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 15, 2008
8:30 a.m.

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I-N-D-E-X

I-N-D-E-X

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

(9:08 a.m.)

MR. ALMANZA: Okay. This morning we're going to get started with some examples of short-term solutions on issues that were presented yesterday afternoon, and our first presenter is going to be Dr. Karlease Kelly. She's the Assistant Administrator in the Office of Outreach, Employee Education and Training. She's responsible for Agency-wide efforts to develop the skills and scientific knowledge of the workforce as well as conducting outreach activities for small and very small meat and poultry and egg processors, to help them enhance their food safety and food defense systems.

Dr. Kelly has over 13 years of Government service in USDA. Her experience includes working as an instructor, a program analyst, Chief of the Program Analysis Branch of the technical service center, and more recently the Agent's chief training officer, and she's a cousin to Colt McCoy, the number one team in the college rankings. So with

that, I know there's some -- in the room but, hey, everybody's got to have their time. Karlease.

DR. KELLY: Thank you. Good morning, everyone. I know I don't look like Colt, but I really am his cousin.

Today we'll talk about our training program that we have for FSIS employees on *E. coli* O157:H7 sampling. And we'll also talk about our outreach to small and very small plants.

So we'll start with employee training, and I'm very much looking forward to the dialogue and questions and feedback following this.

We actually do classroom training for the consumer safety inspectors and the veterinarians who collect the *E. coli* O157:H7, and they in the classroom, employees receive training on all of our sampling programs including the raw ground beef sampling, beef manufacturing trimmings, follow-up sampling after positive testing results, and testing components other than trim and imported raw ground beef. But today I think because we have been interested in talking about the N-60 method, we're

going to focus on that training.

I also want to back up and kind of give you a bigger perspective. Employees also have a much broader training background. We're not just teaching them about how to sample product. We're teaching them about the Federal Meat Inspection Act. We're teaching them about the regulations. We're teaching them about plant's processes, plant's interventions, HACCP verification, sanitation verification. So put this in context. This is just one little piece of the training that they receive, and we're just really going to kind of scratch the surface and see a few sample slides from the training that they receive.

Also, when they're out in the field and they're going to collect a sample, they're instructed by Notice 18-07, which is still an active and viable notice, they're instructed before they collect sampling for beef manufacturing trimmings that they must review the training CD. So that's something that we want to refresh their thinking about, remind them about how to collect the sample.

I'm going to share with you for the next 11 slides just a few excerpts from the CD, the training CD that we have. If any of you would be interested in getting a copy of that CD, if sometime today you could give me your business card and just make a note on the back of it, that you want the employee training CD, I'll make sure that you get a copy of it so that you can have it and review the entire CD.

We'll just have, like I said, 11 slides out of that whole CD.

So, you know, first of all, this is going to give you an idea about the flow of the training. We review the sample supplies and we talk about the importance of sanitizing, you know, all of those supplies. Next we talk about the importance of a septic sampling and show them exactly some things that they can do to ensure that.

We also give them a lot of examples and information on how to collect the sample. We talk to them about the physical dimensions. I know we talked this yesterday, the physical dimensions for collecting the sample. We talk about the amount,

the 2 pounds, 60 pieces, that they are to collect. And, we also review more detailed instructions on taking the samples, taking it from the top, collecting the appropriate number, and making sure that you have 60 pieces.

We also give them some more detailed instructions about making sure that the samples are from the surface and that giving them again something to measure by for themselves, the thumb size from a practical point of view, that really does help people.

We also show them through a video, this video does not have any sound and it won't be nearly as nice as the one that Michelle's going to show you later, but we do have a very visual workforce, and sometimes showing them exactly how to do it is helpful. So I'll play this video. It's about 50 seconds long showing exactly how the sample should be collected, showing how to use the sample supplies and the fact that they need to select the sample from different pieces at different locations, and how to use those supplies. Okay.

We also review with them how important it is that they don't cut a piece of the sample and then right underneath that cut another piece of the sample. We explain to them that any type of meat underneath the surface would be a sterile type of surface. That's not the type of sample that we want. We want the contamination that might be present on this surface. That's what we want to look at in the sample, to see if we can find any contamination that might be present. And we also encourage them not to take a sample from the same piece over and over again.

We talk to them about how important it is to take the temperature of the product, and if it's warmer than 40 degrees, to put it in a bag in a cooler to chill it before shipping.

And then we give them instructions on packing the sample. These are really important instructions, that they're not to wait until the establishment completes pre-shipment review before they submit the sample. They really need to collect it. The only intervention that they need to wait

for is any microbiological test results. That would be the only thing that they would need to wait for.

