UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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ADDRESSING SAMPLING AND TESTING METHODOLOGIES, COMPLIANCE GUIDELINES AND N-60 LABELING

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October 14, 2008
1:30 p.m.

L'Enfant Plaza Hotel
Ballroom D
480 L'Enfant Plaza, S.W.
Washington, D.C.

CHAIR: MR. ALFRED V. ALMANZA
Administrator
Food Safety and Inspection Service

MODERATOR: DR. DANIEL ENGELJOHN
Deputy Assistant Administrator
Office of Policy and Program Development
Food Safety and Inspection Service

FSIS:

DR. DANIEL ENGELJOHN
DR. EMILIO ESTEBAN
DR. WENDY WARREN-SERNA
MR. BRYCE QUICK

USDA:

MS. ELIZABETH JOHNSON
DR. SCOTT HURD

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

ALSO PARTICIPATING:

MR. TIMOTHY BIELA
MS. FELICIA NESTOR
MR. DEAN DANIELSON
MS. CAROLINE SMITH-DeWAAL
DR. DANE BERNARD
DR. BARBARA MASTERS
MS. BARBARA KOWALCYK
MR. YUEN CHENG
MS. MICHELE HATCH
MR. FRANK BURNS
MR. BRIAN McCULLEN
MS. KATHLEEN KRANTZ

I-N-D-E-X

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(1:30 p.m.)

MR. ALMANZA: So good afternoon, everybody. I, if I can get used to this thing, I want to welcome everybody to this meeting. I know that it's a very important topic that we're going to be discussing this afternoon and certainly tomorrow morning, but you being here is very important to me and important to the Agency.

We're going to be taking a look at sampling, at testing procedures, as way to fight one of the Agency's most pressing concerns which is *E. coli* O157:H7, which I'll just refer to as *E. coli* from here on out.

I want to stress that today's meeting, this is an information sharing and information gathering session. We're looking to come away from this meeting with an understanding of sampling and testing from all angles, the Agency's standpoint, the industry's perspective and, of course, we're interested in what consumer groups have to add to the discussion.

You can see from looking over the meeting's agenda that we've done our best to hear all sides of the issue.

Over 25 years after this strain of *E. coli* emerged on the scene, we're still learning more and more about it and looking for ways to eliminate this threat to food safety.

We have made some progress, and we've learned that 34 percent of illnesses from *E. coli* come from ground beef which helps us target our efforts. We've also put some controls, like sanitary dressing procedures in place, and some of you in the room may know the numbers, that up until last year, we reduced the number of regulatory samples testing positive for *E. coli,* but you also may know that last year's illnesses and recent recalls that we have to work with, we have work to do as well.

We've also learned and we found that even our controls on food safety systems and targeted efforts do not completely and consistently prevent, eliminate --

CONFERENCE COORDINATOR: Hello. Mr. Almanza?

MR. ALMANZA: Yes, ma'am.

CONFERENCE COORDINATOR: This is the conference coordinator. Can anybody hear me in the room? Please check your mute button.

MR. ALMANZA: I don't have a mute button (laughter) yet.

OPERATOR: If you're on a speakerphone, please pick up the handset.

MR. ALMANZA: Or maybe I had a mute button that I didn't know I had. Bryce, you want to come up and tell some jokes or stories, so long as they're not about me.

(Pause.)

CONFERENCE COORDINATOR: Okay. I'm not haring anything.

MS. JOHNSON: You're not hearing us. Are you hearing us?

CONFERENCE COORDINATOR: I hear you very, very faintly and muffled.

MS. JOHNSON: Faintly and muffled, okay.

CONFERENCE COORDINATOR: Hello.

MS. JOHNSON: Yes.

CONFERENCE COORDINATOR: I'm not hearing anything.

MS. JOHNSON: Mr. Almanza, can you talk and see if she hears you.

MR. ALMANZA: Can you hear me?

(No response.)

MR. ALMANZA: No, I guess not. My mute button is still on.

MS. JOHNSON: Operator?

CONFERENCE COORDINATOR: Yes, I can hear you briefly.

MS. JOHNSON: All right. Well, we need to get going. We'll get back to you.

CONFERENCE COORDINATOR: Hello.

MS. JOHNSON: We'll get back to you, okay.

CONFERENCE COORDINATOR: Okay. I'm going to hang out right here and just come back to me.

MS. JOHNSON: Okay.

CONFERENCE COORDINATOR: Thank you.

MR. ALMANZA: Okay. So where I was --

UNIDENTIFIED SPEAKER: You're done.

MR. ALMANZA: Yeah, I feel like I'm done. It's warm up here.

So as I was saying, we're working hard to fight this pathogen, and as an Agency we're trying to figure out ways to use data to predict problems, problem areas and building an inspection infrastructure that takes us to a more proactive rather than reactive approach to food safety.

We believe that testing raw beef products for *E. coli* is one piece of a larger puzzle to make sure contaminated meat doesn't make it into any of our grocery stores or homes. We're also looking forward to hearing from you from all sides on this issue. During this meeting, we'll take a critical look at sampling and testing procedures. We want to move us toward a more uniform and consistent approach across the board or should I say across the field.

We want to inform you on our testing methods, like the laboratory enrichment procedure we've been using since January of this year, that

will probably impact sensitivity for finding more positives in beef. In addition, we want to gather input concerning some of the guidance documents we give to industry about testing beef trimmings and using labels that have testing claims.

CONFERENCE COORDINATOR: Hello. Can you hear me?

MR. ALMANZA: And we also want to --

CONFERENCE COORDINATOR: Sheila?

MR. ALMANZA: -- discuss some areas of training that FSIS and industry alike give to Agency and plant employees testing for *E. coli*.

All of those parts, methodology, training, technology, are technical and complex but our goal is simple. We want to make sure that we're doing everything we can, the best way we possibly can, to protect public health through food safety.

Some of you who may have heard me speak before know that I stress communication. It's the best practice for FSIS to communicate with the public, with consumer groups and with industry. These public meetings are an important forum to help

us hear from you.

So we look forward to your comments over the next day and a half, and thank you for being involved in our public policy process. Let's put our heads together to find ways, like sampling and testing, to protect the public from *E. coli.* Thank you.

MR. ENGELJOHN: Thank you, Mr. Almanza. My name is Daniel Engeljohn. I'm the Strategic Risk Manager for FSIS, and it's my responsibility to help strategize as to how we can protect public from adverse consequences from the products that we regulate. And so today we're going to talk about *E. coli* O157:H7 and much of what we have in place today with regards to sampling and testing, getting a perspective from stakeholders as to the issues that we need to put on the table, and hopefully gather comments that we can use to better inform our policies.

To give you a bit of an overview of what we're going to discuss over the course of the next day and a half.

First we're going to have just a brief background by myself on the issues leading up to the need for why we're having this public meeting at this time, a general overview of the order and content of the presentations that you're going to hear over the course of the next day and a half, and then get a perspective as to what FSIS hopes to accomplish with this public meeting.

Regarding the background, last year was a year in which we identified an increase in the number of adverse events and that has continued through to this year. We hosted a public meeting in April of this past year in which we discussed the results of a checklist that was in part a result of needing to know more about the control procedures in place by the industry that we regulated. We did that checklist last fall and reported the outcome in April.

In addition, in April, we identified a number of things that we were considering in terms of putting on the table issues that we thought might need to be addressed in order to get greater

controls for *E. coli* O157:H7, and in particular, we identified that there was considerable inconsistency in the controls in place by industry as well as those procedures in place by the Agency.

In addition, there was an increase in the percent positive results for FSIS test of trim and of ground beef. We started the trim program last year. We didn't do any of the ground beef program for a number of years, really since 1994, and the Agency has found that the increase of positive rate is on the rise again in an adverse way and as of this week, our percent positive rate for our ground been program is double that for which we had it this time of last year.

All this leads us to believe that the signals that we have are percent positive rate in trim and in ground beef, are indicating that contamination, getting through the slaughter and dressing operations is on the rise. As a consequence, getting through that particular operation, as well as getting through the trim, and then into ground beef.

We also identified that there was evidence of primal cuts being used specifically for ground beef operations and that the bench trim derived from those products for the most part were not being addressed in control programs by industry. And so this served as a source in terms of raw materials that may, in fact, be contributing to poorer control for O157:H7.

And then finally, sampling and testing are increasingly being used as components of an effective HACCP system, and *E. coli* O157:H7 has always been identified by the Agency as one of the supplemental controls that needed to be in place by industry but what we found and what we are finding is that for many establishments, the *E. coli* O157:H7 tests are in some cases the only controls that are in place in terms of informing their system.

Improperly designed sampling and testing programs therefore jeopardize the effectiveness of HACCP systems, and there is an increase in likelihood that the public health will be negatively impacted if, in fact, these control programs are not

improved.

As a consequence, we took the information that we gained from last year's experience from the checklist and information that we had gleaned from our own program and developed a draft compliance guideline on sampling and testing. The intention of that guideline was to provide some framework as to how we thought a properly designed sampling and program should be put together for O157:H7 with a particular focus in trim. This would be product for which we would do an excision test as opposed to pulling a composite test, much like we would do for ground beef, but other components that involve trim would include head meat and cheek meat which would not be included necessarily in an excision program.

In any case, the compliance guideline had a special focus on the N-60 testing program that was in use by industry for which the Agency has, as well, adopted in its own testing program, and then we identified a framework for identifying when too many positives are too many in terms of indicating that negative results might, in fact, be false

negatives and that product would be released even though it tests negative that might have a higher likelihood of testing positive if re-tested or found and used later in the system.

And so we invited comment on that particular compliance guideline which issued in August. We reopened the comment period on it in September and it runs through, comments on that particular document through November 17th. And so this meeting is intended to as well gather information that can supplement the information we would use to inform that document, perhaps as drafting it as a final or reissuing it as a draft depending on the types of comments that we get.

In any case, think that it would serve as a useful guidance to industry as well as to the FSIS employees.

In addition to that one particular guidance on N-60 testing, we issued a smaller document that condensed down the information with a specific focus to provide sampling frequencies for small and very small plants which was derived from the larger

program.

Today, as well, the Agency did post another compliance guideline for N-60 labeling, and so you should be able to go to the website and find that criteria. It was posted just before the start of this meeting.

In terms of the overall presentations that we have available over the course of the next day and a half, we're going to first hear perspective on the FSIS N-60 sampling and testing program. This will give you an idea as to how we've designed our program, issues related to the laboratory considerations and things as we go forward into the future as to what we are looking at in terms of enhancing and improving our program.

We'll have a second presentation on a perspective from industry N-60 procedures and effective feedback systems. This would be from the perspective of a user of beef trim making ground beef with helpful guidance as to what should and could be in place to develop and effective program.

That would follow with a perspective on

laboratory methods and consequences of inconsistencies and non-uniformity in N-60 sampling and testing as well as laboratory specific issues. And so we hope to hear issues from experience gleaned from industry in terms of a laboratory and what they receive in the laboratory and then considerations that they have in terms of reporting back results.

That then would be following a perspective on consumer expectations regarding N-60 sampling and testing. So that we can get on the table what the consumers expect, what they believe that they understood the programs to be really from all sides.

And then we will have a public comment period where we can, as well, when feasible, provide some clarification to any issues that arise for which it would be helpful to get more information, and if we have the answers, we'll share them at that time.

I do want to identify that for those of you here today, we are attempting to have a telephone call in so that the public can as well call in and

ask questions. There will be coffee out in the lobby throughout the afternoon, and there is no formal break that we're going to have. So I just invite you to get up and go out and get a drink as you need it, but we're not intending to have formal break. We intend to just make the presentations, follow them up with questions, and then provide clarity as we can.

Tomorrow morning then we'll start up again early with a perspective on what we have in terms of some solutions to get at some of the issues and then get feedback on that. That would involve the presentation on the FSIS training to address issues about our N-60 sampling and testing program. I think we'll probably see a video on that as well as get a perspective from industry on the available best practices for the beef industry with a specific focus on N-60 sampling and testing.

And then finally, we have an overview of the FSIS guidelines on sampling and testing of trim. This really would be an overview of the compliance guideline that was issued that got at the very

specific focus on trim, on N-60 testing, on high event days, and the criteria that was derived around that.

Then in the afternoon, we'll have an overview of the draft criteria for the N-60 labeling in lieu of certificates of analyses. The Agency has been presented on numerous occasions, evidence that small and very small plants in particular are having difficult getting certificates of analyses and this was intended to be one solution to the get at the issue of getting more information to the industry that actually uses trim from suppliers in the production of ground beef.

And then we'll have an industry perspective on the lessons learned from the *E. coli* O157:H7 outbreaks from last year as well as into this year.

And then we'll follow that up with an invitation to provide comment and input on other O157:H7 related issues. Anything that we missed on O157:H7 and then we will certainly open that up to any other issues that you think we should put on the table.

It is the Agency's intention to ensure that we have more technical meetings to address concerns by stakeholders. And so if, in fact, we identify other issues to be brought forward, our intention is to have public meetings similar to this one in order to address the issues. And then we'll have a wrap up after that.

What we hope to accomplish then is to get stakeholder input on issues related to O157:H7 control, have constructive input on enhancing the utility of the guidelines on sampling and testing as well as on the N-60 label draft claim that we are making available as of today, and to get more consistent and uniform application of sampling and testing by both FSIS and the industry.

And then finally, as we all want to do, is to improve public health protection associated with *E. coli* in raw beef. Thank you.

MR. ALMANZA: I don't know how you do that with that right there.

The first presenter will be Dr. Jose Emilio Esteban. He's a Science Advisor for Laboratory

Services and Research in the Office of Public Science, Food Safety and Inspection Service at USDA. Part of his responsibilities include assuring that decisions made at the laboratories are scientifically sound. He's been with the Agency for six years, previously as Director of the Western Laboratory, most recently in his current role as a Science Advisor.

