation to you on the HACCP-Based Inspection Models Project, and I'd like to start by giving a quick review of this program.

When FSIS implemented the Pathogen Reduction HACCP Regulations, it put a bubble over slaughter inspection. While slaughter plants were required to put in place HACCP systems, FSIS inspectors continued to perform their slaughter inspection functions the way they had before HACCP.

To explore how to bring slaughter inspection under HACCP, in 1998, FSIS began to work on the HIMP Project. At that time, FSIS designed an inspection system and then set about effecting a study that would compare the accomplishments of the new system with those of the traditional inspection to see whether the new system was as good as or better than traditional inspection.

FSIS contracted with the Research Triangle Institute to perform a before and after study of the effects of the new inspection system. RTI measured the results of the traditional inspection system in 16 young chicken plants, five young hog plants and five

young turkey plants. RTI measured performance in food safety and other consumer protection categories.

After RTI completed its work, FSIS set a performance standard of zero defects for two food safety categories and used RTI's findings to set standards for five other consumer protection categories.

RTI then measured the performance of the new system that was put in place in HIMP plants. In this system, plant employees rather than FSIS inspectors are charged with the initial sorting of carcasses. FSIS inspectors initially were charged with verifying both through observation and examination of a sample of birds whether the plants were performing in accordance with their HACCP plans for food safety and their process control plan for other consumer protections. The agency said that it would compare the performance of this new system as measured by RTI with that of the traditional system as reflected in performance standards.

When FSIS started this study, it stated the study would continue until there were data from the same number of plants performing under models as there were under baseline, and Dr. Kenneth Petersen will talk after me and describe the protocol that FSIS developed

as part of HIMP.

Today, we're here because data collection for the young chicken plants is complete. Don Anderson of RTI will brief you in a little while on the data that RTI has collected and after Mr. Anderson is finished, Dr. Columb Rigney of FSIS will brief you on the data that FSIS inspectors have collected in HIMP plants during the entire period that the young chicken study has been underway.

We're making these presentations to you because of this committee's close association with HIMP. You've been involved since the inception of the study and Mike Grasso has been coming to committee meetings every time to give you a progress report. Thus, we consider this committee meeting to be an appropriate place to present the data gathered in reaching this important milestone.

Before we get to the data, however, I would like to make a few additional introductory points. First, everyone should recognize that very little about this project has been easy. One difficulty has been that the agency has had to deal with resistance from the leadership of its union. The union and FSIS began negotiations on the project in the Fall of 1998 and did not reach agreement until May of 1999. This agreement

provided that the agency could assign inspectors to perform the new work in up to 30 plants, but this agreement was not the end of the agency's problems with the union leadership. It was only the beginning.

Just as the agency and the union were reaching agreement, the American Federation of Government Employees, on behalf of the inspectors union, brought suit in the United States District Court for the District of Columbia against the agency, charging that the inspection system that was being tested in the models project violated the Meat Inspection Act and the Poultry Products Inspection Act.

After an initial agency victory in the District Court, the union won in the Court of Appeals. The Court ruled that under the inspection system that FSIS was originally testing in the models project, FSIS inspectors were looking at people instead of making critical determinations about the products which is in fact what they were required to do under the Act.

As a result of the Court's decision, FSIS redesigned its inspection system. It put an inspector before the chiller to examine each carcass for food safety defects. It also continued its verification activities, and earlier this year, this revised system was upheld in the Court of Appeals.

The uncertainty created by the union's lawsuit had a significant ancillary effect. Plants were reluctant to volunteer for the project as long as the possibility existed that the whole project would suddenly be terminated. They simply did not want to make the investment that participation required without some assurance that the investment would not be wasted.

There's also a second factor that limited plant participation. The agency's data collection efforts provided new types of information. It made clear, for example, that some products that passed inspection still have, for example, scabs and sores. Groups that supported the union and opposed the project cited this information to deprecate the products of plants that participated in the project. They conveniently failed to note, however, that these products were likely to contain fewer scabs or sores or more likely to contain no scabs or sores than those passing under traditional inspection.

As a result of these problems, the process of enlisting volunteer plants has been slow going at best. It has, for example, taken us four years to complete our data collection for young chickens and this is the first species that we completed.

The latest source of problems for the project

was -- I'm sorry. The latest source of problems for the project was a review by the Government Accounting Office. Even though GAO found merit in the concept being tested in the HIMP Project, it raised concerns about how well plants were actually going about -- what they were actually doing and about the validity of the design of the project.

Despite these problems, the HIMP Project has persisted. What we need to consider is how the project persisted and why. As for how, you need look no further than the people who have made presentations to you in the past about HIMP and will be doing so today.

Mike Grasso, Ken Petersen, Columb Rigney and the people who work with them, Lenny Lange, Bill James, Barbara Dwyer, Delia Parham, Mike Donovan, Carol Fletcher and others, have always viewed the project as a work-in-progress and accepted each new criticism as a constructive suggestion and an opportunity to improve the inspection system.

I've already mentioned that they responded to the Court of Appeals decision by redesigning the system. They responded to questions from in-plant inspectors by making improvements and changes in the instructions issued as part of the project, and they responded to concerns in the GAO report by developing

new eligibility criteria for participants, developing guidance for training plant employees and designing enhanced mechanisms for receiving feedback from FSIS's in-plant employees. This willingness to listen, change and adapt has helped the project to survive.

In describing how HIMP has persisted, there's a second element that I need to point to and that is the willingness of the plants to make changes. For example, as I said, as a result of the Court of Appeals first decision, FSIS put a carcass inspector before the chiller. All of the participating plants cooperated with this change by putting in place with virtually no complaint a platform on which this inspector stands to do his or her work.

This brings us to the question of why the project has persisted. To my mind, there are two reasons. The first is that the agency has learned from its inspectors about the project and what the agency has learned from its inspectors. Quite frankly, the support from the in-plant personnel has been overwhelming. Many have reported that not only is their job better but they are able to do their job better. Over 70 percent of them reported to GAO that food safety was as good as or better under the HIMP System than it had been.

The second reason that the project has persisted is that we in the agency management, based on the interim data reports and our own visits to HIMP plants, have seen nothing that will lead us to believe that the new system is not as good as or even better than traditional inspection.

The birds and animals produced in HIMP plants appear to have fewer important defects and to be cleaner than the birds and animals produced in traditional plants. We believe that the plants themselves have noticed an improvement and that is why they have not objected to the changes in the project.

We now have a full set of data, however, and it is this full set of data on young chickens that we'll be presenting today. Just a word about ground rolls. You'll be hearing a series of presentations. At the end of each presentation, there will be an opportunity to ask clarifying questions, but if you have any other broader questions, we hope that you'll wait till the end of all the presentations and that's basically for the committee members.

Okay. With that, I'd like to introduce Ken Petersen, Dr. Ken Petersen, from the Office of Field Operations.

DR. PETERSEN: Good afternoon.

Before I get started, I'd like to make two introductions. Many of you that have been involved with this project for quite some time, and I guess it has been quite some time, realize that the role of the inspector-in-charge in these HIMP plants is particularly critical because they are the ones who help target our resources in the plant to do the things that we need to do, and I have two visitors with us today. Both are inspector-in-charges of HIMP plants.

One, the first one is Dr. Iris Dixon. If you would stand, please? She is an inspector-in-charge of a HIMP plant in beautiful Alabama, and our second visitor is Dr. Nan Armand, who is an inspector-in-charge in the great state of Texas. Thanks for coming, and we encourage anyone to interact with them at break. You're welcome to do so.

Before we start to hear about some data, we thought it might be useful to go back to how we got the data and really how we started this project. As Mr. Derfler mentioned, the fundamental goal of the project was to integrate slaughter into HACCP and that remains the fundamental goal.

So, to begin to do that, we had to measure for the first time the accomplishments of the traditional inspection system and then from that data

set performance standards, primarily for non-food safety-related defects, and because these are new performance standards, what have been referred to as OCP or other consumer protection defects.

We recognize that there may be more than one way to produce a chicken and produce a chicken that is safe and wholesome and yet the current inspection system limits opportunities for innovation with new technologies, whether they be data management or other ways to process this product. So, the project creates an environment for innovation.

But we have to do all of these things under our existing statutory mandates and then, finally, measure a new system. Back in 1998, we had two public meetings where we discussed project protocols, and the agency largely developed these protocols, and we had two public meetings, as I mentioned, in '98. They were discussed also with this committee and also we had some discussion with our Micro Advisory Committee on the protocols, and from those protocols were a couple elements, but the main one was sample sizes, and in each of 16 broiler plants, we sampled 2,000 carcasses at the end of the production process for organoleptic-related diseases, conditions and defect. This sample size gives us reasonable precision with a 95-percent

competence to estimate those populations in those plants. Those are the organoleptic samples.

We also conducted some microbial analyses, and in each plant, we collected 300 samples, 300 carcass rinses, and the samples were split, half of them, 300 analyses were done for Salmonella and 300 for generic E.coli, again in each of 16 plants, and estimating the prevalence of these various things with a 95-percent competence level.

So, the baseline data collection, as I mentioned, was for the first time to measure the traditional system. We contracted with an independent contractor, Research Triangle Institute, who then collected the baseline data in 16 volunteer young chicken plants, and they were in each of these plants for six weeks total. Each of those weeks, they collected the microbial data and five of those weeks consecutively, they collected the organoleptic data.

These durations were again part of the protocols because they help us adjust for variability in the process. Being in plants and collecting these number of samples over time helps you adjust for worker effects, time of day effects, flock effects, these kind of things that could only be controlled through the design.

The outcome of the baseline data was, of course, to tell us what was happening with the traditional system, but to set the platform for new performance standards for each of the species and, of course, today, we're focusing on young chickens.

The new performance standards, as you'll see in a minute, raise the bar of performance. They exceed the output of the current traditional system. They raise the bar, if you will. Seven performance standard categories were established, again going back to 1998, two were food safety-related, and five were for other consumer protection.

In the HIMP plants, they have a new food safety standard and that is for birds that exhibit a condition known as septicemia and toxemia. There is a zero tolerance standard for this only in the HIMP plants. So, this is a new food safety standard for these plants.

Then we have an existing zero tolerance standard that is unchanged. That same standard applies in a traditional system as well as a HIMP system. Then we have five categories that are listed a little more closely in two of the other handouts from RTI as well as from Dr. Rigney, but these other five categories capture other things that we see at slaughter, things

such as airsacculitis, some skin conditions, bird viral conditions, as well as various processing defects, such as pieces of ingesta or feathers.

This slide is rather important because it shows how we developed the performance standards. The bottom of the slide on the X axis, we see Plants 1 through 16. These are the traditional plants. On the Y axis are percentage of carcasses that had a various defect category that RTI measured during the five weeks that they were in the plant, and we have ranked the results from low to high.

Every bird and every -- this is a hypothetical example. It doesn't reflect a particular OCP category, but the process was the same for each OCP category. Every bar that you see represents product that met the existing traditional system requirements, but instead of taking all of those accomplishments, we decided that it would be more appropriate through the pilot to set a new performance -- a new level of performance. That's been referred to over the past time period as so-called 75th percentile or the 12th out of 16 plants, 12 out of 16, 75 percent.

So, we decided the performance of the bottom four plants was not going to be acceptable in the HIMP system. So, the new level of performance was set at

the accomplishments of the 12th out of 16 plants. So, in a HIMP system, a plant that meets the accomplishments of the 12th plant has in fact already exceeded the accomplishments of the traditional system.

The performance standards were set. The volunteer plants were ready to go. So, they had to revise their HACCP plans, partly to incorporate the new food safety standard I mentioned. They had to develop and implement new process control plants for the OCP standards, and essentially what a plant would do is target their process to meet the performance standard. That is their goal, and then, once the plants ran for awhile, RTI would come into the plant and measure the accomplishments of the HIMP system.

Any brief questions related to how we got the protocols and how we implemented the protocols?

MS. LOGUE: Catherine Logue, North Dakota State. Did FSIS design this protocol and then give it to RTI to do?

DR. PETERSEN: Yes.

MS. LOGUE: Okay.

DR. PETERSEN: We designed the protocol. We discussed it publicly. RTI implemented the protocol that we gave them.

MS. LOGUE: You designed it. Okay.

DR. PETERSEN: Thank you.

MS. SWACINA: Dr. Johnson has a question.

DR. JOHNSON: Yes. Dr. Petersen, I know that RTI went through some training. Do you want to explain how RTI and being able to look at the OCPs, how they -- what type of training or correlation was given?

DR. PETERSEN: Okay. Don will touch on that.

DR. JOHNSON: Okay. Thank you.

DR. PETERSEN: Before we get going, the next speaker who many of you have met is Mr. Don Anderson with the Research Triangle Institute, the RTI leader as far as this project is concerned, and he will walk us through what they found on the implementation of the protocol.

MR. ANDERSON: Okay. Thank you, Ken.

I am Don Anderson from RTI International. You've heard us referred to as RTI and Research Triangle Institute. Like so many other companies, KFC, IDT and IBM, we're not even known anymore officially and legally as Research Triangle Institute. It turns out we are RTI and some day maybe I'll be one of the few people that knows what RTI stands for.

So again I'm Don Anderson. It's a pleasure to speak with you today. I'd like to acknowledge also the presence of two other colleagues of mine who have

been with me and with FSIS since the origin of this project, Ms. Sherry Cates, who's sitting back here. Sherry, I actually would just like you to stand up for a second. Thank you. From RTI, and Dr. Pat Brown, who is our lead scientist, and you'll hear quite a bit more about her role during my presentation.

I'm going to talk about the organoleptic and the microbial data that we collected from the 16 young chicken plants, both in what I'm referring to here as baseline, by that I mean simply the traditional inspection system, compared with the data from a similar set of plants that we collected data from during models we designed. I won't be talking about any other species other than young chicken today.

This is a list of the volunteering young chicken plants and again what I'm calling the baseline or the traditional inspection phase of the project. Data was collected from these 16 plants under traditional inspection over roughly a one-year period of time. Data collection started, traditional system inspection data collection started in August of 1998 and continued through October of 1999.

Our first plant that we ever collected data in was then known as Rocco and now George's Chicken, and I had the pleasure to first meet Charles Link at

that time when we started data collection in that plant, and we finished data collection in the Marshall Durbin facility in Hattiesburg again in October of 1999. In keeping with the FSIS tradition, I've listed the establishments here in order of establishment number rather than when they came into the project.

These are the names and locations of the 16 establishments that participated in the HIMP models redesign phase of the project. I have highlighted in blue here the 11 establishments in which we collected data in both the traditional inspection system and the new models redesign inspection system. You can infer from that, since there were 16 in both, that there were five plants that participated in baseline that we didn't collect data in in the traditional inspection and those plants were, if you will, replaced by some additional firms and you can see there which establishments fall into each of those two categories.

This is a map that shows where these establishments are located. Again, it's color-coded as to whether the establishments were in baseline and redesign or just in one phase or the other. One of the things I would like to point out just so you don't have to count them yourselves, there are 12 states with one or more establishments that were involved in one phase

or the other of the project. We've done a quick analysis using FSIS's own databases, and I can tell you that 80 percent of all of the young chickens that are slaughtered in the United States are slaughtered in establishments located in these 12 states.

The state that we didn't -- a state that we didn't collect data in that would have been the next most active state for slaughter would be the state of Missouri. That is, after these 12 states, Missouri is next in line in terms of production, but even in the state of Missouri, they only slaughter about 4 percent of all the young chickens in the U.S. So, I think the states in which these establishments are located are fairly representative of chicken slaughter.

Now, I'm going to talk about the organoleptic data collection and the results and after that, I'll turn to the microbial data collection. This is a schematic that shows just at a top of the trees level how the data collection, the organoleptic data collection proceeded. The organoleptic data for all of these plants were collected by veterinarians that were hired by RTI and by Dr. Pat Brown. Again, Dr. Brown was our lead veterinarian, our lead scientist. All of the organoleptic data then was collected by veterinarians independent of FSIS.

Even before we went into an establishment to do correlation work, these independent veterinarians, of course, needed some training. They used FSIS-provided self-study materials to study how to call the diseases and conditions of concern in these various species. They also attended correlation sessions.

We use the word "correlation" a lot in a lot of different ways, so I'll try not to be confusing with it, but essentially prior to the start of data collection in either phase of the project, the RTI veterinarian, Dr. Pat Brown, staff from FSIS, and other inspection and company personnel from the establishments where the data were being collected attended what was typically a two-to-three-day correlation session where everybody got together and got on the same page, to the extent possible, on how we would be calling diseases and conditions, and I'll be talking quite a bit more about that.