Then we also instruct them on sealing the sample properly. We have several methods, kind of a fail-safe approach to ensure that the sample is secure and that it is -- the seal isn't broken. So we give them instructions on how to do that.

So that's a real brief overview of what's in the training. Like I mentioned, I'd be happy to give any of you the CD if you want to review it at another time.

Now I'm going to talk about our outreach to small and very small plants. Some of you know that FSIS has been putting some increased emphasis on providing training and education resources to the small and very small plant operators. This is one example of some of the things that we've been doing. The small and very small plants are a very diverse audience. Those of you who are familiar with them know that there are a lot of different sizes, a lot of different ways that these people will be their information. Some of them only prefer to get it in

a face-to-face format. Some of them are very web savvy. Some of them would prefer to get it in a printed format. So we're trying to provide a variety of approaches to meet their needs.

These examples here are things that we've done on the net and in a face-to-face format. In face-to-face, we've conducted 22 sessions we call Regulatory Education Sessions. They bring inspectors and industry together to hear a comment message about the regulations. We think this is a really good format to get discussion going, get people on a common ground, common understanding.

And some of you, how many of you have actually attended one of these sessions? I have a feeling there's some people. Yeah, there's a few people who actually attended them out in the field locations.

We've been to 20 states, and we've reached almost 400 people talking about these policies. The mix of the participants tend to be about 60 percent from plants and about 40 percent from inspection.

When we did this, our regulatory education

sessions, we reviewed with them the draft compliance guidelines that are posted on the web today, and I'll give you some samples of some of the things that we shared with them, and the things that the trainers have been presenting to them.

We also conducted two net meetings, educational net meetings. We had about 125 people present. One of those was done by Dr. Ann Hollingsworth with the Compliance Guidance that we had out and published previously. And the other was by Dr. Kerri Harris, where she talked about a variety of educational kinds of things for risk management practices, and if you're interested, you can -- to actually see what was said and hear, you know, see the slides and hear the presentation, you can go to our website and you can find those. We've recorded those here. We won't go there today but that just shows you that that information is available, not just for the people who sat in the meetings but even today, it's still there.

Now I'm going to show you about 12 slides of about 74 that were shared in these regulatory

education meetings so we can give you a sense of flavor of things that were shared in those meetings.

Before we talk about sampling, we do talk about just in general the importance of controlling O157:H7 and how important it is for plants, if they have prerequisite programs, to follow them and to maintain them. So we do have some preview part to this, and then we also did review the best practices were that were in Notice 65-07 that many of you are familiar with.

Then we start to talk about microbiological testing and when we talk about this slide, the trainer talks about how, as we discussed yesterday, product testing in and of itself doesn't make products safe, but it does provide some evidence for the producer and others about the effectiveness of the process. So we're trying to help them understand, you know, why would you want to test. What are some of the benefits and how will this help you? We also talked to them about the fact that testing today is not mandated. The plant does not have to test, but we explain to them that when they

are producing product, and they are not testing, there's a risk. It's up to them to determine whether this is an acceptable risk, but it is something for them to consider, and maybe some of them haven't really been aware of this in the past.

We talk to them about how if they're going to do microbiological testing, they need to understand that O157:H7's not going to be evenly distributed through the process. It's going to be, you know, kind of in random places, and it may be very hard to find, and that's something that they have to think about when they're collecting a sample.

We give them some information, some basic layperson's terms, in lay terms about confidence intervals. That's kind of a complex topic for people that may be introduced to sampling for the first time, but we do explain, you know, you can do different types of sampling, and depending on how you're doing it, you will have different levels of confidence, and again, it's up to you to decide what confidence level you want for your establishment's

testing program. And we talk to them how it is a balance between the cost of the sampling and the risk that they run.

We also share this guidance that's posted on the web today about minimum sample frequencies. Again we emphasize this is guidance, but this does give them some idea about how much they should be testing, and we talk about the importance of understanding seasonality, how when the seasons change, that the prevalence increases. When the prevalence increases, testing should increase accordingly. So we explain that concept to them as well.

We also pose these questions for the plant to consider when they're designing a sampling plant for O157:H7. Some of those questions would be are you using any type of intervention? What about your suppliers? What types of production processes and interventions are they using? And what about lotting? So we explain that those are things that they need to consider.

We also explain to them that if they have a

testing program for source materials and finished product, that's more effective for them than just one of those programs on their own. And we explain to them that some of the components that they may be using in their product may be riskier than others. So they should consider that as part of their sampling plan as well.