His academic accomplishments include doctor in veterinary medicine, a Ph.D. in epidemiology and two master's degrees, one in preventative medicine and the other in business. Dr. Esteban.

DR. ESTEBAN: Thank you, Mr. Almanza. Thank you all for giving me a few minutes of your time to discuss issues that address laboratory methods and sampling. This has been an area that I have been working for a long time. Even before I came to this Agency, I was working with CDC and focused very much so on sampling issues. So this is close to my heart here.

Okay. So this presentation today is going to address three basic areas. One of the things

particular to the specific method we want for *E. coli* O157:H7, changes that we've done or modifications that have recently happened to the sample collection, and the last part of it will be talking about the sample processing.

I'm going to describe here basically the results. I'm starting with the result -- During calendar year '07, MT03 is an examination we have for *E. coli* O157:H7 within the Agency. We went about 12,000 samples that calendar year, and we had about .24 percent of the samples that were positive. During calendar year '08, up until September 14th, we have close to analyzed 8400 samples and almost doubled the rate of *E. coli* positives.

Now, while it might appear that it is a significant difference, if you were to be very strict statistically, there is still not a significant difference because at those low levels of prevalence, the variation is enormous. One sample more, one sample less, changed that percentage dramatically. But nevertheless, it is an obvious increase in positive prevalence.

So in trying to address what may have caused this, the only thing that we have changed in the last few years have been the median, the method, the way we collect our samples. We went from a complete random or approximately a random program to a risk-based sampling program. And the other thing that could have changed is, in fact, a true change in the pathogen prevalence. So I'm going to look at each one of those, or at least the first two in detail and see what we get.

Okay. The lab method is the same one basically that we've ran for several years. There's MLG Chapter 5. We publish it all the time. We have very consistently. It includes a screen stage, a confirmation stage, and a quantification stage. And the only thing that we have changed recently in the screen is over the last probably four years or so, we changed from a lateral flow device, a quick screen method, to a BAX or PCR approach.

As far as the confirmation, we really haven't changed any of that. It's been basically biological confirmation and genetic confirmation.

The quantification we started doing recently, and that's to get an approximation to the level of contamination that each particular sample may have had.

On the outside table, there was a flowchart with a method. Hopefully a lot of you -- that's very detailed. I'm not going to go through the details that the method has but basically it's a five-day method, five to seven-day method depending on how far you take it. The sample is collected. About two pounds of sample is collected at the slaughter plant. We receive it at the lab at which time we select 325-grams, divide it into 5 subs of 65 grams each. We incubate that in enriched media overnight. The next day we do the PCR screen. If this screen is positive, we report it as a potential positive result. We again re-streak that sample, re-incubate selected media. The next day we pick typical colonies and if that is positive, then we report it as presumptive. And so for the last level, that's when we have -- those colonies are typical. We go forward with that. We do gene

typing. We do -- and biochemical confirmation. So by day five or four, we've got an actually confirmed genetically that there is a positive O157:H7. There's really no possibility that it will be a false positive.

And again, all the details are very, very clearly in that flow chart.

So one of the things that we changed starting in January of this year was our enrichment media. We changed our enrichment because we wanted to have a little bit more flexibility because the number of samples we're processing, sometimes in our three labs, and for those of you who don't know, the Agency has three field services lab, one in California, in Alameda, one in the Midwest in St. Louis, Missouri, and one on the east coast in Athens, Georgia.

We receive either one or two shipments a day by FedEx of samples. In order for us to offer the same service that we currently do which is possibly solve within 48 hours, positive or negative results within 48 hours. We needed to try to reduce

incubation time that we're getting. So they chose to go to a media called TSB. Before you were using media called mEC, modified *E. coli* media, and that needed to incubate about 20 to 24 hours. The new media which, by the way, is the same media that they use in Canada and they use in Europe, TSB, and that allowed us to have flexibility to incubate between 15 and 22 hours.

So we designed then a study to document before we made the change that, in fact, those two media were comparable but yet look at the incubation time. Okay. And for that we have a very detailed process control. It's a multiple page protocol that we go through before we actually do the final study and the data I'm presenting here is basically the last page of that study where we compared the performance of these two medias as regards to incubation time, and -- and I know the top of that slide is a little bit blurry but the first column is the substrate. The second column is the actual CFU that we inoculated those samples with. The third column is the targeted inoculum level. It was

pretty much zero for CFU or 20 CFU, and the last three columns on the right-hand side of the slide present the percent confirmed positive samples.

So what we're trying to compare in this study design is basically whether the media called the same number of positives was positive or negative by changing the incubation time, by changing the type of media. So you have all the media. Potentially we have run through the method, swab the first, sausage which is summer sausage, fermented sausage, beef trim, ground beef and beef patties.

As you can see for swab and for sausage, the two medias perform pretty much the same way regardless of the incubation time. On beef trim, TSB which are the two middle columns if you will, there was no significant difference in how they performed, whether they were incubated at 15 hours or 22 hours, which is really the target for our study. We wanted to make sure that we could incubate a shorter time and get the same result. And the last column is the mEC at 24 hours, and you

can see that media that we were testing, which was TSB, performed at least as well as or better than the mEC and that was the target of this study.

If I can go back one, this data you saw before is based on five sample sets sent to three different labs at two inoculation levels, doing it in triplicate. So there was a lot of samples behind that table to get to those numbers.

So what this tells us basically is that the media perform at equivalent.

Okay. So the next thing we wanted to look at what was whether we had a significant difference in the sampling results based on how we were collecting the samples. Remember, we changed from a quasi-random sampling method of collecting samples to a risk-based sampling protocol.

And what we've done here is summarize the whole experience over the last few years since we've changed to a risk-based sampling method. The dark, on the vertical axis, you have the number of positive samples, and on the horizontal axis is the type of plant by category, 1 through 4. You can see

the dark columns are what -- in looking at the risk-based sampling methodology, the dark columns is what we would have expected to see as passive samples given the new sampling protocol, and you can see in category 3 and category 4, the observed is higher than the expected which means it was not because of the sampling protocol that we're getting more positives because the expected -- we actually were seeing.

Okay. So what has changed? The sample selection methodology, if the risk-based sampling algorithm does not contribute to the increase that we're seeing, if enrichment media have no statistical contribution to the increase that we're seeing, and at least the study that we designed, the purpose was not to define whether we have a better recovery but whether the media was performing the same.

So if the way we collect samples is not different and the way we analyze samples is not different, then the only thing that is left is that maybe there is an increase in prevalence and we at

the Agency don't collect daily data in a quantity you in industry do, to document that this is, in fact, what you're seeing. So I don't have that data available to me. So I cannot say it's actually increasing pathogen prevalence.

All right. So we address issues regarding the media itself and we'll look at examples.

Now, as far as sample processing, as I mentioned before, we are trying to follow industry's lead here in doing an N-60 sampling protocol, and again the purpose of our sampling the ones that FSIS does is to determine whether the HACCP system is working. So we follow the N-60 protocol, but we have their limitation, which their method calls for use to analyze 5 - 65 gram samples which is about 325-grams of tissue.

This is actual data that we received from the lab, and it includes all the samples that we received from April to September of this year. What you see on the vertical axis again is the frequency of samples. The horizontal is the number of pieces. The target here is 60, N-60, which we receive 60

samples in a submission. You can see it's pretty much a bell-shaped curve other than the last column, which there was too many pieces to count that we got back from the field, but for the most part, it follows the bell-shaped curve around 60, which we would expect.

The other thing that is not considered in a lot of those sampling protocols is the type of trim that we collect the sample from. As you can see in this chart, and I apologize. The horizontal axis is labeled estimated percent fat. It's actually proportion. So, for example, the highest column there, the first one, is 10 percent fat is 90 percent meat or looks like meat. So again it declines so that the vast majority of samples have 90 percent, the 90/10 trim, and the next column will be 80/20 and next one 70/30, and so on and so forth. So most of the samples have some fat but the majority of them have little fat on them.

This is some actual pictures of what we receive, and the guidance we have right now for the N-60 protocol is the inspector should collect pieces

that are 4 inches by 2 inches by 1/8 of an inch thick. And for the most part, they are trying really hard to get us that. The problem with that is that in doing their job correctly, we're getting 60 pieces that weigh 2 pounds, but we're only able to analyze 325-grams. So we have conflicting thing here. If we analyzed all 60 pieces, we analyze 325-grams.

So one of the issues that we have to consider here is the sample is collected, is mushed, combined into this bag, is sent to the lab where it's bounced like a football in the FedEx truck for two days or a day, we get the sample in the lab and we take everything out of that bag and cut pieces into 65 gram samples. So even though we're not sampling all 60 pieces, we have a pretty representative sample of what the 60 pieces that were submitted to the lab were. But we cannot possibly, with the way we're collecting our samples right now in the field, meet both objectives, 325-grams and 60 pieces.

And I'm not familiar with how industry is

actually is doing this. Maybe we'll hear that later.

So because we acknowledge there's some limitations how we're doing sample collection and processing, there is a couple of things that I want to show you that are work in progress. One is, and I don't know if some of you go back that long, but we used to collect ground beef samples and ask the inspectors to collect two pounds of sample. When we started sending in the HACCP weighings, it actually allowed them to collect exactly the amount that we need for analysis. We are trying to find an analogous system here where we give them a container that fits the 60 pieces that weighs 325 to 365 grams so that the inspector has a visual guide of what he or she needs to collect, trying to standardize the sample collection, so that when we get to the laboratory, it's more consistent throughout. So we're evaluating different containers for this.

The other thing that is a big limitation is the tools the inspectors have right now to collect the samples, and we're asking our inspectors to

collect literally with clippers and knife slices that are one-eighth of an inch thick. It's really, really difficult to do them. It takes them, you roughly 40 minutes to an hour to be collecting all these samples. You cannot expect the inspectors to do this all the time. So we're trying to look at different cutting tools that will allow us to collect a more standardized, uniform, appropriate sample size.

So those two pieces of work are currently in progress.

The last one, and I think this one is going to be quite interesting because I have no idea what the result is going to be. We're trying to document that there is no significant loss in recovery in analyzing the entire 325-grams as a sample rather than dividing it into 5 subs of 65 grams each. What that would mean for the labs is that it will be an automatic increase in throughput. We'll be analyzing one sample rather than five subs for each sample. So paperwork, processing, reporting, everything will be substantially improved for us.

Again, the only difference that we might find there is that there may be some issues with increased sensitivity because we are analyzing the entire sample now, and I don't know what the result would be like, but we'll keep you informed.

Those are the three things that I wanted to talk about today, sample collection, method changes and sample processing, and I'm really eager to hear any feedback or questions you may have.

MR. ALMANZA: Thank you. We may want you to do a few questions.

DR. ESTEBAN: Sure. Please. Dan, do you want to moderate?

DR. ENGELJOHN: Can you just ask her to --

DR. ESTEBAN: Sure.

DR. ENGELJOHN: We need a microphone and identify your name and association. Sheila's coming with a microphone.

MS. NESTOR: I'm Felicia Nestor with Food and Water Watch. I missed the beginning of your presentation. So perhaps you answered this. The categories 1 through 4 on the plants, did you, did

you tell us what those categories are?

DR. ESTEBAN: No.

MS. NESTOR: Could you explain? Are they the volume categories that are on the recent sampling, you know, over 250,000?

DR. ESTEBAN: Do we have the table? Let me become familiar with this table here. Category 4 is less than 1,000 pounds. Category 3 is 1,000 to 50,000. Category 2 is 50,000 to 250,000. Category 1 is more than 250,000.

MS. NESTOR: Okay.

UNIDENTIFIED SPEAKER: Can you repeat that please?

DR. ESTEBAN: Yes. Category 1 greater than 250,000. Category 2, more than 50,000 up to 250. Category 3 is from 1,000 to 50,000, and Category 4 is less than 1,000.

MS. NESTOR: Just a quick follow up. Am I correct, do I remember correctly that you had the highest rate of unexpected results in Category 3?

DR. ESTEBAN: I believe so, yes. 3 and 4.

MS. NESTOR: Oh, 4. Okay.

DR. WARREN-SERNA: Wendy Warren-Serna, Food Safety Net Services. A question for you on your inoculation study. What were the samples sizes, analytical sample sizes that you inoculated in terms of the beef trim and ground beef? Was it 4 CFUs in a 65 gram sample or 4 in a 325?

DR. ESTEBAN: We inoculated -- we prepared a dilution that was a percentage of 4 or 20 CFU and they inoculated that into one sample and then subbed it out.

DR. WARREN-SERNA: So that would be in a the context of a 65 gram sample.

DR. ESTEBAN: 325-gram sample.

DR. WARREN-SERNA: So 4 in a 325-gram.

DR. ESTEBAN: Or 20.

DR. WARREN-SERNA: Or 20.

MR. DANIELSON: I better spit my gum out here. Old judging team trick. Thank you for the information. I will share with you I guess some anecdotal information so that -- from the industry or at least from -- I'm Dean Danielson with Tyson Foods.

We do a little bit of testing in this method over the years. I believe just last month my lab manager told me that we have exceeded our 1 millionth sample since we started this process in 2002. So we've got a little bit of experience under us in method development and in sampling development.

I can't remember last year if in the October meeting or sometime when the USDA new method was published, but in our evaluation of when that was published, my laboratory micro expert told me you should expect a 2X or more increase in USDA positives based upon this method increase and that's based upon our years of methodology evaluation, enrichments methods and the things that were strictly put into play in the new methods.

So we are not shocked or surprised at all. In fact, we fully expected it to be a little bit higher than what perhaps you are showing. And whether I said that publicly or amongst others in industry meetings, we have professed that several times and feel that the numbers are about what they

should be.

I will share with you that in our trim testing program this year, our trim incident rate '08 versus '07 is down about 25 to 30 percent from '07. We did not see continuing increases, and so we see a downward trend. We believe '07 was an anomaly of a year. If you look over several years, year after year after year, the annual rates change. They ebb and they flow. Obviously seasonally and geographically as well, but our trim data is down 25 to 30 percent.