We actually -- our veterinarians actually collected three types of data. We'll only be talking about one of those today. There was an antemortem data collection phase. There was also a condemned data collection component, but I'm going to be talking today exclusively about the examination of these 2,000 carcasses per establishment that Ken referred to.

The protocol called for our veterinarians to look at 80 carcasses a day for five weeks for a total of 2,000 carcasses over the data collection period. This masks some certain elements that I think are important for various reasons. Most but not all but most of the establishments that were participating in this project were two-shift establishments. Okay. We collected data to the extent feasible approximately evenly over each of the two shifts.

During the first week of data collection because it involved a correlation step with a lot of people coming in from town, we almost always collected data on the first week in what I guess we would typically call the day shift, so we didn't upset everybody's sleeping schedules. Typically, though, in a two-shift plant, our second week of data collection would be on the night shift. Our third week would be back on the day shift. Not strictly speaking, though, because one of the things we wanted to do, to the extent possible, was to announce to the establishment and to inspection personnel when we would be collecting data.

We didn't want necessarily the various -- all the various stakeholders to know five weeks out what day we would be collecting data. So, we announced as

close as we could a just-in-time data collection period. So, it wasn't always known to -- it was seldom known to the establishment much in advance when we would be collecting data. I could go into the reasons for that later, if anybody would like to know about that.

We did have to announce it somewhat in advance, though, because we did need the assistance of certain plant participation, mainly in the condemned activity, to help us move barrels around and things like that. So, we had to announce it shortly in advance but not much in advance.

These data that were collected through the course of the project, remember we looked at 16 plants in each of two phases. We collected 2,000 samples. So, we got a total data set, if you will, of approximately 32,000 passed carcasses. Those 32,000 passed carcasses were examined by 11 different veterinarians, but many of our data collectors, many of our veterinary data collectors, especially in the models phase, were repeat data collectors, and in fact, all of the data collected during the models redesign phase, all those data were collected by just four veterinarians.

We needed multiple teams of veterinarians

because there were times when we would be operating, that is collecting data, in two or even three plants at a time. So, we needed several teams of data collectors that we could move from site to site.

The other thing I would like to point out, which is very important, which is about this correlation activity, and I'll mention it again in a minute, the correlation activity was, I think, in many ways particularly important for the benefit of the establishment personnel and for the benefit of the inspection personnel because for some of the conditions that we were calling, for some of the OCP conditions that we were collecting data on, we were not using traditional what are called finished product standards.

Finished product standards are the traditional way, I guess, of characterizing whether or not a particular passed carcass has a defect or not and the simplest, easiest one to understand is feathers. We could have gone in, I suppose, and collected data and counted birds with feathers as defects and said, well, you know, everybody can see a feather and a feather is a feather and we'll count feathers and we'll count defects. The problem is under finished product standards, and I think I can quote this accurately and somebody can correct me if I've got it wrong, but under

finished product standards, a passed chicken, a passed young chicken doesn't have feathers unless it either has more than five feathers or one or more feathers of greater than, I believe it is, an inch in length. So, that's a finished product standard criteria.

Under this project, we didn't use criteria like that. We used more, I guess I would call them or I think Dr. Brown refer to them as, more pathological determinations. When we observed the bird with a feather of any length and any number of feathers, that bird had feathers. That's how we classified it. There are other examples where there's a difference between finished product standards and the criteria that we used for calling defects. That's probably the easiest to understand.

One more note, and I know I'm spending a fair amount of time here but it's very important to understand this process. I just want to reiterate what Ken said and that is, that these sample sizes, the 2,000 carcasses per plant, can be shown statistically to estimate with a reasonable level of precision a population estimate that -- the population estimates that we're likely to encounter in young chickens.

This is a listing of the other consumer protection conditions. I'll talk about the food safety

conditions a little later. This is a listing of the individual conditions that make up OCP categories. Each of the diseases in OCP-1 and the localized other consumer protection issues fit into each one of these categories.

I'm going to be presenting the data that you're about to see by each of these OCP categories. We actually collected data on each of these individual conditions and we have that raw data. So, we can calculate the prevalence of airsacculitis or ingesta or breast blisters, but I'm going to be presenting data now by these OCP conditions.

I would like to say that these animal disease conditions, if any of the birds that had any of these animal disease conditions also exhibited septicemia or toxemia as a result of that, then we called it a food safety condition, other than an OCP condition. So, these are disease conditions that have not gotten to the point of where they're exhibiting septicemia or toxemia.

Okay. You probably think I've been long-winded till now, but I need to take a few moments on this slide to explain what it is and the elements of it because it's very important. Once we understand this slide and you are with me on this, then the nine slides

that follow will be pretty straightforward to understand because they follow exactly the same format.

These are the results for OCP Condition 1 animal diseases in the traditional -- under the traditional inspection system, and I have a number of things to point out to you. One, and this -- again, Dr. Petersen referred to this, I will always be showing the slides where the results are shown from lowest to highest, okay, in terms of prevalence, and I'll be showing the results for OCP-1 first under the traditional system and then on the next slide under the HIMP system.

One thing again I'd like to point out is that in each case, we've identified the 12th position, that is the 75th percentile, we've identified that establishment in a different color to identify or just to remind you that that is that -- that that's the plant that, if you will, determined the performance standard.

So, for OCP-1, the performance standard of 1.7 percent was set because during baseline data collection under the traditional system, the 12th position had a prevalence estimate of 1.7 percent. So, what does that mean? That means whenever you see a slide that says baseline up here, that's the

traditional system, you are always going to see a 12th position. You're going to see four establishments that didn't do as well as that 12th plant that set the performance standard, and you always are going to see the remaining three-quarters of the establishments that did meet, if you will, the performance standard.

Now, again, remember that under traditional system, there was no performance standard, but rather we collected these data that FSIS then used to set the performance standard.

Okay. Under traditional inspection for OCP-1, this slide shows that OCP-1 defect rates ranged from just about one-tenth of 1 percent to a high of 6.4 percent. In each case, there's a solid line that breaks this bar. This bar indicates the 95th -- that's the confidence interval, 95-percent confidence interval around this prevalence estimate. Okay? So, the mean is about 6.4 percent but then we also show the upper limit statistically speaking and the lower limit. So, that's the meaning of these bars.

One of the things you're going to see repeatedly in this presentation is that these bars are not very high; that is, we have a fairly tight confidence interval. This one actually -- I mean, they actually -- on this particular slide, they actually

look pretty high, but that's only because the scale on this slide is from 0 to 10 percent. So, see, what we're estimating here with the 12th plant, we estimate the prevalence of 1.7 percent but that's plus or minus only about a percent. So, that's a pretty tight estimate of the prevalence of OCP-1 conditions in these establishments.

In fact, it turns out that what this tells us is that in the 12th plant, the prevalence rate that we estimated was 1.7 percent but that's within a range of 1.1 and 2.3 percent. Now, what do we mean by that? Again, this is an important concept of what that confidence interval means because it's going to have bearing and relevance throughout this presentation.

What this means is -- the best way to think of it is there's a supposition, okay, that during the baseline data collection in this Plant Number 12, that there was a true population prevalence of disease. There's a true population prevalence, and we don't know what it is, and the only way to know the true population prevalence would be to sample every bird. That's called a census. We only do that once every 10 years. They're very expensive.

So, what we typically do is we do sampling. We select a random sample from the population, but

whenever we do that, we know that there's a chance that we may not get a true random sample. We can improve the chances of getting a true representative random sample by sampling larger numbers of, in this case, carcasses, but you get diminishing returns. You can collect a lot more samples and you only get a somewhat better estimate, precise estimate here.

What this does mean, though, what we're saying here with these bars, and again I apologize and ask you to bear with me here for a minute, but we'll see this throughout the rest of the presentation. What we mean by these bars is that -- is the following. If we knew that the true prevalence of diseases in these population of birds going through Plant Number 12 during the 25 days that we collected data, if we knew the true prevalence was 1., you know, 7 percent, then we would expect -- okay. Really, I should say if we knew that the true prevalence -- well, that's fine -- was 1.7 percent, we know that if we collected data in that plant during that period time and time and time again, we did repeated trials, we know that in 95 percent of those trials, that we would estimate a prevalence within this range; that is, if we went in time and time again repeatedly, we would come out 95 percent of the time with an estimate, a sample estimate

somewhere between 1.1 percent, which is the lower part of this bar, and 2.3 percent, which is the upper part of this bar.

These are the data that we collected from the 16 plants that participated in the models redesign phase of the project again, of course, for OCP-1. What we've done in each of these slides is we've always kept the first slide and the second slide, that is the traditional slide and the redesign slide, on the same scale. So, this is from 0 to 10 just like the first slide.

We've always now drawn a line that shows what the performance standard was, okay, and what is always kind of easy to remember here and easy to think about is that under the traditional inspection, every time you look at the first slide under traditional inspection for a given OCP, there will always be four bars above that line because that's the definition of how that performance standard was set.

Notice under redesign, there's only -- it's a little hard to tell here, but it turns out there's only one establishment under redesign where our estimate was higher than the performance standard of 1.7 percent. So again it's pretty easy to see for this particular condition that under traditional inspection, this was

the prevalence of these diseases. Under traditional inspection, this was the prevalence of the diseases. Okay. So, that's one thing that you can look at.

Here, you see the defect ranges were from -- anywhere from 0 up to about 2 percent as opposed to under traditional inspection where we had one establishment that was as high as about 6 percent.

I do want to point out, however, and I'll try to remind you occasionally, that these are not exactly the same plants. Remember, 11 of the plants that were under the traditional system that we collected data in are also in the models redesign data, but there are some plants in here that weren't in baseline and vice versa.

Secondly, in many ways, I think even more important to understand is that -- I don't know how I got there. Okay. Almost. Good. Remember where I am. Oh, that these establishments are not always exactly -- well, they're not the same. Under baseline inspection, the traditional system, Plant Number 12 might be -- well, was then the Rocco facility, just to pick one out. Okay.

Under this presentation, Number 12 is typically not the same establishment. Again, what we've always done is listed establishments here from

lowest to highest. So, you can't -- this is not a comparison of, you know, the plant before and the plant after. It's a comparison of the system. What we're looking at here is the accomplishment of the system.

These are the results for OCP-2 which are miscellaneous conditions, which are things like, to remind you, breast blisters and bruises and the like. As you see, the prevalence of these types of defects is far more common in young chickens than the OCP-1 defects. The 12 position and hence the performance standard was set here at about 52 percent.

As always, there are four establishments under the traditional system that didn't fare as well and roughly 11 establishments that fared a little better. Under the traditional system -- that's the traditional system. Under the HIMP system, again you see an apparent improvement. As I said before they were under traditional inspection, there were two plants that were above the performance standard. Now, there are only a couple. So, I know it helps to be able to look at traditional results versus the models results.

I would point out again that the scale now is different. Okay. The scale now goes from 0 to a 100 percent instead of 0 to 10 percent, but the scale is

always listed and, of course, the scale is always the same for traditional versus models redesign.

These are the results for OCP-3 contamination which is simply ingesta. Nothing new here. It looks the same as before, right? You've got 11 establishments below the performance standard. You've got four establishments above it, and then you've got Plant Number 12 which, of course, set the performance standard. In this case, the performance standard for ingesta was set at 18.6 percent. Under traditional inspection, again an improvement, fairly significant improvement, it appears.

There are -- in this instance, there are three establishments under the redesign where the prevalence was estimated to be over the performance standard level of 18.6, but again that's opposed to the baseline system where there were four establishments. So again there's sort of the before picture and the after picture.

I would like to point out again that you'll notice now that these confidence intervals are appearing more squawked than they were before but that's only because the scale of this changes kind of from OCP to OCP. But in general but not always, what we find is that these confidence intervals don't

overlap for these conditions. There are some overlap but not generally. So, typically, usually when you see what appears to be an improvement or a lack of improvement, it's usually statistically significant for these OCP conditions.

OCP-4 are other -- what we call other dressing defects. These include things like feathers that I talked about earlier, pieces of lung or oil glands are examples of OCP-4 conditions. As you see from this, our veterinarians, when they were collecting data during baseline, they estimated or found a fairly prevalent presence of these OCP-4-type defects in passed birds. The 12 position, the 75th percentile is about 80 percent, and of course, once again, there are four establishments that didn't do as well as that but there were nine establishments that did better. The range here appears to be from about 22 percent to almost 99 percent.

Under the HIMP system, you see there's an apparent and indeed an actual increase in the prevalence of OCP-4 defects. We now have frankly most of the establishments are above the performance standard of 80 percent. As I indicated before, these confidence intervals are fairly tight because the sample sizes are fairly large. So, when you see what

appear to be differences, just like when the news is good and statistically significant when the news is not as good, and we'd like to see some improvement there. Again, it tends to be statistically significant. The confidence intervals really don't overlap here because the sample sizes are large.

Let's look lastly at the OCP-5 defects which are dressing defects. Various types of digestive tract tissue, crop and pieces of intestine, and there are other things, I guess, included in that category.

During the traditional data collection period, our RTI bioveterinarians estimated prevalences for these conditions anywhere from near zero in the best-performing plant up to almost 45 percent. Again, you see a real outlier here, but as always, the performance standard was based on the 12th position which is about 21 percent. So, during the -- under the traditional inspection system, approximately 21 percent of the passed birds have these defects.

Finally, under the models redesign, these are the results. This is actually kind of an interesting comparison because there was sort of a bimodal effect here, it appears. You'll notice that in this case, there are significantly more than four establishments that are above the performance standard for OCP-5, but

you'll also see, if you look a little closely here, that there is also kind of a depression in the prevalence of conditions down in this range. So, you see, we've got some real low numbers here and then they start to climb up kind of steadily, whereas under models redesign, they tended to stay a little lower and then kind of increase at a fairly rapid rate, if you will.

So, those are the OCP results. I'd like to now quickly and this can move along fairly quickly because the charts that we show are of the same description. We'll talk now about the food safety conditions. These are infectious conditions as basically birds, passed birds that exhibit sep-tox conditions or fecal contamination, FS-1 and FS-2.

Remember now that for both of these conditions, there is a zero tolerance. Dr. Petersen just informed you that prior to this project, if I understood correctly, there was no zero tolerance performance standard for FS-1 conditions, but a zero tolerance performance standard was set for purposes of this project.

During data collection in establishments under the traditional system, these are the defect prevalences that we observed. Notice that even though

this 12 position plant is no longer used to establish the performance standard, we still have it identified in red here. The performance standard, however, is zero. So, we don't have this dashed line going across here indicating that that establishment set the performance standard because it didn't. The performance standard is zero.

Now, the highest prevalence rate that we observed under traditional inspection was 1.6 percent. If you add all these up, as I did on the plane last night, if you add all these up, it turns out that this is 47 birds out of 32,000. So, under traditional inspection, 47 birds, passed carcasses, out of 32,000 that the veterinarians looked at had these conditions.

Under traditional inspection, one bird, okay, had those conditions. Okay. I actually just -- yeah. That's right. I got that right. So, you'll see now that this is again a significant improvement in the prevalence of this particular condition. It turns out that this establishment here actually had one-half of 1 percent. The 12 position, remember this line is the 12 position from the traditional inspection, it's 0.1 percent, but it was actually .005 percent which is one bird out of all the birds that we looked at, and again only one establishment had a passed bird that fell into

that category.

This Food Safety Condition 2 is fecal contamination. You see again that under the traditional system, most plants but not all plants, we found at least one passed bird that had fecal contamination. What this shows, though, is that while the prevalence was certainly not zero, it wasn't terribly high either. This scale goes from 0 to 5 percent. The performance standard, while at zero, the 12 position that we observed was 1.5 percent. Even this, this bar here, which appears to be about 3 percent, that's about 60 birds out of the 2,000 that we looked at in this particular establishment. So again, this is under the traditional inspection system.

Under the HIMP system, again we see a fairly marked decline in fecal contamination. There were about the same number of establishments under HIMP that had one or more birds with fecal contamination, but you'll notice that the prevalence of fecal contamination in plants was substantially lower.

I want to turn now to the microbial data. This is a schematic similar to the one you saw before about how we collected the microbial -- how we collected the organoleptic data. These data are basically the Salmonella and E.coli rinses and tests

that Dr. Petersen referred to. These data also were collected by employees under the supervision of Dr. Brown and RTI. Basically, they were laboratory technicians, microbial technicians.

We used the same microbial testing protocols that are required by the U.S. Department of Agriculture for its own microbial testing. Indeed, we used the same materials, I mean the same rinses, the same bags, the same gloves. We used the same materials to do our data collection that FSIS uses for its data collection, and in fact, we received the materials from FSIS. They were shipped to us periodically and Dr. Brown could attest to the large volume of pallets of material that they had to store and still store during the duration of these projects -- during the duration of this project.