We talk to them about lot size. For some plants, this is another new concept in terms of how it relates to sampling. They may understand lotting, but how it relates to sampling, that's something that they need to take into consideration. We explained that, you know, lots are units of product that are grouped, and we explain the concept of affected product, if a sample tests positive and how a lot of things might go into determining what's affected, production practices, number of suppliers, the sanitation practices, and we give them some examples of common lotting sizes and some of the, you know, factors that people might consider in determining the lot size because that is their choice about how they would determine that.

Then we talk to the plant operators about what they should think about when they're going to select a sampling method, you know, we will eventually get to the fact that, you know, FSIS has recommended the N-60 method, but we talk about if they're sampling trim, they need to be looking on the surface. You know, the lessons learned over the, you know, past few years have told us, that if we're not looking on the surface, you know, that's not going to maximize the likelihood finding the *E. coli* O157:H7.

We also explained to them that it's really important that they randomly select samples from the product, and we recommend that they look at different times in the production process. That will help them in terms of randomizing their sample selection.

Then we talk about what is N-60, that we recommend N-60 for their consideration, that N-60 is not just 60 portions, but it really is supposed to represent 60 different points in the production, and that's part of what makes it a more powerful method.

So we talk about that in a lot more detail, skipping over a number of slides.

Then we talk about as we, as we mentioned yesterday, the importance of selecting the laboratory because they can do, you know, they can have great plan. They can have a great sampling program that they're implementing, but if they send it to the wrong lab, or the wrong analysis is done, this isn't, you know, this is the end of, you know, the effectiveness of the program.

So we talk about how important it is for them to select the right lab, that they need to look at a lab that has a validated process, and we also explained to them the concept of enrichment to detect *E. coli* O157:H7 again in very lay terms, and we give them an example. We recommend they might want to look at the FSIS testing methods guide that Emilio referred to yesterday that's on the web to get an idea about what they might be looking at.

Then, of course, we've got to talk about what happens if they get a positive? You know, right now, they know from a regulatory standpoint

what will happen, but we explained to them that the positive result represents very important information for them to look at about their process. They need to, as we talked about yesterday, they need to understand what happened. They need to look at their process. They need to make some changes in their process because this is information for them, but they also have to protect public health. We recommend that they report this to FSIS, this is highly important, and that we also recommend that they hold the product.

Then following this, we share with them FSIS policies and how does the Agency, how does FSIS collect the N-60 samples, so they can see some of the things that we're doing so they can understand, you know, how things are happening and how things might have an impact for them.

So that's a real brief summary, and if you would like, we also make a resource CD that has all the information, this presentation and a lot of other resources on it that we hand out to anybody who comes to this regulatory education meeting. If

you would like a copy of that CD, if you give me your business card and write on the back of it that you would like the industry CD, I'd be happy to send that to you or you can write both, and I'll send them both to you.

So with that really brief overview, we do have some next steps planned, and even based on yesterday's meeting, I'm getting some additional ideas, but we are constantly reinforcing our N-60 training. We learn, as Emilio was saying, we learn through what happens at the laboratory, how we can do things better. So we will be reinforcing our training. We also have plans, we mentioned yesterday, how sanitation really is the foundation of, you know, what the genesis of all this is. This is the foundation, and so there is some policy development underway so that we can reinforce the importance of sanitary dressing policies, and I can assure you when that comes out, that we will not only train the workforce reinforcing that, but we'll also share that in the regulatory education sessions that we do with the slaughter operators.

And Emilio mentioned yesterday that we may have some new tools, we may have some new methods. So at anytime that we make some changes, then we're going, you know, train the workforce on that, and we'll also share that in reg ed sessions about the changes that we've made.

What about for our outreach to small and very small plants? We will be sharing the video that you're going to see soon that Michelle shows, the BIFSCO video. I think there's some really helpful information that will encourage the small and very small plant operators to think about testing. We also when we finalize the compliance guidance that Dan talked about yesterday, that's on the web, comments are closing in mid-November, we'll print that and send it out. We're not just going to rely on the fact that it's on the web, and that will be really good, but we want to actually get it in people's hands.

We will be conducting some additional regulatory education sessions and some net meetings, but we also want to conduct some detailed how to,

hands on, a little bit longer than the regulatory education sessions, a little bit more of a how to approach. So those are the things that we have planned for next steps.

I don't know if you're taking questions now or --

MR. ALMANZA: No.

DR. KELLY: Yeah, we're going to wait until after we get the presentation from Michelle. Thank you.

(Applause.)