I'm aware of finished product grind data from a large grinder in '08 versus '07, 50,000 samples analyzed in '08, and their finished grind numbers are down substantially from '07 in a methodology that hasn't changed. So that's anecdotal information that I share.

I am troubled with the not analyzing the whole sample collected. We would submit that that is something that needs to be looked at. In fact, we're chastised or we've been told through FSIS reviews that you've got to analyze the whole sample,

and I find that it's not being done here, and I would, you know, I urge you to look at that.

DR. ENGELJOHN: Thank you.

MS. SMITH-DeWAAL: Caroline Smith-DeWaal with the Center for Science in the Public Interest.

Dr. Esteban, did you -- do you have any statistical backing for the N-60 as your number of samples? Did you test N-80 or N-100? I'm just not perhaps familiar with the statistical backing as I need to be, and I'd like to hear from you. Thank you.

DR. ESTEBAN: Yes. We followed the N-60 because that seemed to be the industry standard. The statistical foundation of the N-60 is part of the case 15 in the ICMSF table. And the only flaw I see with the N-60, and it's not a flaw. It's a simple description of a statistical -- of where the N-60 came from, is that is assumes a 5 percent prevalence and if the prevalence were lower, of course, the end would have to go up, and so that's basically the information for the statistical background.

Statistics are a tool, okay. So if you want to -- your numbers, it'll whatever you want.

MS. SMITH-DeWAAL: I just have a follow up though. It was my understanding that the prevalence that N-60 is based on is a 5 percent positive which I mean we don't think we're -- we hope we're nowhere near that. So has USDA looked at a number that would provide a higher confidence level given the prevalence that you think you may find in trim?

DR. ESTEBAN: At this point we have not, but I'll take that into consideration.

DR. BERNARD: Dr. Esteban, thank you for your presentation first of all. Dean Bernard, Keystone Foods.

Focusing on this slide, there was an earlier question about it, but if you just look at the categories, I'm not sure that it gives us the complete picture here. It certainly makes Category 4 look somewhat suspect, but I'm wondering if the sample sets here are balanced, if you were to look at this in terms of percent positives by sample, what this data would look like. Do you have that

information?

DR. ESTEBAN: I don't have it with me, but we did look into it and adjusted it by sample size within each category, and it still appeared that the expected rate was below what we were observing for those two categories. So after adjusting for number of samples, the sampling proportion within that category, there is simply -- and again, let me emphasize this. Well, two things first. Never leave your slide out because somebody will find something to look into it. (Laughter.)

And number two, to answer your question, remember we're talking about very, very small numbers here, and so a change in one or two up or down. In this case, you know, you go from 10 to 15 or if you compare Category 3 with Category 4, you know, we look at percentage on small numbers. Huge changes. They're not significant. Okay. Here the difference is that it's pretty consistent that the expected is below the observed, which seems to suggest that it was not the way we collected the samples that was causing the effect, but rather

something extraneous. I'm not saying that the combination of changing to TSB, changing the sampling algorithm and something in prevalence, the combination of those three things interacting may be the end result we're seeing, but statistically we can't point to either the media or to the sampling format.

MS. JOHNSON: Excuse me, Dr. Engeljohn. Did you want to take one or two more briefly and then more on? One more.

DR. MASTERS: Barb Masters, Olsson, Frank and Weeda. You can go to the next slide. I'll let you move on. One more slide. On that particular slide, you're looking at the percentage, like 90/10 and 80/20. Have you looked at those particular fat contents?

DR. ESTEBAN: Which one? That one.

DR. MASTERS: That one.

DR. ESTEBAN: Oh.

DR. MASTERS: Have you looked at the particular fat contents and then tried to determine what percent positives you got in any particular

category to see if you had any particular percentage of positives, for example, you might expect to see more positives in a particular category of product, and have you looked across those to see if you got more positives in a particular category of fat to see if that may have had an impact on, since you've got obviously more lean product into the laboratory, and have you looked at that and determined if that impacted on your sample that you received and then did you cut that -- were you able to take that back to see where those samples came from, from the size of plants and that sort of thing? Have you done any more data sort on that?

DR. ESTEBAN: Good question, and actually I don't have the data with me, but I can tell you that the more fat the sample has, the worse our method performs. Okay. So a sample that is 50/50, we rarely, if ever, find *E. coli* on it, O157:H7 anyway, whereas with very lean or very, very muscle intense trim, the likelihood is that we will find more positives. Now, I don't have the statistical analysis done, but it's a work in progress.

MR. ALMANZA: Thank you.

(Applause.)

MR. ALMANZA: We'll have a chance for more questions. I think we should move on though, and as I expected, we're going to have a lot of good comments, and certainly a lot of good questions.

So with that, we're going to move onto the next presenter, which is Tim Biela. I've known Tim from back when I was a District Manager in Dallas. He's the Senior Vice President of Operations and Chief Food Safety Officer for American Food Service. He's got a bachelor's degree of science and biology and a master's degree in engineering, quality assurance, and is directly involved in improving the safety of ground beef industrywide. He is active in several industry organizations and chairs the processing sector for the Beef Industry Food Safety Council. Tim.

MR. BIELA: I know the focus of today's meeting is about testing, and I want to caution everybody about, you know, a premise that we all understand as scientists, and that is that you can't

test your way to safety. We have a good system that's out there today called HACCP, which is a systematic approach towards food safety. It doesn't rely on end product testing to basically have an effective system of producing safe food, and I want to try to cover some of this in prerequisite programs, approved supplier programs, and certificates of analysis.

And I work for American Food Service Corporation. We produce about 7 million pounds of ground beef every week to give you an idea, and I've been testing I think longer than most people. So I do understand the necessity to test as a verification activity for the process controls that I have out there to produce safe products. About 100 million pounds or 120 million pounds of that product goes to retail. So it goes, you know, into consumers' homes, not to commercial establishments, where I believe there's better controls associated with, you know, the CCPs.

Al was the District Manager for many years, and I hope I made his job pretty easy by not

creating a lot of opportunities for failures. You know, going back to 1995, you know, the USDA pointed out that, good sanitation is a fundamental requirement of federal meat and poultry inspection laws and yet poor sanitation practices, and I want to key on this, because I think it's one of the focus areas that we've got to go back and pay attention to, are the most frequent deficiencies found, not just in meat and poultry plants, but in food plants in general, and they create the risk for unsafe production of food products. There's a direct link between insanitary practices and the likelihood of product contamination with pathogenic bacteria.

This was right out of the preamble to the HACCP regulations. So I gave them the credit for that by giving them an approach.

The HACCP system is considered as the right approach, the best approach for creating safe foods, and it's about preventing contamination, not detecting contamination. You cannot test your weight to food safety, and again, this is a guy

that's been testing longer than most people in the industry. When people wouldn't test trim, I tested it myself. I took a lot of criticisms for that. I've took a lot of criticisms, and I'm going to talk about testing in the right perspective, but not the approach that's going today, which is to test and test and test and test and retest, which really doesn't make good scientific sense.

You know, we've got to be accountable, not the Agency, but we as the industry have to be accountable for meeting the standards that we've outlined in our HACCP programs. These are the food safety programs that we've got to utilize.

Regulatory oversight, I believe there's plenty of regulatory oversight out there. You know, the Agency is supposed to be evaluating the HACCP systems, the systematic approaches to develop safe foods in every plant that produces products. And then they have systems in place to verify it.

One of the most recent notices said don't do any of the inspection activities. Go focus on taking a test. I said earlier, don't do that.

Don't take your eye off the process controls that create safe food to do verification testing because again you're going to miss the opportunity. I would have had many more positive events, I think, if I didn't use a systematic approach towards process control, and you can do that by looking at the documentation and the practices that are occurring in those critical areas that create risks.

I heard the conversation earlier about the dressing procedures and the failures. We know where contamination occurs. We know that the interventions that have been researched can have an effective reduction of these harmful bacteria. And then through verification testing and validation of this HACCP approach, I think you can create safe products. And the Government has the ability to take appropriate actions when the industry doesn't do it.

I haven't studied quality for 25 years. I could tell you this Plan-Do-Check-Act, this is about identifying improvement opportunities, identifying who your key customers are. Remember HACCP is a

systematic approach, and it doesn't come from, you know, out in the blue. It really comes from a system of process control and improvement that is continuous. Plan-Do-Check-Act. We've got a system in place. You plan the system based on what you're trying to produce, look at who your customers are, create effective process verification activities, and you can produce safe products, and I've been at this for over 15 years now, producing raw ground products for consumers, and I'm thankful to say that as far as I know, I don't believe our products have ever made anybody ill. I'd like to be able to say that for the continuation of my career, but I'm going to focus on the HACCP system I have in place rather than testing because, again, I'll have a portion that is verification testing, but I won't focus on that as the key component.

When we engage in process improvement, we seek to learn things that cause things to happen and then use that knowledge to reduce variation. If we know that there is an increase in variation, then we can also from that assume that there's been a

decrease in process control. It's pretty obvious. So I would suggest that the Agency focus on the process controls that we all have in place. All I hear about is the inconsistencies, and I hate to tell you, because I've been looking at human behavior for a long time as a part of quality, we're going to continue to have inconsistencies from plant to plant to plant.

Best practices and the best practice documents out there. Not everybody utilizes every step. I would suggest if you use them, that you do utilize all of the process controls that you can apply effectively and then utilize the experts in the industry to guide you that way, but you're going to have people pick and choose, and there are people that pick and choose, and sometimes they choose to utilize raw materials that aren't sampled and tested effectively, or don't go through facilities with proper process controls and interventions. Let's focus on what we need to do, and I'm going to try to do that through the next few slides, talking about supplier programs.

Removed activities have no value and improve customer satisfaction and customer satisfaction is fit for use, that's what it's called. It's called safety as well.

There are a number, and as I said, the focus for me is about HACCP programs first because I think that's extremely important, not just in our facilities but in the other facilities that we purchase raw materials from. I do not slaughter and/or fabricate animals. I buy boneless beef products from USDA-inspected establishments. However, I understand it's my responsibility because I cannot improve its quality to understand what they're doing and how they're doing it to produce safe raw materials that come into our facility. I'm going to do a lot of verification in that, and it's not going to be based on all micro. There's a lot of sampling and testing that I'll do to look for unacceptable, indigenous inclusions, or I will look at other information including cold chain management. I do audits in those facilities. I understand who my supplier is and who I'm buying

from, and I think that's critically important.

There is the part for control programs for O157, and as I say, I do use testing as a way of verifying or validating my system of controls, including the microbiological prescreening requirements that we all talk about, N-60.

When you create something that people won't do, believe me, they'll modify it. I hear questions about, well, what's most statistically important here? The statistics don't fly in the face of this because you can't predict when these occurrences will happen on the high stand, in slaughter and dressing, that will contribute these pathogenic bacteria. It's not predictable. I wish it was and give you my anecdotal information. Fifteen years of doing testing, last year was a catastrophic year. Thirty-seven finished product events for O157. It's the worst I've ever seen. Up to that point, the worst I had ever seen was seven.

So I do know that some things change, but I think part of what's changed is if we take our eye off of process controls and we rely on the finished

product validation testing, then we forget about what actually creates safe products, which is the process control portion of this thing.

Processors like ourselves, and I said that, I know I have a responsibility. I know I have a responsibility to know who I'm buying raw materials from, how those raw materials are being produced, and then subsequently to be able to verify that they are complying with as much as possible the practices or policies, procedures that not only they define, but that I would like to see them utilize. And I've always tried to bring value to them when I've gone to their facilities, not as an audit and I am a sanitarian. So it's easy to walk in and say that's wrong and that's wrong, but the other side of it is to be able to say, have you ever approached it differently, and that's what I'm going to try to get all of you to do is approach this differently. Look at it as a systematic approach towards creating safe products.

Processors do have a responsibility, and we do not have any other methods to control bacterial

hazards than looking at our suppliers. Therefore, it is essential we develop a system that ensures safe raw materials to be utilized for raw ground products. It's important, and I do rely on N-60 screening because I think it's very appropriate and I can tell you it's been very effective.

Going back 15 years, I haven't modified my testing behaviors too much. I used N-25 when I sampled and tested on my own, and it's not any different than N-60. You can make it N-17/60. You could make it combo by combo, and I don't think you're going to improve the quality of the raw materials that are coming at the system.

However, given all of that, I still believe you need to have good consistent process verification going on for individuals involved in producing one of the higher risk products which is raw ground.

Companies are responsible for outlining the requirements, in other words, establishing those process controls and verifying their controls, and then that they're implemented, working as designed,

that's called validation.

We spend a lot of time before we ever buy from somebody, and I've told even the smallest processors, it's important, know who you're getting it from and how they're actually producing it, and I know I've been in most of the slaughter plants in the United States, they'll let you in, they'll talk to you, they'll tell you what they're doing, they'll show you their HACCP program, they'll let you audit their facilities. I think it's important and you have got to define what your expectations are.

I don't care if you're the smallest person. You're out there spending your dollars when you go to the store. You expect to be a good buyer, right? Well, that's what you should do when you process meats is be a good buyer. Define what your expectations are and write them down. Have them acknowledge them.

And then perform consistent process verification. When it comes in, is the trailer sealed. Does it meet the temperature specifications or standards that you've established? Is the

packaging intact? Is it covered properly? Is there no signs of filth? A whole series of things that you need to document. And most of these things are outlined in our best practice documents but I think they're very important.

We do a lot of testing, not specifically for pathogens. I do a lot of profiling, aerobic plate counts tell me about their ability to create safer products through cold chain management. I use coliform and *E. coli* as an indicator of good process controls during dressing. I also test for others but I look at all of these things and I put them into an algorithm, if you want to look at it that way, that tells me what, number one, the industry can do by class of animal or class of facility and who is the best and then I go basically spend my money and buy what I can get to be the best.