Data was always collected over a 10-day period. Basically, what we did is each day, we rinsed 10 birds, approximately one bird every 45 minutes. We rinsed the bird. We poured some of the solution to be tested for Salmonella. We poured some of the solution to be tested for E.coli. Any establishment that wished to receive some of our split samples, we poured split samples for those establishments, so they could do testing of their own, if they wanted to.

After our sampling was done, and all the sampling is post-chill. Okay. All the results you're going to see are post-chill. These are samples that are taken out of the -- taken from rinsed birds after they've come out of the chiller.

I should say again, we talked about how we did our organoleptic data collection across both shifts and two-shift establishments. To the extent feasible, we did the same thing with our microbial data collection, and by feasible, what I mean is this. It is required and we require ourselves very strictly to follow USDA protocols.

When birds are rinsed and the samples are poured into their sterile containers and shipped off to the lab, they have to be shipped, okay, the same day the rinse was done. They have to be refrigerated from the time they're rinsed to the time they're shipped. When they're shipped, they have to be shipped the same day. They have to be shipped in insulated boxes, you know, with cold pack ice and all that to make sure that the samples stay cold during shipment. The samples have to be received by our laboratory that did the analyses the next day. If samples weren't received the next day or when they were received the next day and opened and tested, they were found to be off condition,

they were discarded. We did not analyze rinses that were -- that showed up at the lab frozen. That didn't happen very often. We didn't analyze samples that showed up at the laboratory too warm which is over 10 degrees Centigrade. That unfortunately happened fairly -- not fairly often but more than occasionally.

You know, you rinse these birds. You keep them refrigerated. You put them in the boxes. You put them on Fedex, and they're in insulated boxes, but we're in the Southeast in the summer and sometimes the samples got warm. When they arrived at the laboratory, if they were too warm, they were discarded. We got a call the same day. We called our data collectors the same day. They had to stay additional days during -- at the end of the data collection to make sure that we got our complete sample. So, we didn't analyze rinses that were off condition.

As you see here, the samples went to Silica Laboratory for analysis. Remember that they receive from each bird actually two different specimens. They test one for E.coli and actually they don't do a prevalence test for E.coli. They actually enumerate E.coli, and I'll talk about that. The E.coli was always enumerated using the 3M Petrofilm method.

The Salmonella testing is again a prevalence.

It's a yes or no kind of a test. Silica Laboratories used the Vitus SLM Method to do the Salmonella test. I'm told but I don't fully understand what this is. Apparently it's an enzyme-linked fluorescent immunoassay, and I'm sure Dr. Brown or Dr. Petersen could tell us more about that, if we care to, but it is an AOAC-approved testing methodology, and it's considered to be, you know, a very sound and, I think, state-of-the-art testing methodology.

So again, all of our samples went to Silica. The test results then came back to RTI. So, they would tell us for each sample and every sample, of course, was coded with a number that identified the establishment and the day and when it was taken exactly during the time of day, etc., etc., and they either enumerated it for E.coli at our direction or they tested it for Salmonella.

The Salmonella test was they first used this Vitus method to do what I understand is called a presumptive test and that indicates whether it's positive or negative. Because the -- I think that there is -- I know that there's a low false-positive rate, but it's not, you know, zero. So, whenever Silica found a positive Salmonella by the presumptive test, then they did serological screening to kind of

confirm that it was a positive Salmonella and indeed to find out what the serotype was.

These are the baseline results, the traditional inspection results for Salmonella. As you see, there was one establishment that during baseline, we actually got a zero prevalence rate for Salmonella and the highest rate we got was about almost 20 percent. I think it's 20.2 percent. So, we had a range from zero to about 20.2 percent.

During our under traditional inspection, 11 of the 16 plants actually had prevalence rates below 10 percent. I believe the -- well, 11 of the plants had prevalence rates below 10 percent and then another five establishments had prevalence rates above 5 percent. So, these are the Salmonella data.

Let me point out, too, that remember the sample size is different for our microbial testing than it is for organoleptic. The organoleptic sample size was 2,000. The microbial sample size is 300. Okay. So, these confidence intervals are substantially higher. So, you see that an estimated prevalence in this 12 position plant, let's pick on it, which is actually convenient because it looks like the 12 position, we estimated Salmonella prevalence in 300 birds to be about 30 birds for a prevalence rate of 10

percent, but because we're only sampling 300, it has a larger confidence interval on it than you are used to seeing in the other part of the presentation.

So, actually really what we're saying here is that we're estimating that the true prevalence is 10 percent but we only know with 95 percent confidence that it's between about, you know, 7.5 percent and about 12.5 percent. So, the confidence intervals around these Salmonella estimates are a little bit higher.

This is the Salmonella rate during models redesign. Once again, we're on the same scale here of 30 percent, and once again, as in the -- under the traditional inspection, under traditional inspection, we had 11 establishments that had a prevalence rate of 10 percent or lower. That is once again true here.

I see a lot of people doing the same thing that I did last night, which is, you know, hold the charts up to the lights to do a comparison, but when you do that, you'll see the same thing I do, and that is, that these confidence intervals, because they're fairly tall, these confidence intervals in almost all cases overlap one another. I say almost all cases because you'll notice that under models redesign, we didn't have any establishment that had a zero rate.

Under traditional inspection, there was one establishment where we didn't test any birds that were positive for Salmonella. Under models redesign, there were a few positives here in our exercise. But what you'll see if you do the comparison is that these confidence intervals overlap, okay, in all cases.

The last thing I want to show you are the E.coli results and I'm done. Remember that just as we were testing rinses for the prevalence of Salmonella, we were also doing generic E.coli numerations. This is a little bit different. This is a different depiction of the data than the previous ones and that's because in the PR HACCP rule, there is guidance to establishments on how to do their E.coli testing and how to determine whether or not their establishment has got proper process control, and basically any given E.coli that's enumerated, any given E.coli test that's enumerated, the result is classified in one of three categories.

There's either fewer than a hundred colony-forming units of E.coli per milliliter in which case that sample is said to be acceptable. It demonstrates that there's evidence of good process control there or there can be unacceptable results which means that there are more than a thousand colony-forming units per

milliliter of rinse, and then there are these marginals. These are E.coli numerations between the acceptable range and the unacceptable range.

So, this is just a nice way of showing approximately what the percentage of E.coli results are in each of these three different ranges under the traditional system. So again, we've got -- here, we've got them just as before. We've got the results ranked, if you will, from best to worst, left to right, but the bars appear to be higher because green is good, yellow's caution and red is stop, we need to see what's going on here. Those are the traditional results, traditional inspection results. These are the models redesign results for generic E.coli. A lot more greens, somewhat less red and a little bit more yellow. But again, there's pretty good evidence here, at least qualitatively, that there's some indication that, you know, we've got even better process control here, at least by looking at these E.coli enumerations.

That concludes my formal presentation. I didn't -- as a not-so-great presenter, I didn't look at my watch and I may have gone over, but I didn't want to fly through this material too quickly either. So, I'll let you field questions, I guess.

MS. LOGUE: Hi. Catherine Logue, North

Dakota State. One quick question for you. If you took out the plants that you either -- you know the ones you had at the beginning, those five that didn't participate the second time, --

MR. ANDERSON: Right.

MS. LOGUE: -- and you just worked it on the ones that you could do pre-HIMP and post-HIMP on, what happens to the data? What's it look like? Does it tighten down? Does it get better?

DR. ANDERSON: I'll be completely honest with you, and I don't know the answer to that, and I'll tell you why I don't. The purpose of the project here is to evaluate the system. It's not to look at the performance of individual plants.

You'll notice that for all these OCP -- well, for Salmonella, there is a performance standard that was established by FSIS years ago, based on the pre-HACCP-baseline data collection program. There's a Salmonella performance standard, and the idea is that the regulation is that establishments, whether they're HIMP establishments or traditional establishments, have to meet the Salmonella performance standards. There's zero tolerance performance standards for fecal contamination and for animal diseases. Traditional and regular plants have to meet that.

Now, for the OCP categories, remember there were no traditional inspection performance standards. There were finished product standards but they don't relate really in any way to what we're looking at here. They really weren't performance standards for how many birds could exhibit defects. So, we did our baseline data collection to determine what or to give information, provide information to USDA, to set what those performance standards are.

So, what we're tasked with doing here is looking at the traditional inspection system and how it's performing along several measures and the traditional system.

MS. SWACINA: Okay. Next, Ms. Leech?

MS. LEECH: What was the range and size of the various plants? Were they all approximately the same size in terms of their output?

MR. ANDERSON: I'm glad you asked that because I have a note on that, and I should have commented on that. Let's go back to this. This works. Because, yes, I can answer that for you.

The slaughter volumes in these establishments that we collected data in range from about 12 million birds a year to about 80 million birds a year. Of course, to participate in this project, you had to be,

of course, an FSIS-inspected young chicken plant. You have to slaughter only young chickens. Plants that slaughter other species are ineligible to participate, and, you know, the vast majority of, you know, federally-inspected young chicken plants in this country are large high-volume establishments but there's still a significant range.

So, slaughter volumes range from about 12 million birds in the smallest and it's not necessarily -- smallest might not be the right word. We had some participating establishments that are actually fairly new and they are only operating one shift and indeed I remember one of them was only operating one shift most days and part of a shift another day because they're still building up their business and so on and so forth.

So, we've got some fairly small establishments. The establishment that slaughters 80 million birds a year, that's pushing it. I mean, that's near the upper end. But I also want to note, remember I said that 80 percent of all the chickens that are slaughtered in this country are slaughtered in the 12 states where the plants are located. Eighty-seven percent of all the young chickens that are slaughtered in this country are slaughtered in plants

in this range, in this size range.

MS. LEECH: A follow-up to that. You took the same sample size from each plant regardless. Did you consider a proportional of the whole, --

MR. ANDERSON: I'm glad you asked that.

MS. LEECH: -- and would that have affected outcome as well?

MR. ANDERSON: People ask this question from time to time, and this is the first time I've tried to carry a visual that I hope will help answer that question.

You know, I'll remind everyone that as Dr. Petersen said and I think there was a follow-up question that you had asked about the design of the project and the design of the project was FSIS's design. We implemented the project, but I do have a visual that -- let's see if I can turn that screen off. I don't know if that's -- well, maybe we can cover it. That's always a good -- that's too bad.

(Pause)

MR. ANDERSON: We may have to ask you to turn it back on.

This question comes up from time to time, as you might guess. So, I've prepared just a little primer here and I'll describe it the best I can. This

is a little bit of information about sample sizes for large populations. These numbers are a little different from what I just quoted but only because we've actually indicated what the approximate volume of production was during the data collection period when we were actually in there tracking.

You'll notice even in the smallest plant, in the 25 days that we collected data, they processed about a million chickens whereas in the largest plant over a 25-day collection period, they slaughtered about seven million chickens.

So, the question often comes up as to whether or not this sample size of 2,000 is adequate. In both cases, tuition tells us that the sample size is proportional to population size. But it turns out that for large populations, the population doesn't influence the expected value defect rate for the percentage of the estimate, and I'll tell you what I mean by that.

MS. SWACINA: Can we ask you to speak into the microphone as much as possible?

MR. ANDERSON: Yes. I'll stand here and just move back and forth.

This curve shows the margin of error for the smallest establishment that we're talking about here, 1.2 million birds, and what I want to point out with

this slide is that if -- remember I talked about that the idea is that there's a true prevalence rate of a defect in the population. Okay. This shows an example of a statistical exhibit that says let's suppose that there's a population of birds that we're sampling where if we only knew it, the true prevalence of a particular defect in the population of birds is 5 percent. If we could do a census, that's what we would find.

We can't look at all 1.2 million birds. So, we look at a sample. So, this is the population prevalence, okay, and we're trying to estimate that population prevalence, and if we look at 2,000 birds in a plant of this size, we will estimate over repeated trials, we will tend to estimate a number of about 5 percent, but we'll have a margin of error around that.

So, if we take 2,000 samples in this establishment with 1.2 million birds, we'll estimate in repeated trials this prevalence of 5 percent, but we'll always have a margin of error of about 1 percent or around that. If we double our sample size, okay, instead of looking at 2,000 birds, we look at 4,000 birds, oh, yeah, we'll get a more precise estimate. In the long run or in repeated sampling, we'll still estimate the population prevalence of 5 percent, and yes, we'll have a somewhat different margin of error

but now, by looking at 4,000 birds, instead of being able to say, well, we think it's 5 percent, plus or minus 1 percent, now we can only say, well, we think it's 5 percent, plus or minus about .8 percent. So, see, it's really pretty close.

This is the same margin of error curve for the largest plant where we think, you know, we've got the same population prevalence that we're trying to estimate, and I'll just put this up for a minute because I think what's most revealing is the final slide.

The final slide, which superimposes these, the red line is the margin of error curve for our largest plant, the blue line is the margin of error curve for our smallest plant, and you see that the margin of error curves overlap one another. The point is that when you're talking about populations as large as a million, I mean, a million is pretty big. Okay. When you talk about large populations and you're talking about what are frankly rather large sample sizes like 2,000, it doesn't really matter whether you're sampling 2,000 birds out of a million or 2,000 birds out of 10 million. You get essentially the same precision in your estimate, and I always like to tell people and remind people that when the Associated Press

or any polling organization is trying to figure out who's going to win the presidential election next week, I know there's about 270 million Americans. I don't know what the number of registered voters is, but let's say it's only half that. Right. There's somewhere about a 100 million registered voters in the U.S.

When we want to estimate how many people are going to vote for this candidate or that candidate, they do polls over night, they take a sample of about a thousand people, they report that number and say it's a margin of error plus or minus about 2 percent. So, it doesn't matter whether it's one million or 70 million or seven million or 100 million, when you're talking about, you know, sampling a thousand to 2,000, you're getting pretty good, pretty precise estimates of that population parameter. It doesn't really depend on the volume in this case.

MS. SWACINA: Okay. Dr. Johnson?

DR. JOHNSON: Thank you, Don. I think this was very good. Somebody commented data after lunch was dangerous, but I think you did a very good job, and I liked the colors, too.

I have a question on the results for Salmonella that you have in this one where you talked about some of the differences could be seasonality or

the health of the incoming birds. You said you did the baseline over a year's time, but you didn't have -- you weren't like continually doing baseline?

MR. ANDERSON: I've got -- yeah. Let me -- I do have a prepared comment on that.

DR. JOHNSON: Okay. Thanks.

MR. ANDERSON: You probably thought I took a lot of time. See, I didn't even say everything I was prepared and meant to say here. Thank you. Boy, he's good. Okay. So, let's look at this a minute.

These are the -- again the volunteer traditional inspection system plants.

DR. PETERSEN: Don. Don, we're not projecting. Hold on.

MR. ANDERSON: Oh, yeah. That was Step 1. What's Step 2 here?

DR. PETERSEN: It's coming.

DR. JOHNSON: It's coming. I think it'll catch it.

DR. JOHNSON: While you're waiting on that, can I just ask? You also talked in this about animal health. Did you do any correlation between any kind of antemortem or plant inspection records and Salmonella numbers?

MR. ANDERSON: Excuse me. As far as

antemortem, I showed this schematic that showed we did do antemortem data collection, and I could talk about it a little more. Dr. Brown could talk about it significantly more than I could, if you want to know more detail.

The antemortem activity that we conducted was essentially an interview process with young chickens. Now, with market hogs, it was a different story and we won't talk about that now. But for young chickens, basically what we did is we interviewed the IICs to see whether or not the IIC had done an antemortem inspection and what the result of that inspection was, basically whether or not any lots were found. I believe the terminology is unsuitable for food. So, we did an antemortem basically interview process.

DR. JOHNSON: Thank you.

MR. ANDERSON: During baseline, when we collected data in these plants, as I said, we collected it over roughly a year period, but what I would like to point out, what I meant to point out because I think this is, you know, potentially important. I guess the scientific significance of this is not completely well understood and maybe others will want to address that.

But I can tell you that when we were collecting data under traditional inspection, we

collected -- and this was just, I guess, the way it turned out. Again, we could -- as Mr. Derfler pointed out, we have -- that this project has had many stops and starts and bump along, you know, bumps along the way. It's been a privilege to work on this project, but it's also caused me to lose some nights of sleep from time to time.

But it turns out that during -- under the traditional inspection of these 16 plants, 95 percent of all the samples that we collected were collected from birds during the months between April and October, April, May, June, July, August, September, October. Okay. Basically what I'll call the Spring and Summer and Fall months. Only 5 percent of the samples were collected between November and March.