DR. ENGELJOHN: Thank you, Karlease, and now I'm going to ask Michelle Rossman to come forward and make a presentation. Michelle is the Director of Beef Safety for the National Cattlemen's Beef Association. She directs a research program that includes pre and post-harvest research and dissemination and -- from BIFSCO. She has a Master's of Science Degree in Meat Science from Colorado State University.

Michelle, thank you for being here today and making a presentation of what you and the

industry has done to put together to help industry on these issues.

MS. ROSSMAN: Good morning. I was asked to speak this morning regarding N-60 sampling and training, but I would be remiss to focus on one tool that we have that encompasses the incredible amount of information and training that we have that really illustrates the beef industry's commitment to safety.

When I found this text from the HACCP final rule, it amazed me how it really does fit, how the beef industry has addressed beef safety challenges. Those in control of each segment of the farm to table continuum bear responsibility for identifying and preventing or reducing food safety hazards.

We have multiple programs in place that really do look at the entire continuum from farm to table, and I'll be sharing all that information with you this morning.

As I go through these programs, they really fit into three different categories. Research with data collection and review, technology development

in collaborative projects, knowledge transfer. Obviously all of that data and information that we collect would be useless to the industry and wouldn't have any effect unless we get into the hands of the right people for application. And then system implementation through the Beef Industry Food Safety Council.

So I'll begin with a very brief overview of research. In the early nineties, when *E. coli* O157:H7 showed itself as a challenge to the safety of U.S. beef products, we really had to get a focus. With limited resources, where could we immediately have an impact in addressing this challenge? And when you look at this diagram of the industry, it really makes a lot of sense to focus on the midpart of this continuum or the packing, processing sectors.

In this sector, we have approximately 35 plants who harvest 95 percent of the animals in this country. So it made a lot of sense to begin focusing on this area of the continuum. This is a very busy slide, but to begin with, I'd like you to

focus on the yellow text. This is a list of all of the interventions that were developed through Beef Check Off funded research and other research and implemented by industry.

Across the country today, many of these interventions are in place in processing plants. We evaluated them through research, and they've been applied through an incredible commitment by industry to apply these interventions, and it's an ongoing commitment. These are in place and very effective in plants today, but we must continue to look for new tools that we can use in the processing of beef cattle.

All of these tools are applied today in what's called a multiple hurdle technology approach, and I'm sure many of you are familiar with this approach. We stack these interventions sequentially in processing plants to ensure that we have multiple opportunities to reduce any possible contamination on those carcasses.

After successful implementation of those processing interventions, we really needed to take a

look at where do we move beyond processing, and it made a lot sense to step back in the farm to table continuum and take a look at pre-harvest. We know that carcasses are basically sterile. So where does that contamination come from on carcasses? And through initial pre-harvest research, it became very clear that we needed to develop tools to reduce contamination on animal hides, the colonization in cattle as well as prevalent fecal shedding, that is how contamination gets onto the hides and that is how that contamination is brought into plants. So our focus then turned to the pre-harvest arena to develop tools for producers to use to reduce colonization and shedding of *E. coli* O157:H7, therefore reducing the contamination coming into our processing plants.

So again on this slide, if you could focus on the yellow text, we have over the last several years really focused in the pre-harvest arena, and to begin, we needed to do a lot of basic work. There's a lot we still don't know about how *E. coli* lives in the environment across the country where

cattle are raised, but as we've collected information to understand seasonality and regionality of this pathogen, we have been able to develop tools that have shown to be effective in research settings, things like live animal washing, sodium chlorate which could be a feed additive or a water additive. There are multiple vaccines that are being tested today, neomycin another feed additive and direct fed microbials as feed additives.

Unfortunately, I can't say to you today that we have approved pre-harvest interventions. We have been diligently working with both FDA and USDA to get approval for several interventions that again have shown to be effective in research settings, but we have not yet been able to get approval from the Government to use those. So we will continue to work very hard so that we can get tools in the hands of producers and they can plan a role in this farm to table safety continuum.

All of these interventions both pre and post-harvest are vital parts and are hurdles in beef

production and processing, but we have to remember that there is no silver bullet. We will continue to need to implement the multiple hurdle system. It doesn't matter how many pre-harvest tools that we get approved and are able to use, we're not going to take our eye off what's being done at processing. It will continue to be a multiple hurdle system and we need more and more tools to be used throughout that continuum to address *E. coli* O157:H7.

And we must also remember that these procedures absolutely cannot be applied to replace good manufacturing practices, proper chilling and cold chain management throughout the chain and at the very beginning of the process, sanitary dressing. Again, this is a systems approach and back to the presentations and conversations we had yesterday, we really do need to approach this as a system and as a process.