I require, and this is very important, that every raw material that's used for non-intact raw ground products is sampled, tested, and found negative prior to the time it comes into the facilities. It's very important. You must. We've

heard a lot, and we do a lot of primal specific products as well. Believe me, everything is tested. So even guys that are creating, maybe using the center of the muscle, and then they're using the bench trim, still create a system of verification activity that you've prescreened it. I think that's extremely important. Raw ground beef, my analogy for that is homogenized bacteria because we do distribute it throughout the product. The CCPs still cooking, but there is a lot of verification and process control that we can put in to create safe products.

These certificates of analysis, it's our responsibility as the industry, and if it's not that you don't have an expert, there's experts sitting all over the place out here in this audience that can basically guide you towards what that certificate says, what was the analyte size that was used for testing? What was the enrichment procedure? What was the method, that it meets an accreditable standard, and then it must be signed by the laboratory so you know that, yes, people did

look at the results and they can stand behind what actually happened.

Raw materials, I mentioned, I use a lot of information to basically look at process controls and believe me, I'm getting a lot closer after all these years of putting all this information together, to be able to say, when I believe that plants are changing, they're changing their process controls because I will see changes in these trend data. So we track and trend constantly, and we constantly feed it back to them. We define for them what the expectations are, and then when we document, when they're out of specification, we actually communicate it to them because it's extremely important.

Plan-Do-Check-Act is a feedback system. That's what a feedback system does. When you define your expectations for a supplier and they don't meet it, do you communicate effectively? It's not for somebody else to control your process. It's for you and you should be communicating on a consistent basis.

Require action plans, and I know that sometimes it's a challenge, even for somebody like me to be able to get them to pay attention because there is a lot going on. They've got a lot of focus.

Finished products, I do the same thing. I look at it as a flow. Raw product into finished product. If I maintain cold chain and I'm using the best raw materials I can, I can track and trend the same data and believe me, it tells me whether my process is in control.

There are times, especially for retail, raw ground products, that I do verification testing for O157, but it's not testing my way to safety. You can imagine every time we've gone through an event, and I still do it with every event, we do root cause analysis to try to determine what the contributing factors are and eliminate those factors that create risks for our system. That's what these positive event results, whether it's on the other side as a raw material processor or on the processor side, will give you, but we do have to take responsibility

for basically validating that the process control system, HACCP, works for us, and this is a way to get it, not 0, because I can't test my way there.

You can sample and test all you want, but I know that there are low levels that pass even through my system, but I know that the systems that we've put out there through best practice documents are very effective. I've been doing it for 15 years. I put 1 million pounds literally every day into retail, and I don't think that I've got people chasing me. I could tell you otherwise. I think I'd get the calls from the attorneys. So I'm either lucky or it works. It's not perfect, but I think there is a system that can be utilized.

So you can profile finished products, and I think it's important, and when you do that, I even create arbitrary number because they're not mandatory regulatory standards. I create arbitrary numbers that I look at and say, if it goes above this, I won't put it out there as a raw ground product. I'll only sell it to a processor that will thermally process that, and this is not about O157.

This is just about these other arbitrary numbers that I think might create better risks because I know I can't test my way to find pathogens all the time.

Programs should be designed. You heard this earlier. They should be very robust. They should be scientifically sound, defensible, validated for each individual location because a lot of times what I get is let's just take and can a program and put it somewhere. Well, it doesn't work that way. You've got to go see what's going on in that facility and you've got to design a program that works there.

Our documents that we've put out there through the Beef Industry Food Safety Council have tried to create menus, but I think at times, and we're trying very hard right now to put verification validation data back into those so people know how to do that because one of the things that everybody continues to say is how do we actually do that. So we're trying to put those back in there, but they are very good documents and they create an

opportunity, basically as an outline, for how to create safer products. The programs we have, have to be verified and verifiable.

And then they have to be constantly challenged. You don't just put a program together and then lay it on the shelf and say that's it, we're done. Every event we have, we research it like it was the very first one because we want to find out what's going on and we want to be able to have that feedback and that root cause analysis into the system to create safer products for consumers.

Remember, HACCP is based on prevention, not detecting something at the end of the line, and I think it's very important. So it should reduce, in fact, whether -- we're talking this or any other because again I study quality. So I know that if you have process controls, you are less reliant on finished product inspection to meet the standard you've established. And in this case, it's for safe products.

If, in fact, the concept is applied correctly and actual verification validation are

used, you can, in fact, reduce the risks associated with O157:H7 in beef products.

MS. NESTOR: Thank you. Felicia Nestor, Food and Water Watch. Tim, it's really good to hear you describe your program. This is the second time I've heard you. You described it out in Chicago also. And I wish you were in charge of the way FSIS runs its program because, you know, the commitment to tracing every positive back and finding out why the process control system at the supplying plant did not work is critical, especially when we hear about the difficulties with sampling.

My one question for you though is, you know, you say you've been into a number of slaughter plants, and you not only get a COA, but you verify and the slaughter plants will let you in. I wouldn't doubt that they let you in, but there are, according to my latest calculations from what I got from FSIS, there are 379 plants that do over 1,000 pounds of ground beef a day. There are 940 that do less than 1,000 pounds of ground beef a day, and looking at USDA's recall data, some of those plants

look like they might make 40 pounds a day or 150 or 200 pounds a day. So they don't even get up to 1,000 pounds.

So in terms of expecting these small companies to be responsible for the quality of product coming into their plant, you know, they don't have a travel budget. They don't have any market power because they're not purchasing anything significant from the large suppliers. So what's your idea about that? How can they be as proactive as you are given the facts?

MR. BIELA: Yeah, I have the same concerns over the years. I know there's a difference between smaller companies. When I started for the company I work for, we were smaller. I'll say that. We've grown. I think maybe a little bit of that is maybe because we are doing some good things. I'd like to think we don't sell it in the marketplace, so to speak.

So, believe me, there's no value added to our system for the $3 million I spent on, you know, positive events last year. That didn't include my

testing budget. That's just the cost of the products.

But, you know, the food industry in general has tried to figure out appropriate ways to be able to gather information, this audit information about who's doing what, and how they actually rate as compared to others. And, you know, I don't know if maybe the Global Food Safety Initiative, some of the things that are up and coming and moving as we speak today may, in fact, give companies an opportunity to see something posted on a website that let's them know.

I'll give you the secondary approach. If I didn't have control, I'd make sure I was testing every bit of my finished product. I mean that's -- see, because I like to think that you're always in control until you give up control, and where I don't have that budget, then I'd be looking at something different because knowing what the risks are associated with raw ground and, you know, the one thing I don't want people to say is, gee, I didn't know raw ground beef was dangerous. I've lived with

it for the past 17 years. It could be. I don't want it to be. I wish it could be safer, and I wish I had all the answers as to what you're asking.

As you know, I try to make a lot of these presentations and offer myself up to the smaller processors to be able to call and my guidance would be if you can't get out there, and you don't know where your raw materials are coming from, at least perform finished product testing for O157. It won't completely again eliminate everything but it could reduce the risk. I would also just make sure that I verify my cold chain management, the condition of cartons, all of those kinds of things because I think that can have an impact on reducing some of these smaller events that we see where there's a 90 pound recall and those kinds of things that I think we all, you know, kind of step back and say, why do these things happen?

MS. JOHNSON: We have one back here.

MS. SMITH-DeWAAL: Thanks. Caroline Smith-DeWaal with Center for Science in the Public Interest. I want to raise the same question with

you, Mr. Biela, that I did with Dr. Esteban.

Is N-60 the right number of samples? You are indicating, and maybe your suppliers are using that approach plus something else, but you're indicating a high level of confidence in the products that you're purchasing to go into ground beef. How is N-60 providing that if, in fact, the statisticians tell us that the confidence level should be lower than it is?

MR. BIELA: Well, I'll give you as much information as I have. Going back, and I'm going to have to go back in history a little bit, back when I started testing not just raw materials but finished products, nobody tested raw materials. And I used a five combo sublot and five select pieces, surface material, from that created a N-25 for that five combo sublot and, you know, I'd be happy to share my data with your group. I mean, for the last 16 years, we've offered that information as that we haven't seen any reduction within N-60, and what I do see is exactly what we saw in the slides that were provided, that the method gets beat up pretty

badly because we don't get surface material. We get a lot of internal muscle tissue. If you start analyzing internal muscle tissue, it reduces the confidence even further.

My concern about going to even single combos and those kinds of things is if you make it so difficult that they can't get it done, we're hearing the Agency say, gee, we'll push activities, inspection activities off to get a good sample. We looked at some of the samples that were up there, and it's challenging, and I'm not criticizing them because I see the samples that go from the packers into the laboratories myself. We get them a lot of times for companies that don't have access to certified laboratory in their location where we'll run them in our own laboratory.

The only thing I can say is I haven't seen any reduction or increase in the number of positive events. Last year I said that. Last year was unique. I don't know what happened last year. It was like we all took our eye off the ball. Thirty-seven positive events for us as a company was

astounding. I mean that's, you know, when you're dealing with that, that's almost one a week. I got to where I flinched when the phone rang. It was that bad.

This year, we're back down I think -- to Dean's comments, we're back down to where it's more normal. I've only had six events. That's across five plants scattered all over the United States. It's much better. I haven't seen the high levels of contamination even when I've had events. So I just -- again, we can't test our way into that rather than when we do validation testing, if there's a failure, it really is going back and trying to figure out what's going on as a process control failure. And it does directly relate to appropriate slaughter/dressing procedures. We know that's where the contamination occurs.

So, you know, I hesitate because I know what you're saying and, you know, is 5 percent or 95 percent confidence interval effective? I feel very good that it's being applied on a more consistent basis today than it has been in the past several

years, and my hope is if we continue to educate people on that, we pick one standard, it'll continue to reduce that, and, of course, then I would also carry that through with if you're putting raw ground products into retail, design those products for safety and then do a certain amount of verification testing on that as well because I'm afraid even with the systems that are in place on trim, that there will be some that passes through there that are large enough to cause public health issues and I'd like to see people incorporate a validation step at the end that the other part is working effectively.

MS. KOWALCYK: Barbara Kowalcyk, Center for Foodborne Illness, Research and Prevention.

I wanted to echo Felicia's comment and say that I was very impressed with your presentation, the process that you're implementing at your facilities, as I'm sure other companies are. I am a statistician by training and spent 10 years working as a statistician, and I'm very familiar with statistical process control, and this is more of a comment than a question, but as I'm sure you're

aware, Edward Deming is one of the fathers of statistical process control, and he actually spent a good bit of his early career at the USDA.

In the 1950s, 1960s, he went to Japan, and then by the 1970s, the Japanese have these wonderful products and American companies had rejected his philosophies and couldn't understand why the Japanese were surpassing us.

So in the 1980s, they embraced Deming's management principles, one of which is you cannot test or inspect safety in products or quality into products. Again, the Americans kind of missed the boat. I happened to be in college at the time and did an internship in a company, a large company that had Deming's management principles plastered all over the place, but they got rid of the statistics because it was too hard.

When I first came to Food Safety in 2001, my reaction is HACCP is based on statistical process control, and what happened is everybody embraced Deming's management principles and threw away the statistics because they were too hard, and I think

that the reason we have not seen the improvements from HACCP that we had hoped for is because the statistical process control piece of it has been missing in too many plants, not all plants but in too many plants, and this is a very important issue that the Agency has to deal with, and we have to provide the small plants, we have to encourage all the plants to move to a statistical process control, and you're going to have two types of microbiological testing that will allow you to do this.

One is your in process sampling which will address your process control issues, and the other one is going to be your end product testing which is going to provide your verification and you need both of them and they need to be as your -- I believe one of your last slides stated, it needs to be a robust sampling plan and I am not one to -- as a statistician, I can tell you, you are absolutely right. Every plant should have its own sampling plan because it will be dependent on the variables in that plant. There's not a one size fits all

sampling plan.

But we can do a lot better, and the one thing that I think has been missing in a lot of the conversations that I'm seeing, and I think that these conversations are really great, and a lot of the documents that have been coming out recently from FSIS, I'm very encouraged, but it's the issue that Caroline's brought up twice now is, what is the power of your sampling plan to actually detect whether your process is out of control, to actually detect whether or not you've detected contaminated lots?

And that's a really important way for the public to evaluate the effectiveness of a sampling plan in a process control system. And so that's one piece that I haven't heard much being talked about, that really I think for the benefit of those who are not as familiar with statistical quality control, you really need to look at that power, and that's going to be dependent, N-60 apply -- you could take N-60 and apply it 10 different ways and get different power levels and basically your powers

reflect your confidence.

So, you know, I'm reluctant to say, well, let's do it exactly this way in every plant because I don't think that that's going to be effective, but we need to really be focusing on making sure that plants have a high level of confidence, that their process is in control and that they're detecting contaminated products.

MR. BIELA: I'd just like to make a brief comment, and then we'll let that be the last question, but you're absolutely right. One of the challenges that we have is when we deal with this event associated with pathogens, this particular one, it's not predictable. It's very difficult to design anything that's got confidence. What we do know is this. If you sample consistently across time, then you will detect events, and that's really what it's all about because we do that -- that's what the idea is behind N-60 is you're filling these combo bins, take samples at distinct points across that. So you've got a representation of the population because that's what we're trying to do is

to predict something in a population.

Pathogen testing has its limits, and so we use other data as well. You know, so we may not be able to enhance that because statistics say pretty much what we want them to. We may not get it past 95. I feel like if we apply effectively, and then for those products that are going into the retail marketplace and going to consumers' homes where there's less control at times over the temperature verification activities -- I'm hoping commercial establishments use the food code and cook to proper temperatures and those kinds of things, but where there's potential for outgrowth because of the controls at retail or improper cooking, I would say that people should consistently test, and sampling is the first part of the equation.