Under models redesign, 40 percent, almost 40 percent, 38 percent to be precise, 38 percent of our samples were collected in the Winter months, between November and March, and in fact, 1,400 samples were collected in the months of December and March, and that actually would have been December and March of, I guess, -- well, December of 2000 and through March of 2001.

So, there was a real difference between the seasons when we collected these data. We could get a

lot of Winter sampling. It turns out during -- under models redesign and almost no cold weather or really cold weather sampling under traditional inspection. Why that is is more complicated but that's the fact of it.

MS. SWACINA: Okay. Ms. Donley?

MS. DONLEY: Thank you. Alice actually had zeroed in on the same area I had zeroed in on, and I just want to say the -- I guess I have -- let me just comment first on the seasonality issue and also the health of the birds.

The whole idea with HIMP, it's my understanding, I understand you do get a sick flock every once in awhile, but that these are all -- it's young uniform animals. So, I think the health issue should be minimal at best. Health factors.

But, you know, I'm not a statistician, but something troubles me when we're looking at a baseline where you have something that is -- are we comparing apples to oranges here? When you have something that is significantly different in the time frame of these two studies, and also again not being a statistician, but 31 percent of the HIMP plants, the models redesign plants, were different. They weren't even in the first study, and I don't know how to maneuver this data to

make it a true comparison here.

So, I don't know. Statisticians, am I making a mountain of a mole hill? Should there be some concern? To me, it just doesn't look right.

MR. ANDERSON: Yeah. I mean, --

MS. DONLEY: It's hard to put the two side-by-side.

MR. ANDERSON: Yeah. A comment I'll make is that we -- part of this gets at what -- what the statistician will tell you, okay, what the statistician will say on both of those issues is that when you go into an establishment, whether it's the same establishment that was in baseline or not, and whether you're going in in the Winter or in the Summer, that when you go into an establishment and you draw samples, you are doing your best to estimate the prevalence of Salmonella or of the fecal material or whatever it is you're trying to estimate. You're doing the best job you can to estimate the prevalence of a particular condition or microbial contamination, whatever it is, of the population of birds that are going through the establishment at that time.

Now, you've correctly pointed out that, yes, most but not all of the establishments under redesign were also included in the baseline work, and you also

correctly pointed out that there's a difference in the seasons from which these were collected.

You know, I'm pointing these things out in order to be as, you know, forthcoming as I can about what the differences and the similarities are between these establishments. I think that, you know, what I can say is that the establishments that volunteered for the project in time to be included in the baseline work were volunteer establishments and the establishments that volunteered not in time to be included in the baseline, and by the way, they may have volunteered to be in the project in baseline but they were in line behind other establishments that volunteered even before they did and FSIS could probably comment some about the timing.

So, you know, I don't have any reason to believe from what I can see in the data or from what I could see in these establishments, and I was in every one of these establishments prior to data collection, I went to all of them, and, you know, I couldn't -- I can't see any differences in these five establishments that volunteered later than the others.

MS. DONLEY: If I could just comment? The thing that makes -- I probably wouldn't either, except there's such huge variations when you read some of

these numbers. I mean, just the ranges are enormous, and so we could have something where all of the -- you know, for lack of a better term, all of the worst-performing plants dropped out and were replaced by -- you know. I mean, you can have a half a dozen different scenarios here.

So, -- and so, I don't know. The picture could be much better, the picture could be much worse. We really don't know. So, that brings me to is there any way to extrapolate just the data from the same 11? The -- instead of looking at the 16, let's look at just 11 to 11.

MR. ANDERSON: It looks like Dr. Petersen at least wants to comment on the first point.

DR. PETERSEN: Yeah. A couple comments on the plants and which plants were in which phase because, of course, RTI went to the plants to collect data where we told them to go. So, they had no effect on which plants were in or were not in.

But we did look at -- the five plants that dropped out dropped out for their own reasons. Phil alluded to some of those. Some of the uncertainty that was going on at the time of baseline data collection, they decided for whatever reason that they didn't want to continue. But when you look at the plants that

replaced them, it's -- the question is, are they fundamentally different than the ones that didn't go forward?

We looked at that with respect to their corporate structure, the number of lines that are in the plant, the output of those plants, their geography, their distribution patterns. All of those and the answer is no. So, collectively, those plants are as typical of the industry as the ones that did not go forward. Are they the same? No. But are they fundamentally different? We believe the answer is no.

MS. DONLEY: But then, I guess, how do you account for the huge range of your findings?

DR. PETERSEN: We saw the same range and it's typical of poultry production, if you will. When you saw the same ranges in baselines, some plants do some things very well. Some plants for some reason don't do the same thing very well. There is just -- there are just differences in what they may focus on, but when you looked at the output of the plants and those other factors I mentioned, is there something in there that makes you really question the five and the five, and having looked at it, we just don't see it.

So, but when we're looking at comparing systems, do the 16 plants represent the traditional

system, and we believe the answer is yes. Do these 16 plants and models represent the models production, and we believe the answer is yes.

MS. DONLEY: Could you answer my second question, Dr. Petersen, about being able to extrapolate the information, the data from 11, the same 11 for each one and taking a look at it that way?

DR. PETERSEN: Well, there's always various ways and interesting ways to look at data. We had a design that focused on the amount of information we wanted to collect, and we had a design and we had a protocol. As I mentioned, that protocol reflects information we wanted to see in 16 plants, and so, can we break out segments of that and look at five plants here and five plants there? There's all kind of ways to slice and break the data, but if the initial comparison was designed to be 16 plants before and 16 plants after, that is the appropriate comparison. That's what we intended to do, and to -- that can be changed, but to do it at the end of the study is very problematic.

MS. DONLEY: Is -- so, my understanding is that the Number 16 was a magic number of some sort?

DR. PETERSEN: That was, yes. Magic in the sense that that was collectively what we thought was

the appropriate numbers and the appropriate distributions of plants for us to represent national production.

MS. SWACINA: If I could just add to that? We're going to talk later in the presentations about the third party review that we're going to have done, and I think that's a legitimate question about the 11 versus 16 plants, and I think that that will come up as part of that review as well.

So, I'd also like to say that it's about 3:00, and we have 1-2-3-4-5-6 more people who want to comment. Do you all want to take a break now or do you want to have the comments first? Then how about we just take a 10-minute break?

MS. FOREMAN: Wait a minute.

MS. SWACINA: I'm sorry.

MS. FOREMAN: I think in fact I want to make, if I may -- I'm not next in line.

MS. SWACINA: You're not next in line. I'm sorry. Next in line is -- so, are you saying you want to continue? You all want to continue?

MS. FOREMAN: I would like before we break this train of thought to make some points.

MR. ANDERSON: I'm fine up here. Whatever you want to do.

MS. SWACINA: Keep going? Okay. Who's next? Dr. Morse? Yes?

DR. MORSE: Dale Morse, New York State Health Department. I agree with Nancy's comments about the need to only compare the 11 with the 11. If we were comparing hospital nosocomial infection rates and baseline, we would really statistically have to look at the 11 before and 11 after. You wouldn't be able to publish by putting all the -- adding new and dropping out new. So, I agree that they should be looked at with the 11.

I had three questions. Has there been any repeat testing done to see whether this was sustainable over time? The reason I ask that is because quite often when you tell people they're part of a study and you're going to look at performance, you get improved performance, and it may not be sustainable.

MR. ANDERSON: RTI has not done any repeat testing. I think that Columb will be talking later about the on-going, I guess, never-ending verification sampling that FSIS does.

DR. MORSE: And a second question. I noticed that on E.coli, there's sort of a measure of quantitative results. On the Salmonella, were there any quantitative results looked at in terms of not just

plants that had Salmonella present but percentage but the concentration, sort of the number of Salmonella organisms present?

MR. ANDERSON: No, no, there weren't, and I'd say maybe, Dr. Brown, if you'd like to -- it looks like you're shaking your head. Could you explain -- go to the microphone and explain what that's -- what that means or doesn't mean.

DR. PAT BROWN: The data that was collected was just whether there was a presence or an absence of Salmonella in each of the samples, and it was really done with a very sensitive test and not a count. I think if we were doing just counts on the number of organisms, we'd have to take different types of samples and probably the prevalence would not be as high because the sensitivity of normal counts is a lot lower in terms of isolation.

Salmonella quite often has to be in the pre-enrichment media to be able to detect it at that level. So, what you're seeing here is a very sensitive test for one colony-forming unit in the sample that we collected of 30 mil.

DR. PETERSEN: So, we did a qualitative plus minus and that was consistent with the advice we received at the time from our Micro Advisory Committee?

MR. ANDERSON: And it's also the way that Salmonella testing and analysis is done for regulatory purposes, is it not? The answer is yes.

I think you had a third question.

DR. MORSE: Last question. There obviously appear to be significant differences between plants, and so it seems like there'd be some valuable lessons that could be learned by comparing the practices between the best practice and the not as good practice or whatever. Presumably there's a relationship.

So, is anybody hopefully looking at the different practices between the good and the other plants?

DR. PETERSEN: Not in the context of this project. Other than the fact that as we'll hear a little bit later, some of our next steps are to try to build in mechanisms to make sure that that happens, and I think I'll just leave it there until that discussion. There are some mechanisms for continuous improvement.

MS. SWACINA: Thank you. That's an excellent suggestion.

Mr. Link?

MR. LINK: Charles Link. Looking at these graphs you've been throwing up, the befores and afters, some of them look really good and afterwards they look

great, some of them afterwards don't look so great, but have you done any kind of comparison to see if there's really truly a difference? I mean, when you hold them up to the light, there's some overlap. Is there really significantly a difference between the before and after in each of these categories or have you looked at that to make that determination?

MR. ANDERSON: Yeah. I mean, the answer is yes. I mean, those confidence intervals are pretty much giving you a clear picture, and I think I said that during the presentation, that when you look at these -- when you look at the organoleptic findings and under the traditional and the models and you see what appear to be differences for better or for worse, those are statistically valid. Those are statistically different. For Salmonella, they're not statistically different.

MR. LINK: Because they overlap.

MR. ANDERSON: But that's -- again, that's partly -- you know, it's partly the range which is related to the sample size. Yeah. The differences are real.

MS. SWACINA: Okay. Thank you.

Ms. Logue?

MS. LOGUE: Sorry about that. And we were

just discussing the magic 11 plants again, and one question or one comment I wanted to make was regarding the Salmonella, and there is a seasonality that you will find with Salmonella and there are dozens of papers out there on this, and this is a concern that you sampled at one point in time and then when you did the redesign, you didn't sample at a similar point in time.

This can help skew your results, and anyone will tell you that. That's kind of common knowledge. So, I mean, I don't know. If you were to do this again, would you go back and mirror everything the right way? You can't go back now.

MR. ANDERSON: If we were to do this again, we would do the same thing we did before, and that is, we would go in and sample when Mike Grasso called me on the phone and said it's time to get back in there. It's a complicated series of factors that had to do with it. The timing was complicated by, you know, selecting the inspectors that would be doing the new jobs, for training the inspectors down in College Station that would be doing the new work, in the establishments training the employees that would be stepping up to do the bird sorting.

It had to do in some cases with the

availability of our data collectors. We might be collecting data in three plants. This didn't happen very often, but we might be collecting data with all three of our teams and there would be another plant ready but we didn't have another team ready to go in for a couple more weeks or whatever. So, it's a lot of things influenced the timing of the data collection, and, you know, all of them, almost all of them were beyond my control and I think many of them, as I understand it, were beyond the control of the agency as well.

So, I hear what you're saying. I understand your comment. I think it's a valid one. That's the best answer I can give.

MS. LOGUE: Well, you see, it will account for your -- what we call the peaks and drops that you see. If you do a calendar incidence of Salmonella, you will get peaks and drops, and this may account for some of your wide variation that you're seeing.

MR. ANDERSON: It may. I'm not a microbiologist or a poultry scientist. There are others here on this panel here and Dr. Denton, I'm sure, could tell us more than we ever wanted to know about that, but I'm not qualified to comment on that.

MS. SWACINA: Mr. Grasso wanted to add

something to that.

MR. GRASSO: Just on the rationale, why we had the difference in the time of the year. Once a plant would complete their baseline data, RTI would collect what the accomplishments are of the traditional system in the plant. It would normally take approximately six months for FSIS to get ready and the plant to redo their HACCP plan, do their process control plan, train their people, and it took FSIS a minimum of four months to announce, select and train and get people into the plant. So, thus we always had this buffer of six-seven months going from the warmer part of the year to maybe the colder part of the year.

MR. ANDERSON: Or vice versa.

MR. GRASSO: Yes.

MR. ANDERSON: And there could be other things. You know, we might be ready to start data collection. We sometimes would kind of tentatively schedule data collection to find out that the IIC was going to be on vacation that week. So, we'd have to postpone data collection for various reasons or, you know, it's just -- there's so many factors, it'd be hard to enumerate them all.

MS. SWACINA: Okay. Thank you.

Ms. Foreman?

MS. FOREMAN: Thank you. Carol Tucker Foreman. I think some of the questions raised here are very important. In January, the General Accounting Office raised some of the same questions. They criticized the study because it had no control group. They said that it -- the choice of companies, plants, was not random nor was it representative of the total population of plants, that it represented a very small area of the country, and although that was 50 percent of the young chickens raised in the United States, there were no representatives of that other 50 percent of the poultry raised in the United States. Young broilers.

They pointed out that the study gave no consideration to modifications that were made in the plants during the course of the study which might have affected the outcome. They also pointed -- and that would certainly be a system question. They also said -- pointed out that they were not the same plants involved all the way across, and I would point out to you that when there were only 11 plants considered and before the redesign, only one of the plants met the zero tolerance for visible fecal after it began using a HIMP program; that is, 10 of the 11 failed to meet the zero for fecal. None of the plants met all the

performance standards and Salmonella contamination was worse under the modified system than traditional at five of the 11 plants.

GAO went on to criticize that there was no statistical process control and that plants with large numbers of NRs, including fecal, were allowed to stay in the project. Now, I raised these questions earlier and the answer was simply that FSIS didn't accept GAO's criticisms. I think those criticisms have been raised again here today by a variety of people.

I would point out to you if you haven't had a chance to look at the USDA slide show, it uses 20 plants. So, we've got five, we've got 11, we've got 16, and we've got 20. I don't know how many kinds of apples you can have. Maybe it's a fruit salad.

I think that there are sufficiently large questions raised here to raise questions about the results of the data. I understand how hard it was to do this. My kids always used to tell me how hard they prepared for a test, but when they failed, you know, it didn't make any difference how much effort they'd put in. The grade at the end of the year was based on the final result, and it's very hard to come up with a final result based on this variety of plants and with this many questions raised about the basic data.

Thank you.

MS. SWACINA: Just also on the agenda, we will be talking about the next steps later today, and there are a couple more presentations to come. But hopefully we'll respond to some of the issues being raised.

Next, we have Dr. Denton.

DR. DENTON: Thank you. I want to speak to Nancy's comments as well as Carol's and some of the other folks. Having been involved in doing some of these microbiological types of studies, albeit several years ago, different time period, we were part of a team that looked at trying to establish baseline data with regard to aerobic plate count, coliform count, E.coli count, Salmonella, and Clostridium perfringens, and to do that, we brought in five processing plants within the state that I was working in at that time and to each plant we made two visits. So, we had a total of 10 visits to each of these five broiler plants. We repeated that entire trial again for turkey processing plants.

Now, we didn't have the organized system, I think, that FSIS had with regard to handling the samples, so they could get that done by shipping them to a laboratory. We actually had to make site visits

to each of these plants. So that, by the time we completed the assessment of these five plants, and we visited them back to back in each of the replicate evaluation periods that we looked, it took us 20 weeks. So, by the time we get finished, we've got Plant Number A having a 20-week time period between that time and the time that we assessed Plant Number E.

At the same time we were interested in developing this baseline data, we knew that we had to make a decision with regard to whether or not we were going to assess a true baseline of the industry that was represented in that state or if we were going to be concerned with the time issue, and it's a trade-off that has to be made every single time that you design an experiment like that. You either evaluate the time component or you do a good job of trying to establish your baseline.

Now, I'm not trying to speak to what they did, but I know what goes into making a decision like that, and one of the key things is that you want to have the same number of plants in the pre-evaluation that you have in the post-evaluation, and in their situation, they were presented with, I guess, a volunteer situation with regard to the baseline study and then also making the decision about which 16 plants

are going to be included in the design model phase of the project.

So, in looking at this, I think we have to be fair about what their objective was and how they designed the project and what the objective of the project was when they entered into this.

MS. SWACINA: Thank you.

Ms. Leech?

MS. LEECH: Just real quick. I'll second that I know that it's very often -- there's no perfect study, and I think we need to recognize that. It's always hard to do that.

But I think we really do want to look at what's happening with individual plants in some fashion and know whether overall, even if you don't want to identify them by name, it seems to me that if I could see a chart that said Plant 1, 2, -- and they had a number assigned to them and every slide, they weren't in a different place, and I could kind of see trends of what's happening, I think that's a useful piece as well and maybe that's a forward thing or whatever, but I also wonder about some of the overall rating, if it's possible to create something that, you know, so that somewhere down the road, possibly you could maybe end up being able to do like the health department does in

an A-rated or that but that takes these kinds of factors into consideration. It seems to me that some of that might be useful at some point. So.

MS. SWACINA: Thank you. Thank you. Okay. Last but not least is Mr. Govro. I say that wrong every time. I'm sorry.

MR. GOVRO: That's okay. I'm used to it. Mike Govro, Oregon. Very quick question about -- you said that your cut-off temperature for sample receiving was 10 degrees and that seems awfully high. I wonder if you did any kind of analysis of the data relative to receiving temperature.

MR. ANDERSON: We do know the temperature of every sample that was received. In other words, we didn't -- when we got reports from Silica -- well, again, remember that if they received samples that were too warm and -- I should even start fresher.

We used the 0 to 10-degree threshold because that's what's required by FSIS regulations. We didn't establish that. This project team didn't establish that. That's what's required for doing these tests. That's the rules and regulations.

When a sample was received at Silica and it was too warm, they, as I say, they would call us and notify us that it was too warm. They didn't tell us

how much too warm because it didn't matter, but they told us it was too warm. So, we would know to keep track of that, to continue sampling for the additional few days that we might need to to make sure that we got our 300 samples.

But also, it's true that when the data came back to us from Silica, remember I said that the reports we get from Silica not only tell whether it's a positive or a minus, they also tell us what the serotype is, and they also tell us on the same form what the received temperature was, but we have not analyzed those relationships. We haven't done that.

MS. SWACINA: Okay. I just want to stress again that we will have a presentation on Next Steps, and a lot of you all have made some really good suggestions that need to be considered as part of that, and so we're going to take a 10-minute break and then hopefully we can move quickly through the other presentations.

(Whereupon, a recess was taken.)

MS. SWACINA: Okay. Our next presentation is going to be on the FSIS Verification Data, and it's being presented by Dr. Columb Rigney, who is a veterinary epidemiologist with OPHS.

DR. RIGNEY: Good afternoon.

FSIS Results of Modification Testing. Modification testing is conducted by FSIS inspectors in each of the plants currently operating in the HIMP system on all shifts that they operate.

The first plants went into the models September of 2000. The last plants entered August 2001. From that time until present, there's been between two and two and a half million food safety tests conducted and 700 to 800,000 other consumer protection tests.

The next couple of slides show the 20 plants where FSIS models verification data was collected. Nineteen of these plants are actively in the system, in the project, with one plant having withdrawn from HIMP, and that plant, the data from that plant, the one that's withdrawn, is included for completeness with the other plants in our data.

Okay. Verification testing, other consumer protection category, performed on randomly-selected carcasses from all production lines is perfected by FSIS verification inspectors. It's performed as two 10-bird tests per line per shift, which means if a plant has three lines, 60 OCP tests per shift. If the plant has four lines, 80 will be done per shift. If a plant has less than three lines, one or two lines, a

minimum of 50 tests will be completed per shift, and these tests are performed independently of unscheduled tests conducted at the discretion of the IIC SCMO.

That printed very badly. That's just a -- it's just a summation of OCP Categories 1 through 5. OCP-1 is animal diseases, OCP-2 is a miscellaneous category, bruising, OCP-3 ingesta, OCP-4 and 5 are the processing areas.

As far as the graph for OCP-1 condition, animal diseases -- actually, the OCP-4 and 5 are dressing defects. OCP-1 condition, animal diseases. On the bottom are the 20 establishments where FSIS data has been collected. On the left-hand side is percentage of carcasses with defects.

As with the RTI graphs, ascending from the plant with the lowest average up to the highest average, and again these are averages. So, cumulatively, plants have taken -- some plants have taken 60 to 70,000 tests for OCP and these are the average number of defects seen over the total number of tests taken.

Maybe interesting, which isn't apparent in this data, is Plant 20, which has exceeded the performance standard, that plant doesn't necessarily fail every day. Okay. Daily tests are performed and

based on that, the carcass number, and also down in Plants, 2, 3 and 4 down here, those plants don't necessarily pass every day, but this represents an average of how these plants have performed over time. For some of these plants, it's been almost a year and a half. And for this category, 16 of the 20 plants have met or performed better than the performance standard. The performance standard for the pilot project for this category, 1.7 percent, and that was established in the baseline collections by RTI.

Condition 2, miscellaneous. Pilot Performance Standard 52.5 percent, and in this case, for this category, 19 of the 20 plants had performed at or better than the performance standard.

OCP-3, contamination. Ingesta. With this category, 20 of the 20 plants where FSIS models data has been collected by FSIS inspectors have performed better than the performance standard. The performance standard for this category 18.6 percent again established during RTI baseline collections.

OCP-4, dressing defects. These include feathers. Twenty plants where models data has been collected. Twenty are currently performing on average at or better than the performance standard. Notice that two plants have brushed right up against the

standard which indicates that obviously there are some days when that plant doesn't pass standard, and on average, it's performing slightly better than the performance standard at 80 percent.

OCP-5, dressing defects. Digestive tract tissue. That's CROP, CLOACA. Pilot Performance Standard 20.8 percent. So, the 20 plants where models data has been collected, all 20 plants performing at or better than the performance standard in collections performed by FSIS inspectors, and again this data varies in time and plants. Some on as late as August of 2001 and some as early as September 2000. But there are a substantial number of samples taken. Some of these plants have excess of 60,000 tests performed for the OCP categories.

FSIS organoleptic verification testing for food safety. Again, these were randomly-selected carcasses from all production lines, performed by FSIS verification inspectors, performed as eight 10-bird tests per line which is four times more food safety testing than is currently being performed in the traditional systems, and it's performed independently of unscheduled tests conducted at the discretion of the IIC SCMO.

Two food safety categories, similar to the

criterion for RTI testing, FS-1 infection, septicemia, toxemia, FS-2 contamination, digestive content, specifically fecal material. FS-1 condition, infectious. The numbers are low. Some of these plants have taken, like you said previously, in excess of 200,000 food safety tests. So, even though you can't see any numbers, there may be one or two that were positive. The first five plants actually met the zero tolerance standard and the other plants, there was one or two, a very small number was found, and they're on the order of like .003 percent, extremely low numbers.

The 12th position doesn't represent any sort of a standard. It's just sort of a reference to what the 12th position was back in RTI testing to be consistent with the performance standard 12th position that established it for the OCPs. It's just a descriptive line. Again, the performance standard is actually a zero tolerance standard for FS-1.

FS-2 is fecal material, and it lists the 20 plants, and again there's been in excess of 200,000 tests. Although you really can't directly compare this data with the RTI data since it was collected over a longer time frame and different numbers of samples, it's 2,000 per plant for RTI and this can go up as high as 200,000. A percentage-type basis, these numbers are

lower. We're starting from zero tolerance. We're not there yet, but it's encouraging that these numbers are closer than they were under baseline.

Now, we'll go on to discussion of microbial verification, specifically Salmonella. Again, I apologize that these printed so badly. We're going to put these up on the website and they'll be in a printer-friendly edition that can be printed off so the lines are all even.

Salmonella is tested on randomly-selected carcasses. The tests are performed by FSIS personnel. It's performed as a whole bird rinse, and FSIS regulatory testing is of 51 carcass samples set and generally you take one carcass, one sample per day over a time 51-operating day schedule. So, it's essentially about a three-month period, you take one carcass a day, and it's performed similarly in traditional and models establishments and also the regulatory action, the compliance standards, are the same in models as they are in traditional establishments.

Okay. These are the numbers for the 20 plants as they performed in traditional systems. By traditional systems, these represent the FSIS verification samples for Salmonella that were collected in these 20 plants prior to them going into HIMP. The

errors bars are extremely large for some of these. It's a regulatory sample of 51 and some of these plants may have only taken one or two sample sets prior to going into HIMP. So, that's why the error bars seem maybe inordinately large.

Okay. Into the HIMP system, criterion were similar, seemed to note that in the HIMP system, there were three plants that had zero percent prevalence Salmonella whereas back in the -- oops. Traditional, there was one, and again the error bars are large, and in some cases even larger, because some of these plants didn't come on until the Fall of 2001, and there may have been only one completed sample set performed.

Sample sets are -- it's a directed sample set and sample sets are collected no differently in HIMP as they are under plants not in HIMP. Salmonella verification is done as a part of the Pathogen Reduction HACCP and it's not anything that's specific for HIMP.

Okay. This graph actually shows it similar to how it's regulated by FSIS. The black bar going across at 12 indicates the maximum number of positives to achieve the standard. For broilers, the standard is 12 positives out of a 51-sample set which is the maximum allowed to be considered as passing the test.

Each bar represents a completed sample set. The ones in green are completed sample sets that were done while the plant was in traditional systems, in violet those are the plants that the tests that were completed while the plant was in models.

On a couple of these, one on this graph and the next, you'll see a green asterisk. That indicates that a plant didn't complete a sample set totally under traditional systems. There was a first models project and for a few of these plants, they took some other samples that traditional and overlapped it into models. So, we didn't put it on -- I didn't put it on here as a completed sample set, but the tissue -- the samples that were collected were included back in the percentage graphs. Say, for example, Plant 2, 40 of the 51 were taken under models. Whatever the percentage was there, that's included back in the percentage graphs but it's not on this one.

Anywhere we see a color-coded zero indicates that a completed sample set was conducted and zero out of 51 were found. Say like Plant 7, they took three -- they've taken three sets prior to coming into HIMP and it was zero out of 51, and the violet, I think, in two completed sample sets, those were also zero out of 51.

As you look across for this one, it indicates

there's only one time that a plant failed to meet the performance standard and that would be for Plant 6 and it was on the traditional side in the first sample set.

These are the remainder of the 20 plants, and again 20 plants have participated in models collection, and for these plants, known as Plant 17 on the model side, didn't meet the performance standard, and Plant 18, while it was in traditional, it didn't meet the performance standard.

Plant 17 has been, as in all plants, traditional or HIMP, if a plant fails a compliance set, it's rescheduled for another set, and this plant here is well into its second set and it's performing much better than it did in this one, between 15 and 20 samples have been collected, and as of yet, there have been zero positives for that plant.

Okay. And verification testing, Salmonella verification testing, performance standard's 20.0, national verification average is 11.9. In the models plants, it's a 7.6 -- excuse me -- on the traditional side, that indicates the arithmetic value of all tests that were collected while the plant was in traditional, was 7.6 percent, Salmonella prevalence, all these plants in the HIMP side, is 8 percent. Now, if you were to equate that back to a performance set, that

would indicate essentially four out of 51 traditional and four out of 51 in HIMP were positive.

Just looking at the data descriptively, of the 20 plants that are in, nine of the 20 exhibit a lower Salmonella prevalence in traditional systems, nine of 20 exhibited a lower prevalence in models, one plant, the one that had five zero tests, exhibited no change in Salmonella in models, and one of the establishments just took too few tests in the traditional side to even be comparable. So, nine up, nine down, one the same, one not determinable.

As far as completed sample sets, at least 20 plants while they were in traditional systems, 47 sample sets were completed, 45 passed, two failed. Under the HIMP system, the same 20 plants, 22 passed and one failed. Currently, I believe there are seven or eight plants that are undergoing a second test in HIMP, not that they failed but it was just the normal direct sampling process, similar to PR HACCP plans.

Okay. That concludes the presentation. Do you have any questions on our data?

MS. SWACINA: Okay. Just before we start taking questions, I did -- I again just want to say, I know that we're unfortunately over time already and to ask everyone to please keep your questions to

clarifying questions as much as possible. I want to make sure you do have a break between now and your subcommittee meeting at 7:00. So.

Ms. Foreman?

MS. FOREMAN: I don't understand where these 20 plants came from. Some of them seem to be the same as the 16 plants and other ones seem to be different.

DR. RIGNEY: Right. Well, those 16 plants were used to determine the baseline and the performance standard, and these 20 plants are all 20 plants that are currently in HIMP. Actually 19 currently in HIMP and one that left the program. So, this data represents the data, all FSIS verification data that's been collected since any plant has entered the HIMP system.

MS. FOREMAN: Then why aren't they in the RTI data?

MR. GRASSO: RTI did not collect micro data in those plants. They only collected it in 16.

MS. FOREMAN: So, we have three -- four -- how many different sets of plants do we have?

MR. GRASSO: We will have one more new plant coming in in July 8th, and we'll have 20 plants again.

MS. FOREMAN: So, we have five and then we have 11 and then we have 16 and now we got 20?

DR. PETERSEN: These plants represent -- if any plant were to come in a system, and if we've established a performance standard, how effective are they at meeting these performance standards? Just as when we put in the place the Salmonella performance standard and new plants came in, how effective are plants at meeting the performance standards?

And in the project, we have allowed for up to 20 young chicken plants to participate, of which 16 were part of the RTI activity.

MS. SWACINA: Okay. Mr. Link?

MR. LINK: Charles Link, Cargill. I just -- I guess I want to make a comment. I just feel like maybe it's been overlooked. When we look at HIMP and Don referred to me some time ago at Rocco Farm, but when we looked at HIMP, we were looking at can we take over the system the USDA was doing, and how can we do it, and can we do it better? I think if you look at the data that Don reported, if you look at the data that Dr. Rigney just reported, excuse me, you'll see through the Food Safety Standards 1 and 2, the OCPs 1 through 5, pretty much a significant improvement today and under HIMP than what we had under the traditional model, to the point that even the performance standards that were set up were tighter than the traditional

model, and we're beating that all to pieces.

So, I think that needs to be said and from Salmonella, it was kind of like an oh, by the way, you gotta meet Salmonella and E.coli, too, which we seem to be doing, also, maybe not a lot different under HIMP than what we were under the old program, but quite frankly, in order to make that better, you're going to have put in innovations and antimicrobial treatments and things of that sort which aren't necessarily required under HIMP.

So, I think the data that I've seen here speaks volumes to the success of the HIMP project. I can't statistically argue whether 11 plants, 16 plants or 20 plants ought to be in there, but the data that I'm looking at looks like HIMP is working to me. Just a comment I wanted to make. Thanks.

MS. SWACINA: Thank you. Okay.

The next presentation is on In-Plant Inspection.

MS. FOREMAN: Can I respond to that?

MS. SWACINA: Oh, I'm sorry. I'm sorry.

MS. FOREMAN: The GAO disagrees with you and so do I. I don't think it shows. GAO showed that initially more plants had more Salmonella and more fecal contamination, and now if it's better, it's just

barely better.

MR. LINK: Looking at the data.

MS. FOREMAN: Yeah. You're just looking at the one page. If you go back and look at the details, the GAO said it was something else.

MS. SWACINA: Okay.

DR. JOHNSON: Can I just ask a clarification question?

MS. SWACINA: Yes.

DR. JOHNSON: I really don't know. The GAO report keeps getting referred to. The data that's being presented here in the final form, did the GAO have access to this when they were doing their report?

DR. PETERSEN: No. GAO looked at the data that was available which at the time was the partial results from the 16 plants.

MS. SWACINA: Phil, did you have something to add? No.

MR. GRASSO: But they did have all 16 plants with the data at baseline, how we measured the traditional system and how we established the performance standards, so that when the plants went into HIMP, they were able to adjust their processes to that performance standard.

MS. FOREMAN: Maybe it would be possible to

make the GAO study available to the committee members tomorrow morning.

MS. SWACINA: Gosh, I'm not sure we can get that whole thing copied, but -- no? Could we e-mail it to everyone afterwards? Oh, I'm sure it's on the GAO website.

MR. ANDERSON: It's on gao.gov. I don't even keep a copy anymore. When I want to refer to it, I go up there. I print it just right there.

MS. SWACINA: Okay. Anyone else?

(No response)

MS. SWACINA: Okay. Dr. Petersen is going to give a presentation now on In-Plant Inspection.

DR. PETERSEN: Listening to that group next door, I think I know where I'm headed when we're done here.

So, Dr. Rigney just presented the results of samples that are collected by our inspectors doing their job in the plant every day, and we thought it'd be helpful to -- as he mentioned on some of the bars that he showed, they represent that some days, plants passed and some days they didn't because we, as far as verifying these standards, we do it on a per-shift basis.

So, of course, that leads to the question,

what do we do, what happens should there be a failure, and so, first, I'll clarify how we inspect in these plants and then what we do with those findings.