So, you know, without that, then we've got to dig into what's sensitivity and specificity on the laboratory side before you can actually calculate anything because we can all talk about what these confidence intervals give us, and then I can change everything by just walking into the

laboratory.

Okay. Thank you all.

(Applause.)

MR. ALMANZA: Thank you, Tim, and, yes, you did make my life a lot easier in Dallas.

The next presenter is Dr. Wendy Warren-Serna. She's currently the Vice President of Technical Services of Food Safety Net Services, a network of ISO 17025 accredited laboratories, offering a comprehensive scope of microbiological chemical auditing and consulting services. Dr. Warren-Serna has a B.S. degree from Oregon State University in microbiology and a Ph.D. from the University of Texas Health Science Center in San Antonio in microbiology with an emphasis in molecular immunology.

Dr. Warren-Serna in her role at Food Safety Net Services has spent nearly eight years working with the meat and poultry industries and offered effective testing strategies and solutions, and she's got to be the coolest person in here because she sat right underneath the air conditioner on

purpose to avoid getting warm. So thank you.

DR. WARREN-SERNA: Well, good afternoon. My role here today is to offer some insights and hopefully provoke some thoughts on laboratory testing, testing methodologies. But I wanted to start with a very simplistic overview about the big picture here.

So what we really need to do, and this is obviously a very tall order, is to come up with an integrated use of effective sampling strategies that are compliant with industry standards, and I think Tim had a very good point with regard to consistency.

Proper sample preparation and handling techniques, validated and accurately applied test methods, and informed interpretation and application of test data. So I think each of these components, albeit very simplistically illustrated here, are very important in doing a good job.

I'm going to speak very briefly on the analytical sample, and the reason why is because there are several individuals who are talking about

sampling today, but I did want to make a couple of comments about assessment of the sample in the laboratory setting.

So when we receive samples, we are very interested in the physical status of the sample, and I'm speaking directly about the N-60 collected sample. Particularly we look at the composition of the sample because there is some merit in surface association with that sample. So, for example, the sample would have surface associated fat.

Now, the caveats there are sometimes it's not very clear what is surface and what's internal fat. And we also have to recognize the fact that these samples go through a lot of commingling. Nonetheless, the surface of the carcass is, of course, the first place that would be vulnerable to contamination by fecal material or dust particles or water particles that are carrying *E. coli* O157:H7.

We're also very interested in looking at piece count and weight compliance. So to address an earlier question with regard to what is the industry doing in terms of collecting a N-60 sample, well,

the industry is doing a very good job collecting 60 pieces. We know that in the laboratory setting because we can easily identify those folks that have really paid a lot of attention, put a lot of consistency and trained their staff in terms of how to collect an N-60 that will fit into the analytical sample that we utilize in the laboratory.

Now, the industry over the years has grown comfortable with using a 375-gram sample. A little bit different approach than what FSIS is doing, and it really had an economic basis in terms of coming up with a 375-gram sample. The FDA has also utilized this technique in terms of a dry composite. So you could actually compile in the analyses that were performed several years up to 15, 25-gram samples, which at the time that was a popular sample size. You could combine up to 15, 25-gram samples for a 375-gram sample of analysis.

So there was a lot of emphasis placed on that sample size, more sample, more opportunity to find the organism, and we've done a great job as an industry figuring out how to get all of those 60

pieces into a 375-gram sample. Not to say everybody does it 100 percent of the time and that there aren't opportunities to improve techniques, but for the most part, we do a good job. So I do know it's possible.

Test method considerations, that's really something I want to focus on today. So one question I get a lot is the question is my test method equivalent to or as sensitive as the USDA FSIS method, and this becomes a challenging question to answer because right now in our industry, we haven't really stacked the cards in our favor per se to measure tests against each other. And I'm going to go through a few of my thoughts in terms of why that is, but I would just ask you to ponder the question, how would you determine if the method that you're using is equal to or as sensitive as the USDA FSIS method?

So when we get different methods that have different sensitivities or different performance characteristics, they could be singing different messages. And that adds to the variability of what

we're doing in industry.

I was speaking recently with a family friend who is a physician, and we were talking about a therapy that was going to be applied to one of our family members, and she looked at me and she said, well, you know, we really don't know if this going to work or not, and she said, but why do you think we call it practice medicine? Because a lot of times there's some practice that goes into it.

The truth is, there's a lot of practice in microbiology, and while we try to abide to standards, there is some practicing. What I would like to do is see this practicing stay within a certain lane or within certain gates so that we can trust the data, make messages out of the data as industry to see how we're doing.

So there are many drivers when it comes to method selection. A few of them might be turnaround time. How long is it going to take me to get my test results? Costs certainly is a factor. The target, how is the target detected? So is this a protein-based test or genetic-based test, and the

perception on whether one of those might be better or more sensitive than the other.

Comparison of available test methods really does require our reliance on validation data. So I don't know about you, but if I'm the one who's charged with having to pick a method, I want to see what sort of validation data do we have? Even when I'm asked to use a test method for a food matrix that may not be down the beaten path, I look at the validation data and say is this a fair choice to use this test on a particular test matrix that it might not have been validated for? So I would certainly look for in this validation a definition of the performance criteria and validation. How was this validation study designed?

So we're looking for some key things. I'm going to talk in a little how do we come up with performance criteria. What should these performance criteria be to set us up for success? Validation study design, we're talking about statistics of sampling, but there's also a very important role of statistics in determining the validity of a test.

So we want to make sure that the validation study design was statistically significant.

Validation reports are ideally authored by a third party relative to the test kit manufacturer, and they're available in a complete and original format. So if you're looking to see how a test performed and what sort of validation was behind it, you should be allowed to inspect to the validation report and be able to scrutinize the design and also these statistical significance. You should also be able to see that the test method is being applied in the laboratory is, in fact, the method that's included in the validation.

Basic principles, again a heavy reliance on basic principles of the scientific code of ethics, you can actually download this from the ASM, at asm.org, but true alliance on code of ethics surrounding method design and application in the laboratory.

Laboratory and test methods needs to be transparent. Now it's true, test kit manufacturers have oftentimes proprietary targets that they

utilize. That's how they make a business. That's how they succeed. You can still do this in a very sensitive manner to the proprietary information.

The test method needs to be replicable. So robust and repeatable across multiple laboratories across the industry, and there needs to be a proper balance of science and economics. This is a very challenging one for those of us who make a business out of science but also for those who have to include science in their business. So what sort of choices, what sort of structure are we putting together to make sure that we've properly balanced science with economics because we can design the most statically valid sampling and testing plan but the truth is, we'll probably put a company out of business. Okay. Is that what we want? Probably not.

We can also make the best economic choice for the company, but we may be completely lacking on the science. That doesn't benefit the industry either.

So it seems like there should be a

validation agency that's responsible or overseeing validation of test methods. Well, in the years that I've been in the food testing arena, particularly focused on beef testing, I've seen an evolution away from what once used to be and that was the use of AOAC as a validation tool.

Particularly I'm referring to the AOAC official methods of analysis, which is a robust, very statistically significant validation procedure that test methods could go through to determine if they perform according to the criteria that were stated in the original proposal. This was a multiple laboratory validation. So you get that reproducibility, that robustness, but it's also very lengthy and it's also very expensive, and what we've seen is that the industry has allowed or been receptive to a very much abbreviated version of this validation. And that's called an AOACRI. That is a 1 laboratory trial, 20 samples, not very statistically sound in my opinion, validation of a test method, and that's really where we have to rely more on field testing and use in multiple

laboratories to gather performance data on a test method.

There's actually more recently been a processor specific requirement on test methodologies that is more robust than the AOACRI. Specifically this method requirement requires 3 trials of 25 samples each for a total of 75, and those statisticians in the room, which I am not one, can appreciate why 75 data points would be more powerful than 20.

I would contend that in the absence of oversight and requirements for test methodologies, method validation does vary and so do the methods. So this is a bit of a concern that I have because we are drifting away from multi-lab validations. I understand the driver's there, the economic drivers, the timing driver's there, the business drivers. AOACRI, is that a good compromise? I would question that. So we are a bit in a custom validation arrangement and very much reliant on independent scientists making independent choices, and again I think that is putting us at risk of having

variability in the validation requirements and variability in the test methods.

Inconsistent methods can lead to inconsistent results and expectations. So again if we're having expectations of the data, are we chasing the same range of information if we're using different test methods?

Method consistency is driven by the establishment of performance criteria. So how should a method perform? Proper validation and verification of consistent compliance with a method. So not just validating it but also verifying that the test method is being properly performed as its being used.

Scientific consensus on the key elements of method performance for *E. coli* O157 detection in beef is important to properly define criteria, the performance criteria and direct method validation.

So I brought an example with me of an activity that happened recently. I believe it was in May of this year. There was what we called a think tank that occurred, and that was driven by the

Beef Industry Food Safety Council or BIFSCO.

So this approach, it can be a very good approach, task force or committee approach to outline method performance criteria. So what is good for all? So one person really can't come up with a one size fits all approach. You get lots of very smart people in the same room, and we come up with some really great ideas.

So the drawback sometimes can be that the timelines are long when you put committees together, you put working groups together. It can draw out for weeks and months and years, and also who pays for it? So again, going back to what we did in the BIFSCO meeting, which I thought was very fruitful and informative, is we had a multidisciplinary team with key stakeholders in a room. So government, academics, test kit manufacturers, laboratories, industry, and we came up with some important elements of method validation relative to industry needs and in the interest of science.

It was deemed in terms of STEC which would include *E. coli* O157:H7 and non-O157:H7 that

produced Shiga Toxin. So Shiga Toxin *E. coli*. So very relevant to our discussion today.

And when we came up with key validation elements, and by the way, this is available on the Internet, if you'd like to look at the summary from this meeting, and I've included the website. Hopefully you can see it on the bottom, but when I looked at these validation elements, I found they were interestingly similar to current *E. coli* O157:H7 method inconsistencies. So I think there might be a message there.

Product to enrichment ratio, a lot of variability on this one. Type of product to be used in the validation. We heard earlier that higher fat means the method doesn't perform as well. So we need to look in terms of fat content, ground beef versus trim. I would argue that different levels of background microflora would make tests work differently.

The analytical sample unit size, so weight of the sample, what should it be? Because there's no doubt that putting more samples together has a

dilution effect, and it can affect your ability to recover a target. So does the media ratio. These are all very dynamic components of a method validation.

Pre-warming of media and a product temperature and how that impacts the overall enrichment. So these are key elements. When we're wanting our test to performance faster, what effect does product temperature, incubation temperature have on our ability to replicate the target to the required levels to detect it in our detection system?

The type of enrichment media. What should we be using? We've heard some indication that enrichment media change overall sensitivity or your probability of detection in these test methods. And the effect of the initial inoculum dose on sensitivity. The industry's really been pushing hard on lowering that initial inoculum level in the test sample where you see some amazing differences in the efficiency of the test methods that are available to us in terms of recovery and sensitivity

specifically here would relate to the probability of detection of the organism.

The truth is, going back to the practice comment, practice of microbiology, recovery of *E. coli* O157:H7 from beef requires careful compliance with validated methods. There's an equal importance of sampling, sample prep, enrichment, post-enrichment handling as applicable and detection. So sample prep and enrichment activities must yield the proper number of cells for delivery into the detection system.

Activities must be prioritized to optimize the probability of detection, and we certainly don't have time to go through all the micro components that are important but just a few comments I think that are very important in these areas. Enrichment, we have to provide the best opportunity for growth. Basic needs including nutrient time and temperature. So we want the optimal selectivity of our target and efficiency or ability to replicate those cells in the shortest time possible.

Product impact, we need to consider that as

we're enriching the composition and again the competing microflora that might inhibit your ability to grow the target.

Environmental impact. We have to consider that all of these interventions and product handling conditions affect our ability to recover the organism. For example, an acid treatment or a freezing treatment that might be applied to a product is going to injure the cells in such a way that we might have to further coerce them and really engage them into a replication cycle. Maybe we have to lengthen our incubation time.

Post-enrichment handling. Should you -- the point here is not reducing your probability of detection. Validation within a specific detection system is a must. So you must validate any post-enrichment sample handling procedures. For example, in a wet composite or wet pooling arrangement, which we have learned about in the recent guidance document, storage of enrichment during the detection phase of testing is critical, especially if it may be subjected to further testing. The results can

vary considerably especially if the organism is near the limit of detection of the assay. So again if you are enriching a sample and handling that sample enrichment in some way, performing the test method and then you expect to come back to that enrichment and perform further testing, sometimes this was referred to in the guidance document as retesting, don't think that the organisms are in a sit stay position if you have a dog. They're not. They're doing things. They're interacting with each other. So dynamic activities are occurring in this enrichment and it needs to be taken into account in the validation data.

Detection, so it's very important to have a complete understanding of the detection targets. Even if it's proprietary, you need to understand the nature of the detection targets. So is it multiple genes from a general enrichment, an individual protein, and individual protein and individual gene, et cetera. So you have to understand this in a complete format so that you can truly measure the pros and cons of a specific detection system, and by

that, you can make a very well defined and informed decision about the test method you're using.

Knowledge of the threshold level of cells required for delivery to the detection system for a consistent positive result, if the organism is present, is key. So that the probability of detection can be properly calculated and, in particular, if post-enrichment handling occurs and further testing is possible.

Laboratory considerations. ISO 17025 accreditation is a good way to support a laboratory's quality system. The reality is, it's not a thorough auditing process by these agencies in terms of technical technique. You are somewhat at the mercy of your auditor in terms of how much technical auditing you are allowed in this process. So it really does rely on the quality and the depth of the laboratory staff that are employed at a particular laboratory to self-police the technical aspects of the laboratory.

Ethical structure and influence of management of a laboratory is very critical. A

laboratory should, in fact, welcome auditing, transparency, peer review of methods employed at the laboratory. So if you have questions or concerns about the methods that are being used, you should be able to review it all in intensive detail.