Essentially, there's three inspection components in a HIMP plant, the first of which is called carcass inspection, where we have a federal employee in a chicken plant at the end of the line at a fixed location that inspects 100 percent of the birds that go down the line. That inspector's job is to make a critical appraisal on each carcass, to make a decision that it is not adulterated.

If a carcass is adulterated, they stop the line and that carcass is removed from production. They are supported by the verification inspector which are the results from Dr. Rigney. These are either random or biased samples to enforce the performance standards that were presented earlier. So, they collect a variety of samples, the first of which are carcass samples, random samples that they collect at the end of the process right before their carcass inspector, but they also do microbial sampling, the pathogen reduction sampling under the PR HACCP rule. They review plant records to see if what's happening in the plant is reflected in what's happening in the plant records, and they verify the plant's HACCP system as well as the

process control system that we mentioned that the plant has to put in place to describe how they're going to address these non-food safety defects.

And finally is the systems inspector, and two of them are the ones I introduced earlier. They are the supervisory veterinarian on the shift, and their responsibility is to assess the execution of all of the plant HACCP and other plans in the plant. What is the integration of all of these processes going on in the plant? That is their responsibility.

They also are responsible for assigning inspection resources within the plant. They can target sample collection. They can request unscheduled sample collection so that if they have a question about the process, they have the opportunity to step in with the inspectors and see what in fact is going on.

So, we look at each carcass at a fixed location. We do scheduled verification os live birds at antemortem. We do scheduled verification of product for food safety hazards. These would be the septicemia and fecal-contaminated birds. As was mentioned, we have the opportunity to do that at an increased frequency because of the flexibility in our staffing resources. We do scheduled verifications of product for these non-food safety defects, and we have the

opportunities to do unscheduled verification should we question what's going on in the plant.

Scheduled verification of the various plant HACCP and the process control records, unscheduled verifications of those. We document our findings and we do all of this with the same regulatory authorities that we have in a traditional system.

So, looking a little more closely at what happens with these verification results. For food safety in a HIMP plant, we do scheduled as a routine, 80-bird checks per line per shift for these food safety defects; that is, on a scheduled basis more frequent than we do in a traditional plant.

The verification checks are enforcing, first of all, a new food safety standard that only these plants are subject to as well as the existing checks for the zero tolerance for food safety. Any failures on these verifications is by definition a critical limit deviation of the plant's critical control point. That generates a non-compliance record and the plant must initiate their regulatory responsibilities under the HACCP regulations. They must bring the critical control point under control. They must identify what led to that failure. They must implement preventive measures, and they must ensure that no adulterated

product has been shipped. That is their responsibility for food safety critical limit deviations.

We talked a lot about doing more checks, and this slide shows that. When we do these food safety verifications, we track those in an existing agency database called PBIS, and for slaughter, this procedure code 03J just happens to be a slaughter food safety procedure code, and when we perform procedures or when non-compliance with these procedures is found, we enter that into a database.

So, we have lines for two time periods on this chart. The bottom line reflects 12 months prior to when plants came into HIMP, and what it shows is a level of our ability to do these food safety verifications, and we see that on a monthly basis, we do varying numbers of these food safety verifications.

In a HIMP system, we talk about our ability to do increased verifications and that's shown on the upper chart which is last calendar year which is the first full year after we implemented the redesign system, and what it shows is that, yes, we are in fact doing more food safety verifications in these plants compared to before the time they came in. So, we look more at what happens.

This slide is for procedure 03J01. These are

randomly-scheduled verifications of the plant slaughter-critical control point. Largely these reflect zero tolerance results, and here, we're looking at two time periods while plants were in HIMP. The percentages are relative percents. These are not actual percents of failures divided by procedures. They are relative to other procedures in the database and they're relative to each other, but the trends are the same. They're relative in that if we look at the top line, the calendar year 2000, we did more checks and plants were failing at a higher rate during that year. We look more, we find more, but we also expect improved results when that happens, and what we see last calendar year is a percentage of improved performance when we do these checks. So, we have the ability to do more checks. We're not surprised initially when we find more failures, but as a result of that, we expect plant performance to improve and that's what we're seeing in our database on the bottom line.

So, any verification test finding of a septicemia, toxemia or a zero tolerance failure generates an NR. The plant initiates the corrective actions that I described. Ineffective preventive actions in these plants, as in all plants, puts them in

potential enforcement jeopardy under what's called the Rules of Practice. These would be things such as Notices of Intended Enforcements and these types of things. So, the consequences of failures are the same in all plants because these are food safety defects associated with HACCP.

For the non-food safety defects, we have these other consumer protection categories. They were shown, the results of which were shown earlier, on a scheduled basis. We do them at a different frequency than we do for the food safety. That puts the focus on where we want to see it at this point in the project. On a routine basis, we check OCP records by the plant, meaning does the plant records reflect what's actually going on in the plant, and we do 10-bird verifications again at the end of the line.

But the inspector-in-charge has flexibility to move the sampling around. So, we have routine checks of 20 birds on each line, but what we noticed in some plants, in any plant, is some lines do well, some lines for some reason don't, and so the IIC can shift their sampling from a line that appears to be doing well and target that sampling to a line that they have questions about. He or she can also request unscheduled sampling. So, if they have questions about

what's going on in the process, they will do the verifications necessary to either find out what's going on and potentially lead to failure of the performance standard.

So, the plants are expected to meet the OCP performance standards that have been listed on a per-shift basis. The IIC documents these results, and we expect to see maintenance of process control over time. For the OCP-1 category, this is the airsacculitis and some other defects in that category, there is a daily limit that cannot be exceeded on that performance standard. That was discussed at the public meeting two years ago and I believe also before this committee.

If the plant fails that daily maximum limit, an NR is generated, but we have questions about that product, so the plant must then do post-chill testing to ensure that that product, if it's out of compliance, does not enter commerce. So, any failure of this does lead to additional testing and the possibility of product rework before that product gets shipped for this OCP category.

For all of the OCP categories, as I mentioned, we expect to see process control over time, and we look at this over 25-day windows for defects, such as feathers and these things. Failure of that

results in a non-compliance record and the plant must reassess their program to determine whether there is something inherent in the design of that program that led to that failure.

So, inspection in the HIMP plants. We look at every carcass at the end of the line. We exercise our full range of authorities. We do increased verification of product. We assess the non-food safety process. We look at OCP-1 on a per-shift basis, and we have the staffing flexibility to adjust to what is really going on on a day-by-day basis.

Any questions with how we inspect in these plants?

MS. SWACINA: Mr. Govro?

MR. GOVRO: Yes. How long does each carcass inspection take?

DR. PETERSEN: The carcass inspection -- you're referring to the verification inspection?

MR. GOVRO: On the line, when product is going through.

DR. PETERSEN: Okay. On the line, we have the inspector at the end of the line, and they are looking at birds that have completed the sorting, trimming, and washing process. So, they have been pre-screened, if you will. So, the level of defects that's

presented to them is very low, and it depends on the -- how fast the process is running.

Currently, in HIMP, typically most of the plants that I'm aware of are running in the 90 to a 115 birds per minute range. Some plants are running upwards of 160-165. Some are running in the 85 birds per minute range. It depends on the particular plant. So, they make decisions based on what's presented to them.

MS. SWACINA: Oh, Ms. Foreman?

MS. FOREMAN: On line speeds, how many plants are running at a 160?

DR. PETERSEN: That I'm aware of -- well, let me back up. In a traditional system, many plants run at a 140 birds per minute. In a HIMP system of the 20 plants, I'm really guessing, but I would guess somewhere in the neighborhood of three.

MS. FOREMAN: And how many inspectors are on that line?

DR. PETERSEN: At a fixed location would be one inspector. Now, that's the maximum line speed, and it depends on the quality of those birds that are going down the line whether the plant's able to operate at that speed.

MS. FOREMAN: Can the inspector see inside

the bird?

DR. PETERSEN: The inspector is required under the statute to make a decision on each carcass, and to make a decision on the safety of that carcass, they are looking at the external surfaces of that bird as it goes by, and when they have questions, they stop the line and that bird is removed.

MS. FOREMAN: So, ordinarily, going down the line, the inspector is not -- in the HIMP plant, is not seeing the inside of the bird. Unless there is fecal material or some problem on the outside, he's not going to hold it to look on the inside.

DR. PETERSEN: That's not part of their inspection procedure because they don't need that information to make a decision on that carcass.

MS. FOREMAN: In traditional inspection, an inspector looks at the inside of the bird and quite frequently fecal contamination is on the inside of the bird because that's what happens when it -- you puncture the gut. So, nobody's looking at the inside of these birds unless there's something on the outside?

DR. PETERSEN: In a traditional system, they are looking farther upstream, and so birds have not been pre-sorted, if you will, but even if they see birds with fecal contamination inside in a traditional

system, if a plant has an on-line antimicrobial, they leave that bird on the line.

MS. FOREMAN: But they know that it's there? So, they know --

DR. PETERSEN: It does not affect their decision.

MS. FOREMAN: Right.

DR. PETERSEN: If they --

MS. FOREMAN: I've watched a traditional line. I've watched an inspector tilt that bird and look at the inside of it and tell the plant employee to take it off.

DR. PETERSEN: They are looking in that instance not for fecal contamination but for some other process which we are -- for example, airsacculitis.

MS. FOREMAN: You're telling me that an inspector who looks and sees fecal contamination in a bird in a traditional system is not obligated to tell the plant employee to take it off the line?

DR. PETERSEN: If the plant has an on-line antimicrobial, no, they are not. That is the subject of a proposed rule that we have put out on on-line reprocessing.

MS. FOREMAN: A proposed rule? It's not a final rule? You're doing this without a final rule?

DR. PETERSEN: This is separate. The on-line is a separate issue.

MR. DERFLER: We've issued a waiver under --

MS. FOREMAN: You've issued a waiver.

MR. DERFLER: We've issued a waiver.

MS. FOREMAN: You've got a proposed rule that's not final, and you gotta a waiver, too?

MR. DERFLER: And our regulations provide for that. 9 CFR 303.1H provides exactly that.

MS. FOREMAN: So, we've got birds now out there that have fecal matter on the inside of the bird that the inspection force isn't required to remove because you waived the requirement?

DR. PETERSEN: But the best indicator of fecal material that we have is the generic E.coli results, and what we're seeing is those are going down. So, if we have a microbial indicator and on-line antimicrobials subject to this proposed rule, it was working on it.

MR. DERFLER: And the plants are meeting a performance standard before the chiller with respect --

MS. FOREMAN: I thought we were talking about a traditional plant here.

DR. PETERSEN: Yes.

MS. FOREMAN: Because Ken's saying that

they're not looking for fecal on the inside of the carcass in the traditional inspection system.

MR. DERFLER: Use on-line reprocessing. To use on-line reprocessing, you have to meet certain standards before the chiller.

MS. FOREMAN: And that's in the traditional system and that's in place now as a waiver to the old rules?

MR. DERFLER: Any plant that has a waiver.

MS. FOREMAN: Any plant that has a waiver. Okay.

DR. PETERSEN: The on-line reprocessing is in independent of HIMP.

MS. FOREMAN: No. I understand. You just gave me information I wasn't aware of, and I'm a little surprised to learn of it, especially the line that it's being done on a waiver, because the -- could we start enforcing the Listeria rule on a waiver since that one doesn't seem to be able to get to the final stage?

MS. SWACINA: Dr. Johnson?

DR. JOHNSON: Dr. Petersen, if I understand, the -- in order to look at the performance standard, even in traditional, you've got inspectors that after the antimicrobial intervention, are pulling birds off, looking and doing zero fecal checks. Are they doing

that still?

DR. PETERSEN: Yes.

DR. JOHNSON: In the traditional? Yes. So, you've got so many checks, even if you've gone through the on-line reprocessing. Basically, they're just checking after the antimicrobial for their performance standard?

DR. PETERSEN: The plant implements a system and, of course, we monitor that system on various levels of both how the system itself is functioning and then we verify that food safety standard, as you said, after the antimicrobial. So, it's not simply looking for the birds. There's other -- they can put in place a process but we make sure the process is doing what they say it will do.

DR. JOHNSON: Okay. And in the HIMP plants, we saw somewhere where they -- now, it's USDA that is actually doing this, not the plants themselves, where they've doubled the checks for the zero tolerance standard pre-chill. I want to clarify that it's USDA that's verifying, and you said how many more times than --

DR. PETERSEN: We're doing four times the number of checks in HIMP for zero tolerance than we are in the traditional system.

DR. JOHNSON: Okay. And that's USDA. That's not counting the in-plant checks?

DR. PETERSEN: Those are our inspection personnel doing their job every day.

DR. JOHNSON: Okay. Thank you.

MS. FOREMAN: Did I misunderstand that -- I thought I had asked were the inspectors looking for fecal material on the inside of the bird.

DR. PETERSEN: And the answer is the verification inspectors are verifying, pulling the birds off line and looking inside and outside as part of their verification activity. The on-line inspection activity is as I described it.

MS. FOREMAN: So, you can have fecal contamination inside the carcass of all the birds that aren't being pulled off to do the verification check?

DR. PETERSEN: But the numbers reflect that the percentages are going down and the indicator of that defect, generic E.coli, is also going down.

MS. FOREMAN: But you said something about an antimicrobial treatment.

DR. PETERSEN: Right.

MS. FOREMAN: So, you have sterile fecal matter inside the bird?

DR. PETERSEN: The antimicrobials have never

been associated with that. They lower the bacterial level.

MS. FOREMAN: But do they lower the fecal matter inside the carcass?

DR. PETERSEN: The way we look at that is through our verification checks, and the numbers have gone down and that appears to be good.

MS. FOREMAN: But it wouldn't be reflected in the E.coli data if the antimicrobial has been applied?

DR. PETERSEN: I'm not sure I follow.

MS. FOREMAN: You said the E.coli numbers had dropped.

DR. PETERSEN: Which is an indicator of fecal contamination.

MS. FOREMAN: But if it's already gone through an antimicrobial treatment, it's not because the antimicrobial would kill it. So, you may still have fecal material there but just not registering as present because of the antimicrobial. It won't make you sick.

DR. PETERSEN: We may have -- what we've noticed is that the zero tolerance findings have gone down.

DR. JOHNSON: Can I just ask one thing kind of to -- I'm trying to clarify some things that are

being said, too, here. The antimicrobials were not put in place just because of HIMP. In some of these plants, even on baseline that you were comparing, were the antimicrobials already in place or was that a requirement to go under HIMP?

DR. PETERSEN: Yeah. Any use of an antimicrobial has -- is independent of HIMP. That is not a requirement.

DR. JOHNSON: Are there any --

DR. PETERSEN: Plants use it for various reasons.

DR. JOHNSON: Are there any plants that you know of in the 16 that were already using something that would have --

DR. PETERSEN: Yes.

DR. JOHNSON: -- been a part of baseline?

DR. PETERSEN: My understanding is if they were using antimicrobials before, they are using antimicrobials after.

MS. SWACINA: Okay. Ms. Donley?

MS. DONLEY: Thank you. Phil, do you know -- do we know how many waivers are out there? How many plants have waivers?

MR. DERFLER: We know how many waivers. I don't know as I'm sitting here, but I know.

MS. DONLEY: Are we talking a handful, a hundreds?

MR. DERFLER: I think it's less than a hundred, but there are a significant number of waivers out there.

MS. DONLEY: Can we get -- have that number tomorrow? Find out and get that number for tomorrow?

MR. DERFLER: There's no secret.

MS. DONLEY: Yeah. I just would -- I just want to know.

MR. DERFLER: Yeah. Fine. I don't know the number.

MS. DONLEY: Okay. Hopefully we can have the number tomorrow.

Question. Under traditional inspection, when do you have the number -- what is the line speed at which you add the second inspector?

DR. PETERSEN: Okay. When we talk about traditional inspection systems in chickens, today we're typically talking about what we call SIS Systems, NEL Systems or New Tech Systems. A SIS System runs -- most of them run at 35. The line speed is either 70 or 140 with either two or four inspectors. So, they are further upstream making all of the decisions at a different line speed.

MS. DONLEY: So, a plant that's under traditional inspection has four inspectors at a line speed of a 140. Under HIMP is now -- and I know where that inspector is. I've been in a HIMP plant, and I've been in a traditional plant, and I know where that inspector is, but so, we are now down -- there's been no provision made for additional inspector -- one inspector now is looking at a 140 birds a minute.

DR. PETERSEN: If the process is running under optimal conditions, and they have a partner, a verification inspector, as well as a systems inspector who helps make that determination. They're able to do the verifications to know what's going on in that system.

MS. DONLEY: I have -- I don't have a whole lot of confidence with just, you know, one guy standing there at the end of the line with a 140 birds kind of whizzing by. It doesn't give me a whole lot of confidence.

But I do have one -- just another question here. On the in-plant controls, the overview here, where you said scheduled verification of product for food safety hazards increased frequency. You didn't specify any amount like you did for the zero tolerance where it's four times the number. Does -- is there a

set number here?

DR. PETERSEN: Yeah. I'm sorry. If you're referring to the food safety, that is the zero tolerance food safety four times an increase.

MS. DONLEY: Right. Is that that same thing then on -- in the beginning of your presentation where it said the in-plant control?

DR. PETERSEN: Yes.

MS. DONLEY: That's this?

DR. PETERSEN: Yes.

MS. DONLEY: Okay. And that's the same throughout each plant? It does not vary?

DR. PETERSEN: That's the minimum we expect.

MS. DONLEY: Minimum.

DR. PETERSEN: And we have the opportunity to do more, but when we talk about -- somebody earlier mentioned the number, I guess it was Phil. Our own inspectors tell us in the HIMP plants, over 70 percent of them said they believe, and these are the folks on the line you referred to, they believe food safety is as good as or better, over 60 percent of them said the same thing for -- approximately 60 percent for the non-food safety. That's what they're telling us.

MS. SWACINA: If I could, we've got to move on. I'm sorry. There's two more presentations to

make.

Mr. Link, can you be very brief?

MR. LINK: I can be very brief.

MS. SWACINA: Okay.

MR. LINK: I just wanted to point out in the HIMP, the whole purpose was to allow plants to kind of take charge of their own destiny with verification by USDA, I mean, so that you have some comfort level. The plant basically has taken over the responsibility of looking inside the bird, removing the diseased birds, taking care of fecal contamination, and then the verification inspector obviously checks what we do every day. They check up and down the line to see that we're following our procedure, not to mention our own in-plant quality control people do the same type of thing, to make sure that our people are doing the jobs, are doing it properly. We're pulling off -- USDA's pulling off 80 birds, we're pulling off a 180 birds, looking to make sure that we are meeting the requirements for the food safety and other consumer protection standards. So, I mean, it's not like we're just turning our head and saying good, USDA's off-line, let's get it. That just doesn't happen. It's not the case.

MS. DONLEY: I just have to respond because

I'm responding to his response, and I will make it brief.

My organization did not get behind -- and was open to the whole idea of the HIMP project because it was going to allow HACCP down the line into the slaughter. We backed the concept of HIMP because it was going to theoretically lead to improved food safety, period. That's the only reason. It's not for the convenience of FSIS. It's not for the convenience of industry. It is only if we find significant benefits in food safety from alternate inspection systems.

Now, I don't agree with Charles here about that I see some significant improvements. Maybe in the OCPs, but I just -- if -- I've heard now today, it was said that the main goal was for it to be gotten down into the -- the fundamental goal was to extend HACCP systems to slaughter. I think we're just going to have to back off our support of it. It's food safety, it's increased food safety, period.

MS. SWACINA: Thank you. Okay. We really need to move on here. Otherwise we will all be complaining later.

Okay. Let's move on to the RTI Correlation Presentation. Mr. Anderson, again.

MR. ANDERSON: Okay. Thank you very much.

I'm probably the last person you wanted to see back up here at 4:30 and I feel the same way.

I was asked just about, I guess, 48 hours ago to make some comments on what -- on -- the agenda says the RTI/FSIS Correlation. The term "correlation" has been used a lot and is used in a lot of different ways. I talked about in-plant correlations and all that.

What we're really talking about here is a comparison of the agreement between the FSIS verification inspectors and the RTI veterinarian data collectors. Remember that at the same time that RTI was collecting data in these models redesign plants, FSIS was doing its own verification checks, as you've just heard Columb talk about extensively and showed you the numbers. And indeed, when you looked at the numbers that he put up, you could probably quickly and easily see the same thing I did, and that is, that the food safety conditions in the so-called RTI data are very low bars, very low numbers, and they're a little different but they're low numbers, and in the OCP, some of them are pretty low and some of them, like OCP-4 and OCP-4 in particular, are considerably higher.

About -- I guess it was about January, we were asked by FSIS, RTI was asked by FSIS to do a quick

comparison of the verification data with the RTI data, and it was -- we were asked to do that because they could show us the verification data and we could continue to maintain the confidentiality of the identities of the plants and particular results from plants.

So, they asked us to look at that data, and it was -- I think it was primarily driven by FSIS was interested in seeing whether there were any particular OCP conditions in any particular models plants where maybe additional training or correlation work might be indicated. So again, they were interested in kind of the agreement between our data and their data.

It was done, as I say, it was done in January when we had partial data, and it was also in the context of the GAO report. So, the comparisons we made were for the 11 plants again. So, the question really was whether, you know, what is kind of the level of agreement between the verification inspectors at FSIS and the RTI data collectors.

Now, of course, we can only compare data for the same 25-day window that we collected data in and they collected data in. So remember, for the 25 days when we're in there, of course, FSIS is collecting data, also.

There are two kinds of error, I guess, that we might be interested in looking at. One is what I would just call traditional measurement error. Any time you try to measure something, there's going to be some amount of measurement error. Measurement is inherently imprecise, and another concern which is maybe of greater concern is a measurement bias. It's a systematic error that may or may not be occurring.

So, what we were interested in seeing is whether there tended to be agreement between the RTI prevalence estimates and the FSIS prevalence estimates. I don't know if I mentioned this before. I think I did. But the FSIS data collectors, the veterinary data collectors, totaled four. I mean, we only had four different veterinarians doing all the organoleptic data collection in the models redesign plant in the plants.

The FSIS verification inspectors in these 11 plants surely number, you know, 30, 40 or 50 people even. I mean, there are different verification inspectors on the various lines. So, there may be inherently some tendency for there to be more measurement error in the FSIS data than there would be in the RTI data.

One of the -- always, one of the recommendations when you're conducting experiments

where you have humans doing measurement is to the extent that you possibly can, you try to reduce the number of people doing the measurements because there are differences across people in how they measure things. I mean, ideally, everybody would measure things exactly the same way but they don't always.

So, there's one other thing that I guess I would like to indicate here before I explain the numbers, and that is, that while the data we looked at were FSIS data or RTI data, the data we looked at was from the same 25-day period, but remember on any given day that we were in a plant, we may have been sampling from the first shift or from the second shift. We sampled on one shift or the other on any given day. The FSIS verification data is from both shifts. Okay. So, there's some question, I think, as to whether it's exactly the same population or not. Was the population of birds going through the plant on the second shift on the day we were looking at the first shift the same or not, I don't know. We don't know the answer to that. So, there's some question as to whether the population is exactly the same.

A final thing before I talk about some of the numbers, is that, remember, RTI looked at 2,000 samples. FSIS in its verification sampling has

thousands and thousands, I guess, Columb, you mentioned that some of the Ns were 200,000 or something data points for verification data, but I have to take my own medicine here and remind you as I remind myself that whether you're looking at 2,000 or whether you're looking at 200,000 in a population of this size, our estimates, you know, we should be coming up with approximately the same prevalence estimates with approximately the same precision because we are talking about large sample sizes.

Now, we would expect to see differences, measurement differences, to vary by OCP condition. I mean, for example, remember that for the OCP-1 conditions, animal diseases, whether you look at the RTI data or the FSIS data, the prevalence rates are very low. They're on the order of, you know, 0 to 2 percent. So, looking at that data difference of a few percentage points wouldn't be appropriate. It would be -- that would be a cause for alarm if there was a difference in observation of a few percentage points when you're looking at something that should have a very low prevalence; whereas, for OCP-3, ingesta, remember again, depending on what data you're looking at, which set of data, the prevalence rates are higher. So, there, a difference of few percentage points may

not be any particular cause for concern.

I do want to -- I wish I had color which somebody liked earlier, and I wish I had had time to do a more thorough or a more sophisticated analysis but I didn't. So, I kind of tried to cobble something together here, but I do want to thank Barb Dwyer. I know she worked after hours last night to put this together which I will refer to and hope it helps.

But again, remember, we've got 11 establishments here where we have 25 days of verification and 25 days of RTI data corresponding, and we have five OCP conditions. So, this just demonstrates the comparisons I'm about to make. There are -- in this matrix then, there are 55 comparisons. So, you can compare in Plant 1 for OCP-1, you can compare our estimate with their estimate or in Plant 2, you can do the same thing and so on. So, there are 55 different comparisons you can make.

But again, as I pointed out, the differences that you would expect to see between data collectors would be expected to vary by OCP condition. Here, because the prevalences are low, you would want to see, you know, agreement within a percent or so; whereas, for conditions like OCP-4, you could have a greater level of disagreement, if you will, and it wouldn't

necessarily be a cause for any concern.

So, what I did is for each of the OCP-5 conditions, okay, 1, 2, 3, 4, and 5, for each of those conditions, I calculated an average difference. Okay. So, for OCP-3, I looked at the difference between the RTI data and the verification data here, and I did it here and I did it here. So, and we get differences, and I calculate, okay, down here, I calculate the average difference, and then, what I did is I looked at how often the actual difference, that is, for any particular cell, I looked at whether or not this difference was greater or less than the average difference and how much greater than the average difference it was, and the criteria I used, because I could easily do it on my calculator and crunch these numbers in the last 24 hours or so is I said, well, look, let me look at the average difference and let me flag any cell where the difference is greater than twice the average difference.

The easiest way to understand this is with a simple explanation. Let's consider OCP-3. Okay. OCP-3 is ingesta. The FSIS verification prevalence estimates range from about 4 percent to 21 percent for OCP-3 across these plants. Across the same plants, the RTI prevalence estimates range from about 1 percent to

about 21 percent. So, it's 4 to 21 or 1 to 21. So, that was the range of prevalence estimates that we see.

Now, continuing with OCP-3, okay, the average difference, that is, if you look at the difference here and the difference here and the difference here and you sum them up and you divide by 11, the average difference is 5 percentage points and twice the average difference is 10 percentage points. Okay.

Now, for OCP-3, in nine of these 11 cells in OCP-3, the difference between the FSIS estimate and the RTI estimate was less than 10 percent. Only in two cases was the difference greater than 10 percentage points. So, we had two cases out of 11 where the RTI estimate was substantially different from the FSIS estimate. So, that tells you something about measurement error.

But as I say, we're also concerned or, you know, we can ask about systematic error. I mean, is there a systematic difference in the RTI estimate from the FSIS estimate? Are we systematically higher or lower? It turns out that in OCP-3, ingesta, that where we had two significant differences, we found that in one of those plants, the RTI estimate was higher, and in the other plant, the RTI estimate was lower. Okay.

Overall, if you look at the 55 comparisons

and follow the same procedures, do the same thing, it turns out that in 47 of the 55 comparisons, which is about 85 percent, those differences are within range, and in eight of these 55 cells, those differences are out of those range. So again, we have eight that are outside the range of agreement that I somewhat arbitrarily selected, but of those eight, of those eight significant differences, the RTI estimate was lower than the FSIS estimate in four of those and the RTI estimate was higher than the FSIS estimate in the other four. It was evenly balanced.

So, you know, I think this is where -- a little more of a recommendation, and I think there is -- you know, it's a little hard to stand up here and talk about this because, you know, we can't go back and do the same thing. We can't really say, well, maybe the RTI data collectors could have done a better job because they've done their job. We did the best job we could. The data's collected and it's there. The verification data continues and continues.

So, to the extent that we can identify, you know, differences in -- well, to the extent that we can use our data in concert with their data to identify particular plants and particular conditions where additional training, work correlation might be done,

then we can do that. So, we've given those results to FSIS, and I think that they'll probably talk about that in some of their next steps. I think that's part of the next step.

MS. SWACINA: Okay. If we could, can we go right to the Next Steps and hold your questions till the end? Is that all right? Okay. Thanks.

MR. DERFLER: Actually, what Don just said is not part of my presentation. So, it's okay.

Let me just go -- it seemed to me in preparing for this presentation, that there were three questions that the next steps will revolve around. First of all, what do we do with the data? Second of all, what do we do about rulemaking to put in place the system of inspection that we studied with the young chickens, and third of all, what do we do about market hogs and young turkeys?

Let me take the last question first. Right now, in market hogs, we have three plants for which we've got HIMP data. We have two more that are signed up, and we should be taking -- we should start taking -- RTI should start doing their data collection there soon. So, we have the prospect of completing the market hogs study fairly soon.

As for turkeys, there's two plants where we

have models data and a third plant which RTI will begin collecting data later this month. That leaves two plants for which we do not have RTI data and we have no plant in the offing. We hope that a plant -- two plants come forward.

Turning to the question of what do we do about the data which is obviously what we've heard a lot and talked about a lot today. With respect to the data, because of the questions that have been raised by GAO and by you and by various sources, FSIS believes that it would be appropriate to have the data reviewed by an independent third party. It's to the third party that we could present a lot of the questions that we've heard today.

We've tentatively decided on a course of action for obtaining a third party review, and what I want to do is outline our course of action and how we arrived there and then, if there's time, there will be an opportunity for you to comment on it.

To start, we decided that we want to pursue a sole source contract. We believe that it is appropriate to do so for two reasons. First, as I talked about before, it has taken us a long time to get where we are now, and we want to move forward, and the second is that the models project, quite frankly, is

not cheap for the agency. We have detailed a number of employees out of models plants and we have extra costs as a result. Thus, we're interested in moving forward on with a decision on the project with deliberate speed. We're not interested in proceeding with undue haste, but we do think deliberate speed is appropriate.

To do a fully-competitive contracting process would take approximately six months. We don't consider that to be deliberate speed. We think that's too long to wait, and so we're looking to contract sole source. In identifying possible institutions to contract with, we considered several factors.

First of all, because federal support for research and extension work is provided to land grant colleges and universities, we thought that we should use a land grant institution with an agricultural extension office.

Second, we felt that a robust review of the data and the design of the study in which it was developed required a multidisciplinary approach. The data relate to zoonotic diseases and conditions of poultry, carcass defects commonly identified in the poultry processing environment, and microbiological testing of poultry carcasses for Salmonella and generic E.coli. Therefore, we felt it desirable to use an

institution with a poultry science department, a college of veterinary medicine and a food microbiology department to participate in this review. We also felt that a statistics department was needed.

Finally, given that the review will be of the poultry slaughter inspection system, we felt it necessary for the institution to have some familiarity with large-scale poultry slaughter systems. We identified four institutions that seemed to meet all these criteria. However, three of the four institutions had ties either to poultry plants that are involved in the study or to RTI. Thus, the institution that emerged from our consideration was Mississippi State University.

We would appreciate your thoughts on the factors that we considered in the process, our reasoning in selecting these factors and any other considerations that you might consider relevant.

Now, that brings me to the question of rulemaking. Obviously, we have not made a decision as to whether or not to go forward with rulemaking yet. We're holding that decision until after we've had the benefit of the third party review if in point of fact we do it. But the important thing to keep in mind is that if we decide to go do a rulemaking, in any

proposed rule, we're going to have to respond to the concerns that we've heard. We're going to have to explain why we think what we're doing is the appropriate course of action and there will be an opportunity for public comment on those concerns, and then we will respond to those comments, if this is the way we go, and ultimately the process will be subject to judicial review.

Judicial review in the past has already told us that we took one wrong step and there's no reason to expect that that wouldn't happen again unless we do our job correctly and fully explain and justify what it is that we do, and so, that's where we are. That's where we see ourselves going.

MS. SWACINA: Okay. Let me go back to Mr. Govro. Sorry.

MR. GOVRO: Govro.

MS. SWACINA: Govro, Govro. I'm writing that down.

MR. GOVRO: Just to comment on the table that was up on the screen a little bit ago. I'm obviously challenged in the area of reading statistics because if that was anything more than a list of the numbers from 1 to 55 arranged consecutively in five columns, if there's anything to be inferred beyond that, it escapes

me and that information needs to be presented in some other fashion.

MS. SWACINA: Is there -- Mr. Anderson, is there maybe a bottom line you could give everyone from that chart?

MR. ANDERSON: Let me first say that nothing escaped you. That's exactly what it was. Again, we -- Barbara put that up there so that I could point out that we were talking about five OCPs and 11 plants and where I was calculating the within-cell differences and the within-OCP differences, and I gave the best example of it that I could. That's the best I'm able to do, you know, on this short notice. That's all it was.

MS. SWACINA: Okay. Thank you.

Ms. Foreman?

MS. FOREMAN: I don't know where to start really. Phil, you talked about trying to avoid another mistake. This is replete with mistakes. It just looks like you're absolutely bound and determined to set up a situation where you will be challenged every step along the way.