Conflicts of interest should be clearly communicated so that third party guidance can be employed as needed to insure proper balance of science and economics. Any of the hardcore scientists in the room understand that it's very important when you're balancing a science with a business discussion, and there is a clear conflict of interest, you need to make sure that there is third party oversight to insure a proper decision is made for your specific needs.

So some concluding thought, test method consistency can be achieved by establishing expected performance criteria including the probability of detection of *E. coli* O157:H7 at a specified level in the test sample, such that methods can be validated for compliance and in the context of a reference method.

In the absence of a method validation body, an established industry accepted performance criteria, test methods will continue to be inconsistent.

In the absence of technical policing of laboratories, test methods may be improperly performed and/or applied, which to Tim's point is you can set up all this sampling design, all of this process control but the truth is, if it gets to the laboratory and the laboratory doesn't know what they're doing or they are improperly applying methods, it's a bit futile.

Thank you for your time.

(Applause.)

DR. ENGELJOHN: Are there any questions? In the back.

MS. CHENG: Thank you. My name is Yuen Cheng (ph.). I'm from the Grocery Manufacturers Association. My question is in the testing laboratory, the commercial testing laboratory, how often is the FSIS method is being used? And is it considered the reference method for testing for

O157? And what are some of the primary considerations in your decision of using or not using, you know, the FSIS method? Thank you.

MS. WARREN-SERNA: So the FSIS method is used certainly if a customer asks us to specifically follow it. With our knowledge in terms of performance characteristics of various commercially available method, we can also serve as a technical guide for our customers in weighing the pros and cons.

The truth is, with the FSIS method, we know specifically what the targets are, what it's looking for, what the scientific caveats might be in terms of various targets to help guide them through making a good choice in which method they should follow.

Certainly we can look at the information that's available to us in terms of what inoculum levels are used in validation data, which is why I asked the question I did, to get a better idea of what sort of efficiency does this method have in terms of probability of detection of a contaminant at a specified level.

So it's not a very straightforward answer, and it's most definitely not a one size fits all. So I could not represent the base, the industry in toto if you will, in terms of why they would or would not choose to perform a certain method.

Now, certainly, if they're wanting to determine if the organism is being detected at an equivalent level to what FSIS is testing for, then you would want to follow a similar method.

MS. SMITH-DeWAAL: Caroline Smith-DeWaal again from Center for Science in the Public Interest. In terms of the variability of the lab results and methodology, I mean kind of everything from the inputs to the outputs, is there any benefit to requiring accreditation or the use of only accredited labs to help address that variability?

MS. WARREN-SERNA: What I would say again to the comments I made in my presentation is that accreditation of what falls under calibration laboratories, through the ISO 17025 standard, is a good idea. It is a good way to assure the quality system of a laboratory. It's certainly not all-

inclusive in terms of technical applications of test methods and data. So again that goes back to who's running the laboratory? Is it a microbiologist, a scientist who can make informed decisions about what test methods should or should not be used to advise an individual, this is a good idea or this is a poor risk management decision?

So again, you know, the ISO standard is a great idea to accredit quality systems. I would say that the nature and the depth and the quality of the staff of the laboratory in making scientific microbiological decisions is more important.

(Applause.)

MR. ALMANZA: Thank you, Wendy. Our next presenter is Felicia Nestor. She's currently a senior policy analyst with Food and Water Watch and worked for nearly a decade as Food Safety Director at the Government Accountability Project. Ms. Nestor has had extensive contact with FSIS inspectors, learning how FSIS policies are implemented in the field. She also issued several reports based on analysis of FSIS microbiological

testing.

(Pause.)

DR. ENGELJOHN: We have some technical difficulties at the moment. I would just suggest perhaps that if you need to take a restroom break, now would be a good time to do so.

(Pause.)

MR. ALMANZA: We're going to get started.

MS. NESTOR: Good afternoon, everybody. Sorry for that technical difficulty. I actually have two presentations I'm going to make. The first is a presentation of the consensus that's been reached by a number of groups, and they're listed there: Center for Science in the Public Interest, Consumer Federation of America, Food and Water Watch, Safe Tables Our Priority, and United Food and Commercial Workers Union. After that, I'm going to make a presentation about Food and Water Watch's position, which is not a matter of consensus.

Okay. So as a group, the consumers believe in these general principles, that a primary goal of meat and poultry inspection is to protect public

health by reducing foodborne pathogens in meat and poultry products. It's the government's role to set public health standards and assure that the products resulting from industry process control programs meet those standards. A strong microbiological testing program is essential to determine whether those standards are being met.

Both the government and individual companies must perform regular sampling of meat and poultry products to verify company process controls are working as intended. All sampling should be consistent with the protocol established by FSIS.

The objectives of microbiological testing must be clearly identified. FSIS must identify its public health goals and the specific objectives of the microbiological testing programs it conducts and oversees, identify the particular sampling plan or plans its considering, identify possible sampling options, for example, stratified sampling or purge sampling. We've heard about those, but we have not been given much information about them, and the public health benefits possible with each option.

Finally, the microbiological testing must identify techniques to improve the effectiveness of sampling.

Currently, neither FSIS nor companies are sampling sufficiently to protect public health. Increased government and industry sampling should occur in the context of the development by FSIS of a comprehensive program designed to trace contamination back to its source, and the requirement that FSIS inspectors review sampling results regularly.

FSIS should increase its own level of sampling in both slaughter and processing plants. Specific goals for increased sampling should be identified and reasonable timelines should be set. FSIS should periodically report on its progress in achieving these goals.

FSIS should require companies to increase their sampling frequency. FSIS should recommend some sampling standards that are statistically valid for the specific purposes for which they will be used. Companies can develop alternative sampling

regimes if they can demonstrate that they are equal to or more effective than the one recommended by FSIS.

FSIS should make available sufficient resources and technical assistance to smaller plants to help them develop adequate sampling plans. We couldn't really make a determination of what smaller plants meant. It certainly doesn't mean only the very small plants or all small plants, that that's something that should be discussed.

Periodically FSIS should review its overall sampling program to determine whether his performing the necessary functions and after seeking public input changed the program as necessary.

FSIS should report aggregated or individual plant testing results to the public on a routine basis but not less frequently than biannually.

The adequacy of each plant's sampling plan must be evaluated and certified or approved by an independent third party such as ANSII. Sampling plans must be implemented correctly and there need to be mechanisms for verifying this.

FSIS must identify standardized procedures for taking the sample, ensure that inspectors are trained to carry out sampling procedures correctly and routinely verify that industry employees are collecting samples correctly, instruct inspectors to collect a list of suppliers for any lot of product that it samples at the time of sampling, instruct inspectors to request and examine each plant's most current sampling results, each plant must keep records on the source or sources of material for each lot that it samples, provide the most recent sampling results to FSIS inspectors immediately upon receipt of the results, notify the FSIS inspector or local officials if the plant receives notice of a positive result when the inspector is not in the plant, provide FSIS with a list of the source suppliers to any lot from which FSIS collects a sample at the time FSIS takes the sample.

FSIS should clearly define the actions it will take based on the results of microbiological testing. Trace back is an essential element of effective process control. When a positive is found

in the processing plant, trace back to the supplier is critical and must be done as quickly as possible so that other potentially contaminated products in distribution can be identified.

FSIS must hold a public meeting to discuss issues associated with sampling.

Finally, we recognize that what we are recommending involves additional costs. However, we believe that what we've outlined here has a public value that is worth an investment of public funds. FSIS should provide the public with a progress report in how the Agency is addressing these issues within six months.

The consumer groups also have a consensus document that we've released, and it's available. It has more detail than what was in this PowerPoint.

And now I'm going to discuss Food and Water Watch's position if I can figure out exactly how to -- no. And there we go. Okay.

Again, I want to say this is Food and Water Watch's position. I have not discussed it extensively with other consumer groups, and it's not

a matter of Safe Food Coalition or any other consumer group consensus.

My comments are going to focus on FSIS because consumers really don't have influence over industry. Customers have influence over industry, but we are recognized by FSIS as a stakeholder, and we assume that we have some influence over FSIS.

I'm going to be talking a lot about data from the past, but I'm not doing that in order to rehash the past. I'm identifying trends that I see still influencing the Agency's policies at this time that I think might be part of the problem and really need to be reviewed.

The reason I'm focusing on trace back and FSIS actions at source plants is it doesn't look like we're close to finalizing what kind of sampling should be done, who should do it, when it should be done, and work all the bugs out of the system but trace back and increased actions for process control by FSIS are things that can occur immediately and I think will provide, you know, some benefit, public health benefit in the near term.

Okay. The perspective of Food and Water Watch is that consumers deserve effective government oversight of the food supply. We also are concerned about increasing consumer desire for locally produced meat. Many people are concerned because of the massive recalls by large multinational conglomerates, and they feel that the food may be safer in local markets or farmers' markets. Consumers are also increasingly concerned about environment and sustainability, and for that reason as well, they want locally produced meat.

So far, FSIS' *E. coli* testing policies have harmed both of those goals. FSIS has consistently focused its enforcement at the end of the line at grinders and very small plants. More than 40 percent of the very small grinders that were producing ground beef in 2003 have stopped. FSIS has also avoided identification of plants that could have been the source of the problem particularly the large slaughter plants.

As a result, we believe that FSIS policies have prolonged unnecessary danger for consumers and

created undue hardships for many smaller plants that received contaminated supplies for making ground beef yet had good process control systems themselves.

If you look at *E. coli* testing data, from 1998 through 2007, you can see up to 70 percent of the tests were taken at the very small plants which FSIS estimates to produce 1 percent of the product, and the large plants which the large slaughter plants make approximately 80 or more percent of the product, and they have gotten about 1 percent of the testing. It's increased recently, and we're encouraged to say that in 2008, the Agency actually has it up to 6 percent, but it probably should be more.

Okay. This is a hypothetical diagram of the beef production system with a few notes. The yellow circle is the slaughter plant, and there are approximately 35 large slaughter plants that produce more than 80 percent of the beef. The slaughter plants then sell numerous types of products, coarse ground trim, carcasses to other plants, and one lot

produced by a central slaughter plant can get divided up so that it is going to hundreds, if not more, very small grinders. And the little circle there is, you know, FSIS has taken most if its samples at the very tiny grinders that make less than one percent of the product. It might have been a good idea if FSIS then traced those positives back to the slaughter plant and required some cleanup, but it appears that that has been a very rare event.

I'm not sure what's going to happen here. It's doing it one by one. I'm going to be giving a copy of this to FSIS, so I'm not going to go through all of these, but I'll just say that FSIS has publicly committed to trace back on a number of occasions, and I can tell you that consumer groups are under the impression that it is FSIS' goal to identify as much contaminated product as possible when FSIS finds a positive. And it's my understanding that that is not a goal of FSIS. FSIS' current trace back policies have specified actions, and one of them is not to quickly go back to the source slaughter plant and then trace forward

to all plants that might have received some of the same lot of contaminated product.

The Agency has not been transparent about its use of trace back, which is why I think so many of us are confused about what actually happens when FSIS finds a positive, but the evidence that I've been able to get through FOIA and the recall website suggests that it's been pretty rare.

Since 1998, from 1998 through the end of 2007, FSIS test data showed that FSIS found *E. coli* contamination in over 200 plants. Around 80 percent of these plants were only processing plants. They did no slaughter themselves and only reprocessed product they got from other FSIS slaughter plants.

It is our position that FSIS has the responsibility to trace back to the source of the problem when either FSIS or plant testing indicates that the FSIS inspection program has failed to prevent contamination from leaving a plant. There's a lot of focus on what industry is responsible for, what companies must do, but we believe that FSIS is in these plants every day, FSIS puts the seal on the

product, FSIS is responsible for all of these plants, and it's incumbent upon FSIS when there's evidence that contamination is getting out these slaughter plants, to go back to the slaughter plants and find out what the problem is.

I tried to find out how many times FSIS has traced back since 1998. The recall database shows that there were 11 recalls based specifically on FSIS trace back after FSIS found a positive in another plant. So that's 11 out of 207 positives.

The test data that I've gotten from them only shows three plants that were tested as part of a trace back investigation. Now, I don't know if that's the limit of it or not. There's a possibility that FSIS didn't code earlier or, you know, didn't have its coding up to speed, but that's what the data I received through Freedom of Information Act shows.

Okay. When FSIS conducts a recall after illness, that is a trace back investigation. And this chart shows the amount of product recalled based on particular causes. The top line is

illness. That's 58 million pounds. There were 38 recalls after someone got sick. You can see that the bottom, FSIS testing, there were 48 recalls after FSIS found a positive in a plant, and you can see really how little contaminated product was identified and removed from commerce after those positives.

In contrast, if you look at FSIS trace back recalls, there were only 11 of those, and there was much more contaminated product removed.

FSIS not only has failed to trace back, but there are other ways in which it's sort of taken its eye off the ball at the large slaughter plants. I'm sure everyone's familiar with the testing exemptions. I analyzed how many tests were actually done under those. Most large slaughter plants went three or four years without one FSIS test. Some went five years without one test. Some were tested one year, skipped for two years. So it was very, very sporadic and minimal testing at most large slaughter plants.

The large slaughter plants failed nine

Salmonella sets. There were five recalls because of other indicators of *E. coli* positives, and FSIS continued to believe in the interventions until the ConAgra recall caused a real public scandal.

There were also failed FSIS tests at closely associated processing plants. We know from the OIG report that FSIS ignored the numerous failure of company tests at ConAgra, and presumably other large plants, and that there were repeated fecal NRs which were an indication of lack of process control, and there doesn't seem to have been much done about it.

FSIS' risk-based *E. coli* test proposal continues to recommend less testing at plants that use interventions. Now, I don't know whether this -- I've heard that this part of the test proposal has not been implemented yet, but if it is implemented, we'll have very serious concerns about that.