You talk about it being too expensive to do a multisource contract. It's pretty damn expensive to go through another court case and, boy, that's where you're going. If I'm a little agitated, it's because I

tried to be supportive of this project as did my organization, and we got kicked around a lot, and now it turns out that kicking us around was absolutely justified.

The data don't -- you see everybody around this table smiling. The data don't pass the laugh test, and now you're going to go to a sole source from a land grant university that has substantial poultry industry connections, and why do you think anybody's going to believe that that's a dispassionate study?

Now, when -- wait a minute. When BSC was a question, you went to Harvard. That was an animal disease. But now we're back to Mississippi State to do a review of data that the GAO has questioned and that we question and that we can't even find out what the number is, and I think you're just about to guarantee another court challenge because every step along the way, you've decided where you want to go and you say this is where we're going to go and this is why we're going to do it, and you're going to get challenged, and the next time out, by golly, Consumer Federation will be a plaintiff in that suit.

MS. SWACINA: I think you answered my question, but I was going to ask you, if you had a suggestion beyond Mississippi State? Shall I take

Harvard as a suggestion?

MS. FOREMAN: Harvard Center for Risk Analysis has substantial experience in going through data reviews. Don't go somewhere where you have people who do not have connections to the industry that has a vested interest in the outcome of this project. You've got it -- this is such a controversial area. Why make it more so? That's what I don't understand.

MS. SWACINA: Okay. Thank you.

Dr. Denton?

DR. DENTON: I fully appreciate the situation that the agency finds itself in with regard to trying to look for sole source, but I think I have to agree with Carol on one point, in that one institution is probably not the appropriate way to handle this.

Representing the National Alliance for Food Safety as part of my duties, we do have 16 land grant universities complete with departments of poultry science that have expertise in some of the issues, colleges of veterinary medicine that have expertise with regard to some of the issues that need to be addressed in assessing this data. We also have medical schools that participate in that national alliance as well as statistical expertise and most of the other issues that Phil mentioned in that.

I would offer for the committee's consideration that they communicate with the National Alliance to determine if that is something that would be appropriate for the committee's consideration.

MS. SWACINA: Okay. Thank you very much.

Dr. Johnson?

DR. JOHNSON: Okay. Let's have a different slant so we can get a little more discussion going here.

Anything you do in a proposed rule and any type of review that's done, whether it's a Mississippi State or a Harvard or the Alliance that Dr. Denton talked about, in the preamble to any type of proposal, if you choose to go forward, you would have all the information that was presented for this third party review as well as the information that the third party review provided you, correct? I mean, that would be spelled out in pretty much detail in the preamble?

MR. DERFLER: Right. And whatever we sent would -- and get back would be part of the record that underlies the rulemaking.

DR. JOHNSON: And everybody would have access to that record?

MR. DERFLER: Yes.

DR. JOHNSON: So, as part of a comment for a

proposed rule, someone could take that information and provide their own analysis or -- of the outcome of the third party as well as what you had presented them, correct? You'd kind of expect that in comments? Yeah. Okay. So, we would have access to everything.

MR. DERFLER: I mean, I think this meeting today makes clear that the agency is trying to be as forthcoming and putting out as much information as we possibly can.

MS. SWACINA: Ms. Donley?

MS. DONLEY: Thank you. I just -- I think the idea of going forward with rulemaking at this point is rather premature. We -- the agency's taken a huge hit, the Department of Agriculture, a huge hit with the Supreme Beef lawsuit. I think there needs to be -- to just -- you know, to consumers, the fact that you have had a critical enforcement tool withdrawn from you and until we figure out what we're going to do even just in the status quo, that to go forward with this HIMP project is very premature.

To our way of looking at things, there's just no verification. You can do the verification. I know you're doing the Salmonella performance, but as we heard earlier today, you do the tests but then your hands are tied of what you can do with it afterwards.

I would just really caution this agency. I think that it's -- until we get a good set of data which I appreciate what you're trying to do is to take a look at it, have a third party review it, let's see if it makes any sense. Do we have to go back to square one? If we have to to have some good data, that's important, but I will repeat what I said earlier, and that is, that if the data doesn't come out showing a marked increase in food safety protection, my organization has no interest in it.

MS. SWACINA: Okay. Thank you.

Is there anyone else who wants to comment? Dr. Morse?

DR. MORSE: Dale Morse, New York. I haven't read all of the GAO report, but what I have skimmed certainly raises concerns, and so the credibility has been challenged of the data that's been presented.

So, I mean, I don't know whether it's salvageable. They raised a question whether the data can be salvaged. Certainly somebody else needs to look at it that's a neutral party with good statistical analysis to see if you could -- for example, could you look at the 11 plants that they had pre- and post-data? Could you try to control for temperature times a year and things like that to get credible data from it?

But if it's not, then you can't really use this as -- it would damage the credibility of the agency to go ahead with rulemaking with -- in the current situation.

So, I think it has to be reviewed by someone else or else published and take the criticism of people through a peer-review system, but this has raised credibility questions that you really need to address before you can go ahead because it'll come up anyway.

MS. SWACINA: Thank you.

Let me just clarify. We are not moving ahead with rulemaking at this point. There are a lot of issues that you all have raised today. There are issues, as you said, that GAO has raised, some of which we've responded to, some of which we clearly need to do more work on.

HIMP for us is a work-in-progress, and it is part of our continuing search to find continuing improvements in food safety. So, we really do appreciate all the comments that you all made today and all the input that we've had.

Let's see. Before we move on to the public comment, were there any other committee members who wanted to comment?

(No response)

MS. SWACINA: No? Okay.

MS. SWACINA: The first person is Dr. Buzz Clopp from Townsend's, Inc.

DR. CLOPP: Yeah. It's been a long day. So, I'll try to keep this brief. My name is Buzz Clopp. I'm a veterinarian with Townsend's, Incorporated, and we have two plants in the HIMP program, and the first point I wanted to address was the time factor, and specifically what got me thinking about this was a long discussion on where'd the plants come from?

The volunteering for this program was a major, major, major decision by my company. It entailed everything from evaluation of resources to public notoriety and public exposure. It encompassed every area from the very beginning, breeder department, right on through our sales department, and I can see now that that -- we were a lot smarter to take a year to think about it, and I also still believe that we were smart to participate in this program, and it's the first time I've heard about the third party audit. That will certainly extend the time.

I think it's a very logical decision and certainly to have a medical school, such as Harvard, which I might add my father was a graduate of Harvard Medical School, but I think also to include veterinary

schools, poultry science departments, because you can get outside the box, but you also need to have somebody that's been inside the box which leads me to my second point.

There's been a lot of discussion about all the variables involved in do you compare 11 plants to 11 plants, 16 to 16, 20 to 20, and the reality of this is as we looked at HIMP and I looked at HIMP, it was a matter of trying to study how a new and different inspection program would work within all the variables that are involved in a poultry operation, and there are folks in this room who know all the variables, and there are a lot of them because chickens are biological systems, and we can sit here and say all chickens are the same. I don't believe that any more than I believe that all people are the same. So, please consider that, that you're never going to be able to exclude all the variables.

The other -- my next-to-last point kind of leads into this. It's the relationship of HIMP and Salmonella. I have significant questions about the relationship, but a bigger question gets into isolation of HIMP and Salmonella or isolation of HIMP with anything because what you're doing with HIMP in an inspection program is you're putting it in a plant

again with all these variables going on around, and we get these new technologies, such as antibacterial rinses, and we have a HIMP program. Are we supposed to say no, no, no, no, no? We're not going to use that because we're on HIMP. Why, shucks, no, we're not going to do that.

We see that as a new technology, a new improvement. It's the same thing with new pieces of equipment. I hear all these discussions about line speed. Line speeds in and of themselves don't mean a thing. They really don't. What matters is your performance standard, your ability to do a quality job. That's what matters, and if we think the equipment and the people on lines are the same as they were five years ago, 15 years ago, no way. It's a better system than what we used to have.

My last point, and it gets into the better system, is, as we worked in HIMP, we spent a lot of time talking with not just our employees, company employees, but also USDA employees, the veterinarians, the GS-8s, GS-9s, and if FSIS is intending on keeping its good veterinarians and on keeping its good line people and on hiring good veterinarians and on hiring good line people, you better make some changes from the traditional inspections because I've talked to -- and

I'll tone this up a little bit and you'll see why. The one veterinarian who is now an IIC at a HIMP plant and he said, "I never viewed my future at looking in the butt end of a chicken."

He or she was absolutely correct, and that's where you get into the verification concepts of this, the whole food safety program of this. Don't get bogged down in trying to isolate HIMP because you can't do it. Just look at it as part of the process.

Thank you.

MS. SWACINA: Thank you very much.

Next is Tony Corbo, Public Citizen.

MR. CORBO: I have some Farm Bill questions. The Education Program that's called for under the Pasteurization Section of the Farm Bill has a program. Has a curriculum been developed? What technologies and treatments are going to be covered in the Education Program, and how much money are you seeking from the Congress to appropriate?

MS. SWACINA: We haven't sought any money in particular yet for education. We -- the answer to your other questions are, I think that that's -- those decisions have not been made. We're just getting this underway, and we're at the moment just having internal discussions as to what we can do absent having any

money at the moment, and at the moment, I think the only thing that's going on is a review of the documents that are on the website, and I'm not sure exactly where we're going to go from here.

MR. CORBO: One other question. Last year, the FDA conducted some focus groups on food irradiation labeling, and I understand you all have done the same thing and you've gotten some results back. Are those results going to be made available? Are the transcripts going to be made available?

MS. SWACINA: I do not know. I don't know what kind of focus groups we might have done on irradiation.

Phil, are you aware of any?

MR. DERFLER: I know we did some focus groups with FDA on labeling. I'm not sure that they -- that the ones that we participated in covered irradiation, but, I mean, we've sort of tied our labeling policy to FDA's, and, you know, we'll look at what they do.

MS. SWACINA: We'll check on that.

MR. CORBO: Okay. Yeah. I believe that Mr. Engeljohn at a food irradiation or the pasteurization conference in Nashville made reference to some focus groups that you all had conducted on the issue.

MS. SWACINA: He just walked in. I saw him

walk in. Sorry, Dan, wherever you are. Did he walk back out? Nope. There he is.

MR. ENGELJOHN: Yes, actually we did do some surveys as part of a broader effort and that information is not yet available, but when it is available and analyzed, we will make it available. But we did ask some specific questions about consumers understanding of the term "pasteurization".

MR. CORBO: Thank you.

MS. SWACINA: Thank you.

Okay. Next is Felicia Nestor of the Government Accountability Project.

MS. NESTOR: Hi. I just wanted to reiterate the concern that I've heard from the other consumer groups here, that it seems like the Department has been using science and modern techniques, including statistics, to justify pre-determined decisions.

When Dr. Murano took over FSIS, she was repeatedly quoted as saying that there is no such thing as good science because if it's not good, it's not science, and at that point, I was encouraged to hear that, then disappointed to see the report of the Salmonella data put out shortly after that.

Consumers today cited the Department's failing to compare apples to apples in HIMP. Last

week, GAP and Public Citizen released analysis of the Department's Salmonella statistics that raised issues about FSIS analysis of that data. Both HIMP and the Salmonella analysis involved methods that raised the eyebrows of anyone that studied high school science.

I've gone into a number of congressional offices and what I repeatedly hear is I'm not a scientist, I'm not a statistician, and, you know, I know that's not right. I would encourage FSIS to move in the direction where science is associated with the agency initiatives in other than a cynical manner.

I also would like to say that I've been to a number of these meetings over the years, and GAP and the other consumer groups and I think industry have often put out their public -- for the public studies, and we did that today and for the first time, surprisingly, our report was confiscated, and we weren't informed. Luckily, someone saw that, and I just -- you know, I think it's a sad day when at a public meeting, the agency stoops to some sort of subterfuge to keep information from getting out in what is supposed to be a forum where stakeholders have a free flow of ideas.

MS. SWACINA: Thank you.

Okay. Is there anyone else who wanted to

comment on the committee on any of that? Ms. Foreman?

MS. FOREMAN: It -- I'm really surprised. Is there a reason why the papers were --

MS. SWACINA: They were not confiscated, is my understanding. I -- they were returned.

MS. FOREMAN: Were they removed from the table out front?

MR. GIOGLIO: They were removed from the table out front where we were readying to put out the FSIS material for the committee and the others. One of the staff folks took them off the table and we returned them to Ms. Nestor who I believe distributed them to the folks here in the room.

MS. FOREMAN: I'm really surprised. That's never been done before. Caroline and I both have put papers out there on that table before and they've never been picked up. I'm just really surprised to hear that.

MS. SWACINA: Thank you.

Okay. Dr. Johnson?

DR. JOHNSON: Carol, I know industry's done a survey, and we tried to put it out. It's been a couple of meetings ago, maybe last year, I guess, and the agency felt it was inappropriate for us to do that as well. I wouldn't use the word "confiscated", but we

got told not to put that out there.

MS. FOREMAN: Would you join me then in suggesting that in the future that not happen?

DR. JOHNSON: I think what we need to do is look at the by-laws, whatever the rules are for the committee, because I'll have to admit I don't understand about the submission of materials and how that gets done, if it's supposed to be done pre-meeting and if it has to go through the agency, but I do think there needs to be a clarification on how we do certain administrative things within the committee.

Yes, Carol, I would agree with that.

MS. FOREMAN: I don't think that I need anybody to filter the information that's available to me at a public meeting, and I think it's a bad idea.

MS. KASTER: What we said last time, when the information was presented on the industry petition for HACCP, was that any of that type of information was going to go to FSIS officials for that distribution, and I don't disagree with what you're saying about censorship. We're all adults here, but on the other hand, I think we need to send a consistent message because that was directly relevant to an issue that the committee was discussing at that time.

MS. FOREMAN: Maybe we could have a separate

table. Thank you.

MS. SWACINA: Alice, did you have -- you were done, Alice? Okay.

DR. KRUCZYNSKI: My name's Beth Kruczynski. I'm a veterinarian with Pilgrim's Pride Corporation.

I would like to personally applaud the agency for the HIMP project. I think that's been a breath of fresh air from the inspection standpoint. I think as an industry, we welcome the opportunity to take control of the process. We are committed to producing safe products for our consumers, and I believe this is a step in the right direction.

I want to just say, to reiterate a point that Dr. Clopp made, in that I think that we need to be careful about evaluating the success of HIMP based on Salmonella numbers post-chill, carcasses post-chill. In my opinion, Salmonella is largely a pre-harvest issue that needs to be addressed in that arena. It is not in the domain or in the -- it's not possible for that to be completely controlled at the plant level, and I think it's a mistake to think that it's something that can be isolated from the live bird environment pre-harvest.

The second point I'd like to make is I think that the RTI data is important, but I believe that

there's a much larger data set available through the verification checks in the processing plants that is collected every day, and I encourage you all to analyze that data on an on-going basis, perhaps even break it up into some kind of period, six-month periods or something. I think our process has improved the longer we're on HIMP, and the data from the first six months might be completely different than the outcome from the data two years later.

So, I would encourage that to be included in the analysis, not simply the isolated data set. I realize the statisticians are wedded to the central limit theorem. However, I think more data points strengthen our confidence in those results.

Thanks.

MS. SWACINA: Thank you.

Okay. Ms. Kaster, did you have a comment?

MS. KASTER: Oh, I'm sorry.

MS. SWACINA: Okay. We'll go ahead and break for the evening. The subcommittee meeting. Just a reminder, they start at 7:00 tonight. Subcommittee Number 1 meets in Conference Room Number 2, which I understand is a left and a left outside the door, and Standing Subcommittee Number 2 meets in Conference Room 4 and Number 3 meets in Conference Room 5 and 6, and

both Conference Room -- well, Conference Room 4, 5 and 6 are all out on the main hallway out there on your way to the bookstore.

Carol?

MS. FOREMAN: Thank you. I am unable to be here tonight and Nancy is going to take my place on Subcommittee 3 so that we have that subcommittee covered.

MR. GIOGLIO: Just one other thing. There were two other handouts that were handed out to the committee just now. One was the background material that was asked for on the federal-state -- you know, the interstate shipment issue, most of the information that was presented and the reports and so forth from the September '97 meeting, and also the other paper that was given out is the current FSIS Directive on New Technology that Patrick Burke talked about first thing this morning. So, you have those for your deliberations tonight.

MS. SWACINA: Again, 7:00. Other than that, we're adjourned until tomorrow morning.

Thank you.

(Whereupon, at 5:23 p.m., the meeting was adjourned, to reconvene at 8:30 a.m., tomorrow morning, Thursday, June 6th, 2002.)