Since 2004, FSIS has allowed plants to use a sampling scheme that was not well-founded and effectively created a regulatory standard other than

zero tolerance for *E. coli* O157:H7 without public input or knowledge. We weren't notified of this, and it was only last year based largely on information that I got from inspectors that we really started looking at the N-60 sampling and what the result of positive tests was.

Also after 2004, FSIS tested only pretested product at the plants that were testing. Therefore, it didn't have a good idea of what levels of contamination were coming off the slaughter floor, and certainly FSIS must have known that small processors were using the primals and bench trim from other products coming off the slaughter floor.

Inspectors in those plants were not instructed to scrutinize how the plants were using the sampling, despite the fact that the testing was a fundamental part of the plant's HACCP program and the inspectors therefore would have had jurisdiction over it. And FSIS kept no records of how many thousands of pounds were diverted to cooking between 2004 and 2007. So this is a problem in other areas of FSIS oversight, but a lot of these records are

kept just in the plant or just in the district office, but certainly out of the Washington, D.C. headquarters.

There are a number of ways that inspectors lack control at the large slaughter establishments. Inspectors at high-speed plants have said repeatedly that they don't have time to do an adequate check for fecal contamination at the final rail, and the fecal NRs from the coolers and the processing floors confirm that fecal is getting off the slaughter floor.

In contrast, a very small plant that has a fixed point, that carcass cannot leave the floor until the inspector has had a chance to look at it and look for fecal on the whole carcass.

You know, we're talking about process control and experimentation. It seems to me that a good experiment to do would be to find out whether inspectors and employees can actually spot fecal contamination at line speeds going that fast. You know, it's one thing to say that you are looking to improve a process but then refusing to ignore lots

of evidence that there's a problem.

Inspectors also complain about a new limiting definition of fecal contamination which requires texture or granularity, a number of other things. It has to be the right color and, you know, once, once the fecal contamination goes through the interventions, there's a good chance that the hay and the grains just may have been rinsed off, but it's not necessarily the case that the contamination is no longer active or dangerous.

Another limitation on inspectors is that the line inspectors who are looking at every carcass are not authorized to identify fecal. They have to call the IIC to confirm that it is fecal, and they cannot write a NR. Only the IIC can write a NR for fecal, and very often in plants where you have inspector shortages, the IIC is on the line and the IIC is not allowed to write a NR for fecal contamination that he sees while he is acting as an inspector.

You know, in the new policies, FSIS is recommending that small plants audit their

suppliers, and that if they get a positive, that the plant notify the supplier and I guess give them some tough talk or something. But given what I mentioned before, you know, the minimal amount of product that they are buying, they don't really have the authority or market power to make any impact. We also know small plants have been threatened with blacklisting if they test.

In this situation, it says the sale of unadulterated food is a matter of private contract, and we don't believe that at all. FSIS has a responsibility to make sure that adulterated product is not leaving plants, especially routinely or on a repeated basis when there's been evidence of product at a slaughter plant.

So our recommendation is that FSIS must get more involved by strengthening its trace back program and increasing scrutiny and oversight at slaughter plants, particularly the large plants at which FSIS has decreased oversight since the beginning of HACCP. Thanks.

(Applause.)

MR. ALMANZA: Questions?

MS. NESTOR: It looks like I said everything I needed to say.

DR. MASTERS: Barb Masters, Olsson, Frank and Weeda. Ms. Nestor, you indicated that your combined document, the consensus document, there was a more detailed that was available. Where is that document available?

MS. NESTOR: Oh, I think it's probably outside. Oh, Chris has them.

DR. MASTERS: Okay. Great. Thank you very much.

UNIDENTIFIED SPEAKER: Thank you. Felicia, thank you for your presentation. There was an item I believe on your first set of slides from the consensus document, and this is a comment, and maybe my industry colleagues would like to chime in here. There's a continuing, I see coming back, this concept of sampling purge which we did some work with some years ago. We found it to be very undependable.

MS. NESTOR: Undependable?

UNIDENTIFIED SPEAKER: Right. It's not always present in the combo even at the point where we are which is somewhat down the line, and it certainly isn't present in combos at slaughter, which is where most of the sampling that you're talking about is going to be taking place. There's a lot of things that contribute to whether you have it or not, and we're not going to go into that now, but it certainly in our experience is an undependable sample matrix. Thanks.

MS. HATCH: Michelle Hatch with Greater Omaha. One thing that I would like to mention and actually in FSIS' defense here is the fact that, first of all, I just want to comment that the information that is FOIA-able I think has been taken and skewed. Information even put in newspapers can be skewed. So I think that needs to be reviewed a little better.

The other thing I want to say is that in looking at things from a microbiological standpoint, which is definitely my background, when you go to homogenize anything, you definitely are taking that

and multiplying that bacteria over a surface area, and so there are other places to test that, which is why they do test that on an end sample to get that, and it's not that testing is not being done at a slaughter plant because it is being done at a slaughter plant, and I think that that needs to be noted.

MS. NESTOR: Yeah, the slides I put up were analysis of the testing between '98 and 2002, at the large slaughter plants when there was the exemption. When ConAgra hit, dramatically, all of a sudden everybody's being tested, and I can show you the chart. It's a very dramatic difference.

MR. BURNS: Hi, Frank Burns with DuPont Qualicon. I have a question. You mentioned blacklisting. Is that -- I'm assuming you're talking about when a grinder is told if they test incoming trim from a slaughter plant, that they will no longer be supplied by that company?

MS. NESTOR: Yes.

MR. BURNS: And is it your understanding that that's widespread?

MS. NESTOR: It's my understanding that it's not rare.

MR. BURNS: Okay. Thank you.

MS. NESTOR: And part of it is what I've heard from small slaughter plants. The other part of it is what I've heard from large industry, and I think, you know, there is an arguable basis for that. If a large slaughter plant produces a lot and wants to know that it can release that safely into the public and it's done testing itself, it wants to know what its liability is. So I'm not saying that there's, you know, that it's not rational. It's rational behavior, but it's just not good for the public and, you know, FSIS with its testing, that's why FSIS with its testing should be doing more trace back, and whenever any small plants find a positive, I think FSIS needs to get involved with the trace back and not just put it on the tiny plant.

MR. BURNS: Thank you.

MR. DANIELSON: Thank you, Felicia. Dean Danielson with Tyson.

I'd like to, a couple of things here. On

your slide that you showed 38 million pounds that was illness related --

MS. NESTOR: 58.

MR. DANIELSON: -- 58 contaminated product, I think the FSIS trace back was 3.8 million, something.

MS. NESTOR: Yeah, something like that, yeah.

MR. DANIELSON: -- from FSIS and then -- of contaminated product, and FSIS testing was 194,000 pounds.

MS. NESTOR: Right. Potentially contaminated. I mean that's the product that FSIS identified.

MR. DANIELSON: Associated product. You didn't say potentially contaminated. That was not all contaminated. That 38 million pounds, I mean there's some big recalls in there that went over numerous days, and it was an arms around, mainly because there was a lack of records and documentation. So it wasn't all contaminated product --

MS. NESTOR: Right.

MR. DANIELSON: -- that was entered or that was captured, and the differential is not -- when, you know, it's associated product. So that differential to me becomes a little bit less alarming from that context.

Clarification for me. Fecal you said is a new definition includes texture. It's my recollection that that definition has been in place since zero tolerance came into play in 1994.

MS. NESTOR: No, I think it was later than that.

MR. DANIELSON: 1993, and that's been a component in my recollection of the definition of fecal applied at the plants and utilized since the very start. If I'm wrong on that, then somebody -- you guys can correct me up there. And more fecal getting into the coolers, I don't know what that timeframe is. I can assure you from today versus 10 years ago, versus 15 years ago, these carcasses are immaculately clean compared to what they were in the eighties and the early nineties, when I started in

this business. They are like night and day difference, and I just wanted to share that from a timeframe standpoint. Thank you.

MS. NESTOR: I would like to see data on that. I mean I would like FSIS to provide the fecal NRs. I mean I've always advocated that FSIS needs to collect more of this data, and as far as the definition changing in 1993, I think it may be one of those situations where some policies were in force some places and not others because it was, I would say, towards the end of the nineties that inspectors were still complaining that they had just been informed that they were no longer allowed to identify it as fecal unless it had grains.

MR. McCULLEN: Brian McCullen (ph.), National Beef. And, you know, it's always an eye opener to hear different viewpoints when we come to these meetings, and as an industry person, we don't always hear the consumer groups like we probably should, but I do have to ask just a couple of questions.

One is you said four percent of small

grinders since 2003 has stopped grinding. Where did you get that number?

MS. NESTOR: I have FSIS' *E. coli* testing data, and they identified every plant that was tested in 2003, and then every plant that was tested in 2007 for *E. coli*. And so by state we have identified the plants that are no longer -- the very small plants that are no longer grinding beef under FSIS inspection. Now, perhaps they're grinding it under retail. The most recent information I got from the Agency shows that just since 2007, I think it is 60 plants that make less than 1,000 pounds have stopped grinding. I'm not sure. It's either 40 or 60. There's a difference in number.

MR. McCULLEN: Well, I appreciate that clarification. I just want to caution. It's easy to make references and assumptions that people have stopped grinding because of bad things going on. There's a lot of other reasons for it, and the data or the presentation that was given, there is a lot of innuendoes there that I hope that when you provide the data, the paperwork for everybody to

look at, they support some of the claims that you made up there, basically state them as fact, and then I'd like to see the backup data that supports everything you've said.

MS. NESTOR: Sure. My understanding is not about plants stopping grinding, the very small plants. It's not based solely on the data. I've just worked on a report on the disappearance of small slaughterhouses and processing facilities around the country and have had occasion to talk to a good number of very small plants. And they've talked about how difficult it has been to be held responsible for contamination coming into their plants, and that the FSIS expectations, while they may be appropriate and very doable by large processors, are much less so for the smaller plants.

MS. JOHNSON: Mr. Almanza, how many more questions do you want to take before we get to open comment? We have four people signed up.

MR. ALMANZA: We'll take one more question.

MS. JOHNSON: One more question before we go to open comment. Okay.

MS. SMITH-DeWAAL: Felicia, thanks. Ms. Nestor, thanks so much for your comments earlier, and I do just want to draw back attention to the consensus points. It's critically important as the Agency moves forward that you do, in fact, and many of us feel, and I think the consensus document reflects that, the need to get more and better testing in, and we will continue to challenge you to make it as good as it can be, but don't question at all that we want more testing in your program to validate it. I certainly don't think this is the best time to be debating visual inspection criteria because visual inspection is part of the program. It's been part of the program since 1906, but we need to improve on that. So I really do. I think Felicia's made some excellent points, but I really want to make sure the Agency goes back and focuses really on the issue of the sampling. Thank you.

(Applause.)

MR. ALMANZA: Thank you, Felicia, and thank you for warning me out in the hall not to take this

personal. (Laughter.) Maybe that's why it's so warm with this flack jacket on.

But all kidding aside, one of the things that surprised me is the reference to the slaughter inspectors because one of the things that I've done as a District Manager and Deputy District Manager and as the Administrator is I walked up there on the rail every single time, and every single plant that I go to, I have not had one single inspector tell me I have a problem with fecal material or detecting ingesta, and that's so foreign to me because they have eight feet to inspect. I stand up there next to them. I inspect with them, and none of them have ever had any problems with that. So it kind of caught me by surprise. I do make it a point to go out there and put my whites on, and I'll go out on the kill floor with them to perform post-mortem inspection duties with them, and I do hear some comments about things that they don't feel comfortable, that they can't write NRs and, of course, we have a response for them, but to be able to go out there and stand there with them and

perform post-mortem inspection duties with them, ante-mortem inspection duties, and to live what they live, I'm just not hearing those comments, and I just wanted to make that point.

The first person that signed up is Gina Bellinger (ph.) from Food Safety Net.

MS. BELLINGER: I'm good.

MR. ALMANZA: You're good. Okay. The second person is Sherrie Jenkins for Food Safety Net.

MS. JENKINS: I was going to talk tomorrow.

MR. ALMANZA: You're going to wait and talk tomorrow.

MS. JENKINS: Tomorrow.

MR. ALMANZA: Okay. And then, Felicia, you're third.

MS. NESTOR: No, I didn't sign up.

MR. ALMANZA: Somebody signed you up. (Laughter.) Maybe they thought you didn't have enough time. And then Barbara Kowalcyk.

MS. KOWALCYK: Do you want me to stand?

MR. ALMANZA: However you're most

comfortable.

MS. KOWALCYK: Okay. Barbara Kowalcyk, Center for Foodborne Illness, Research and Prevention. And the first comment I wanted to make is I really appreciate the Agency putting together this meeting and responding to a lot of issues that I, as well as many others, have brought up about sampling in microbiological testing. And as we heard earlier today, HACCP has largely been discussed as a preventative type program or type system, but from a statistical standpoint, HACCP really would be more appropriately described as a means for minimizing the variability of a system. And as I said earlier, my biological testing is a critical component both for process control and verification testing.

That said, microbiological testing cannot replace effective prevention strategies and process control which are key to controlling microbiological contamination. Any microbiological testing must address the following five points, some of which overlap what Felicia presented earlier.

The first is the objectives of microbiological testing which must be driven by public health goals and should be clearly identified. I won't go through the CDC stats, but as we all know, foodborne illness is a serious public health issue that affects too many American families each year.

The second point is a robust sampling plan that is designed to meet the objectives, the microbiological testing objectives, with a high degree of confidence must be developed. This is critical to the generalizability and interpretability of the results. And it's key to any effective microbiological testing program. Since it is not possible to conduct 100 percent testing, one must use a sample to draw inferences about the entire population. A robust sampling plan will, one, ensure that the samples collected are representative of the entire population; two, minimizes bias; three, addresses potential statistical problems such as confounding, collinearity and error actions; and, four, ensures

that the sample size is sufficient to provide the desired level of confidence.

Further, it is important that the sampling plan address the fact that foodborne pathogens are heterogeneously distributed throughout food products and there is significant variability and prevalence rates over time. Due to the complexity of designing such a sampling plan, it is highly recommended that a statistician or someone with equivalent training is involved in the development of the sampling plan.

Of course, developing and implementing such a robust sampling plan will require FSIS and industry to invest sign additional resources compared to that that is currently being expended.

CFI recognizes that some plants may not have the necessary resources to develop such robust sampling plans, and as a result, we recommend that FSIS provide those plants with the necessary technical assistance to develop robust sampling plans.

In the compliance document, which I'm sure we'll be talking about tomorrow, it was suggested

that small and very small plants use extension specialists for this purpose. However, I do not think that that's sufficient unless, of course, you provide additional money for extension specialists. Specifically, FSIS needs to provide statistical consulting services in some form or another to the very small and small plants or basically any plant that can't afford it.

Third, my third point is the adequacy of the sampling plan should be evaluated and certified or approved by an independent third party. Basically we heard this already before.

One, you need to have representative samples. These sampling plans must be implemented correctly, but more importantly, you can make statistics say whatever you want it to say. As a statistician, I've heard too many times statistics being called black magic, and it's true. If you dig deep enough, you will find the answer that you want, but that doesn't mean that it really represents what's going on in the plant or it really affects the interpretability and generalizability of the

results.

So my fourth point is that FSIS needs to establish mechanisms for verifying that industry and government sampling plans are implemented correctly. And FSIS and industry, as I said earlier, must specify the power of the results to achieve the testing program objectives. This will allow the public to evaluate the reliability of the results.

This also goes hand-in-hand with analyzing the data using proper statistical methods and having inferences drawn from that data be based on statistical theory. For example, as many of you know, I've been highly critical of the way that the FSIS verification testing data has been used over the past several years, and that program is specifically designed to test whether a specific plant is meeting the HACCP performance standards at a specific point in time. It is not designed to make year-to-year comparisons, which I frequently see the data being used to do. So we need to make sure that not only once you have the robust sampling plan put in place, that you actually interpret the

data from that plan appropriately.

And finally as Felicia said earlier, the results of the microbiological testing program should trigger some actions which should be clearly defined by FSIS and as well as the circumstances surrounding those actions.

Again, to conclude, I want to thank FSIS for holding this meeting and for the compliance documents that you recently published. I think that this is an important step in the right direction. Of course, the devil is always in the details, which I'm sure we'll get to tomorrow, but this is an important step. As I said earlier, we need to basically put the statistics back into statistical process control. Thank you.

MR. ALMANZA: Thank you. Next is Dean Danielson, Tyson Foods.

MR. DANIELSON: I need a place to put my notes here. There's been a lot of discussion about the history of N-60, the basis of it, where it came from, when it came from. So I thought important for this meeting and this group of people for me to

share some historical perspective on it and the basis and nature of it since I'm the one that created it at least at Tyson. So if you bear with me a few minutes, I think it's important that we touch on some of these things.

The basis of N-60 testing came about actually in the winter of 2002. I've heard 2004 thrown around. It was the winter of 2002. It was designed at that point after the reassessment that came out, requirement, in the fall of 2002 as a result of some serious events to the industry that previous summer.

So as a result of the reassessment activity, and the new challenge presented to us, as O157:H7 is reasonably likely to occur, one of the tactics or one of the strategies we put in place at that point was doing testing of 100 percent of the trimmings from a beef carcass destined for raw ground beef, whether that be ship trim or internal grinds.

So that came about in the winter of 2002, became fully implemented by us in 2003, and we had a

first full year's dataset in 2003.

Now, I'm going to get into some of the statistical basis here in just a second, but interestingly enough, that first full year, 2002, when we weren't doing N-60, we were doing some other things, N-25, some core grinding, core drilling things, that first full year that we put N-60 into place without a whole lot of other changes, the incident rate, the findings, the sensitivity jump, I can give you numbers. I've got all that data. It jumped monumentally.

It clearly brought to us the foresight. Prior to 2002, as an industry, our methods were not very good, laboratory methods were not very good. We weren't sampling robustly across the industry or the -- we didn't know how to find O157:H7. We've learned a lot in the last four or five years. We've gone through those learning processes, and we came to a great awakening in 2003, with an incident rate that was quite a bit higher than anybody thought. You know, we used to think point 1, I think in '94, when we, I say we, made it an adulterant. It was

made an adulterant. The prevalence rate was believed what? .1 percent, something. It was very, very low, and that was all based upon industry and academic methods that really couldn't find it. We had not a clue how much or where or how widespread it was. So learnings have increased dramatically over the last six, seven years and even more dramatically over the past two to three years. So in 2003, we got the first set of data.

Now, I want to walk through some of the elements that went into how N-60 was created. Obviously you all are aware of the ACMF (ph.) Case 30, Case 15, that defines the most serious level of sampling out there from that particular table, and that's an obvious place to start, and it tells you that it's an N-60, and there's criteria around it for 95 percent confidence, and it makes an assumption of a 5 percent prevalence rate in the population being sampled, all right.

So, back in 2002, we really didn't know a great deal more than that. We didn't know how much was around and out there. However, in searching and

supporting the process, we reached some conclusions on a 5 percent prevalence rate in the basic statistical assumption that all statistical programs need, that the prevalence rate of the population was 5 percent. I didn't say the incident rate of the trim, or otherwise, I would have picked .1 percent of the ground beef, what we knew at those days.

In the preamble of the Directive 10,010 back whatever year, that must have been 2002, the preamble specifically shows a table and states that trimmings from cows and bulls have a low prevalence rate of greater than between 5 and 30 percent. That's assuming that there's 1 CFU per gram, or no, excuse me, at least 1 CFU in a combo of meat. That's a range of 5 to 30 percent that was in the preamble. It also said steer and heifer trimmings had a range of 20 to 60 percent, at least of combos with at least one cell in that combo. So there's a number that we observed and rationalized it into the development of the prevalence rate that goes into the statistical conclusion supporting a 95 percent confidence level of a testing program.

Additionally, we researched the literature and an article published from the Clay Center Research Station in 2002, I believe, shows the post-intervention carcass to be 5.7 percent in this particular study. That 5 percent number of the prevalence rate of the N-60 program is and has been represented and is transparently represented to represent the post-intervention carcass. The prevalence rate of the post-intervention carcass is how we've always presented, always designed it.

So it's not the incident rate of the trim. It's not whether we have good methods or bad methods. It's academic research. It's what we took out of the preamble.

Additional information then that we further gathered through looking and assessing binomial distributions and comparing the actual data we got from validation studies of N-25 comparative samplings to core drill samplings to N-60 surface slice samplings, and applications within the binomial.

And another key element that we used to

support this statistical assumption, and it is an assumption. You may disagree with what the assumption is, but it is a valid assumption to put into the confidence interval development, is we used the Poisson distribution. The Poisson distribution shows us that a contamination, a very low contamination level of 4 CFU per thousand centimeters squared, the detection probability is 95 percent with an N-60 sampling plan.

So there is a statistical basis for N-60. It's multi-tiered. You make assumptions and you go with them, or if they're not valid, they're changed.

So in 2003, once we had a full set of data, we implemented this program and we did it across the board. In 2004, we said, okay, now what -- how do we validate this, and part of that validation process was a pretty in depth third party review that we invited some noted independent reviewers in, Dr. Ann Marie, Dr. Mohamed Kumari, Dr. Randy Huffman, all three in like a two, two and a half day conference. We went through every element of what N-60 was, the sampling, the testing, the statistics,

the data and from that presentation, that independent review, we came out of that with an awareness of that group and an acknowledgment from the people that we recognize in the third party review, that the basis of the decisions and the actions we took were sound in the way that we were interpreting and applying them.

I point you to another study. I've seen some criticism that there is no published data out there. I'll share this with you. There's a study published in the Journal of Food Protection in '04 by Murphy and Seward, and the summary statement is from their study of industry data, at a 95 percent confidence level, a sample size of 52 is recommended for a process that has an *E. coli* occurrence rate of less than 1 percent. That's a published peer reviewed paper. So I'd point that out to you.

Then along in 2005 I guess, it became more and more important to us, and you've seen references to total N-60 versus N-60. N-60 is just 60 samples, boom, boom. This whole program of *E. coli* assessment, we've heard it from the lab methods,

we've heard it from the sampling, how do you do the thin slice samples, analyzing the samples. It's a total program, and we've learned a lot over the last few years about the totality of that program, whether it's FSIS inspectors doing it or people we're buying meat from or selling meat from. It's a total program, and all elements, a three-legged stool, have to be in place. If you're going to have the robustness and sensitivity of the testing program, again the process control that we're talking about.

E. coli testing in a slaughter plant has two functions. One, it's a verification of the process. We call it a process beacon. When we have hot event days or multiple days, it tells us that we have a system or a process, a control that needs to be assessed and taken care of and take product actions and do corrective actions necessary. It's a verification of the process. It's also an accept/reject of the trim that we manufacture. So it has two functions. The 95 percent confidence, it's not 100 percent. We don't get it all. We know

that. We understand that. It would be nice if we could, but we don't. So I just thought I'd share with you some history so that everybody in the room understands it as we talk about it for what it's worth.

MR. ALMANZA: Thank you, Dean.

DR. ENGELJOHN: Thank you, Dean.

(Applause.)

MR. ALMANZA: Felicia, you want to --

MS. NESTOR: Yes. I just want to bring it back again to FSIS, and we hear now that the industry didn't really know how to sample and didn't know what it was doing, but in 1998, when FSIS told us that the large plants were not going to have to -- or that FSIS was not going to be testing them, it was because FSIS was working on the best science, and this was a scientific program and everything was, you know, everything was known.

And so, you know, again I mean FSIS needs to be clear with the public what it knows and the limitations, you know, how confident it is in the assertions that it's making because I mean, really

to hear now that we didn't know is pretty surprising after seeing the testing data at all of the large slaughter plants for five years.

MR. ALMANZA: Thank you. Barbara.

MS. KOWALCYK: Barbara Kowalcyk, CFI. I just wanted to follow up on a couple of things.

I'd love to see the Journal of Food Protection references that you referred to, but -- and I have no doubt that maybe the initial prevalence level, assuming the initial prevalence level of 5 percent may or may not be appropriate, and we can debate that.

It is true that in statistics you have to make assumptions, but I want to bring up about statistical process control and what Tim discussed earlier, the whole plan, do, check, and act. All right. The whole idea of statistical process control is you track your data and you continually improve the process until you have a very tight narrow region of variability around a target.

Now, obviously here the target is zero, and I would love to say that we'll someday get to zero

contamination, but I fully realize as a scientist that that would not happen. But we want to improve the process, and one you do that is by plan, do, check, and act. So if we set the prevalence rate right now under the assumption at 5 percent, and say, yes, N-60 is appropriate for a prevalence rate of 5 percent, what happens when that prevalence rate goes down and as we improve the process? Will that assumption then be adjusted?

In the past, that has not happened. The whole idea about HACCP, and I'm specifically talking about the microbiological baseline studies is the whole idea is you're going to set these performance standards, and then Agency was going to continually redo those studies until and keep bringing those performance standards down, and while the Agency has, and I do commend them doing more baseline studies, most of the original ones have not been repeated, and we are still dealing with performance standards that are over 10 years old.

And so I think one of the concerns that, I'm not going to speak for all consumer groups, but

one of the concerns that my group has is that if we agree to an assumption of 5 percent, and maybe it was appropriate in 2002, I'd like to see if it's appropriate now, if as industry improves the process and reduces the prevalence on trim post-intervention, are we then going to go back and readjust the number of samples and re-look at sampling plans to make sure that they're actually detecting what we think it out there?

So I have not seen that plan, do, check, and act part being played out within FSIS and within the public policies, and that's a very critical part to making HACCP really work.

MR. ALMANZA: Thank you.

MS. KRANTZ: Yes, Kathleen Krantz with Greater Omaha Packing. I think we've heard a lot of data and history of where we were and where we are, but I don't think we can lose sight of where we're going, and I think as an industry, we've spent a lot of money in protecting public health by food safety interventions within our slaughter plants, within our whole food processes, and I think with the

assistance of FSIS, in working through food safety assessments and working through how can we do things better, we must not lose sight of where we've been, where we're going and how we're going to continue to work together to improve the process, to get that confidence level of the consumers.

As a matter of fact, we're all consumers. We all have children, grandchildren. We're all eating our own products.

So our goal is to continue to continually improve the process, and I think that whether we're on the FSIS side of things, the consumer side of things, or the industry side of things, we must continue to work together. Thank you.

MR. ALMANZA: Thank you. Anybody else? Over here against the wall.

MR. BURNS: Frank Burns again from DuPont Qualicon. As the incidence of O157 continues to go down, it's useful to us as an indicator of process control also goes down, because if it's too infrequent, then you really don't get any feedback on your process. And I was encouraged a lot by what

Tim Biela said about using a lot of other fecal indicators, and at some point, if we continue to get lower and lower levels, doing a lot more testing or taking more samples is not always going to suffice to measure our process control.

So I think, you know, thinking a little bit beyond a single organism as an indicator of process control might be a fruitful way to go.

MR. ALMANZA: Thank you. Anybody else?

(No response.)

MR. ALMANZA: Okay. Then we'll close out the comment period. I do appreciate everybody's participation. I think that as we anticipated, these are painful meetings somewhat, but they're necessary and -- well, for me, but they are necessary, and I think that they will give us additional information to be able to make decisions on. The one thing that we have to be careful of is that we have the right information and the right data to be able to move forward, and I certainly believe that. So thank you again, and we'll see you all tomorrow.

(Whereupon, the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

ADDRESSING SAMPLING AND TESTING

METHODOLOGIES, COMPLIANCE GUIDELINES

AND N-60 LABELING

Washington, D.C.

October 14, 2008

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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TIMOTHY J. ATKINSON, JR., Reporter

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