As I said, none of this information would be useful unless we transferred it into the proper hands of those who can apply the knowledge and we do this in various ways. We have a lot of printed

materials that are available. We also have multiple websites. If you have any interest in seeing the research that has been conducted through the Beef Check Off, the site to look at is www.beefresearch.org. This is a site that's used by industry. We post final reports here so that industry can immediately see that data and apply that knowledge in their daily activities.

Now moving onto the Beef Industry Food Safety Council, BIFSCO was formed in the late 1990s as a result of ongoing challenges in relation to *E. coli* O157:H7, and industry leaders really saw a need to get representatives from every single sector again of that farm to table chain together in one room to talk about how we all can play a part in addressing beef safety challenges. This group is committed to developing industrywide, science-based strategies to solve our food safety problems. They address these issues by identifying, prioritizing research, and when we do that, that could then be research that is addressed through Beef Check Off dollars. It could be research addressed through

USDA via the Agricultural Research Service or other funding programs that they have. So there's various avenues for communicating these research needs and getting the research completed.

We also focus on developing programs that can be used by the industry to operate into today's business environment, and I'll speak to best practices in a minute.

We also work to speak with one voice as we look to regulatory and legislative solutions, to some of our challenges and industry information programs are also a key component of this group.

BIFSCO is primarily funded by the Beef Check Off, but we also have a membership program and we have a very diverse membership. Our members include trade associations, universities, companies representing every sector from farm to fork, so production, processing, distribution, retail and foodservice, and also allied industry, intervention suppliers and commercial laboratories all participate in the Beef Industry Food Safety Council.

In 2003, we held our first annual meeting, and this was in response to again ongoing challenges from *E. coli* O157:H7. And our chairman actually describes this meeting as a family meeting. We bring together industry representatives over a two-day period to sit down and talk very openly about the challenges that we have addressing food safety as well as the successes.

We have all decided that food safety is a non-competitive issue. We can learn from our successes, and we can learn from everyone's challenges, and it's been an incredible venue for open sharing and development of new ideas to address our safety challenges.

Initially, at this 2003 meeting, we saw the need to develop best practices, to really develop documents that contain all of the information that one would need to apply across a safety system and develop a document for every single segment of that farm-to-fork continuum. And these best practices were developed in 2003 and have continued to today. They are a continued improvement process. Obviously

there's new knowledge that we gain all the time about this pathogen and how we deal with it, and all the other safety challenges, and we continually update those documents to ensure they contain the latest knowledge and information.

We've recently expanded beyond our printed documents and online documents to include a video component, which I'll share with you shortly, as well as some online interactive resources.

These best practices I said really are a summary of information. They include information of available technologies to each sector. They actually lay out the processing steps involved in whatever particular product you're processing, what the individual steps are and the technologies and information that can be applied there, and guidance on implementation of process control steps. We talked about that a lot yesterday and again going and stressing that this really is about process control.

We also have references to other guidance materials. As we all know, USDA puts out a lot of

guidance material, and it really helps to have all of this referenced in one document so you don't need to search for all of that guidance material. They include flowcharts and what I feel is one of the strongest parts of these documents is we actually have expert contacts listed in each best practice document.

So individuals like Mr. Tim Biela graciously have agreed to have their name listed in those best practice documents, and if someone has a question about how to implement best practices, or a question about some of the information in that document, they can pick up the phone and call Tim and get that technical guidance that they need.

We fully understand that there are small and very small processors out there who do not have the technical expertise and staff on hand to implement this knowledge and work through these documents, and therefore some of our members have agreed to serve as those expert contacts and answer some of those questions.

This is a list of all of the current best

practice documents that are available, and you'll see that we start with pre-harvest and walk the whole way through the chain to retail and foodservice.

At the bottom of the list is actually our latest document that was produced, Best Practices for Using Microbiological Sampling, and this is a focus of this meeting, and in conjunction with that best practice document, we really saw the need to develop a visual tool. As Dr. Kelly mentioned, a lot of people are visual learners, and to read the text of how to conduct N-60 and then apply it, obviously we have great variation across people, across plants on how that is applied. So really saw the need to develop a visual tool and a video that could be used by industry to apply N-60.

So as soon as this comes up, I would like to share this video in its entirety with you.

(Playing video.)

MS. ROSSMAN: This video has been well received by industry, and we certainly appreciate USDA's willingness to help us with outreach and to

disseminate this to small and very small plants.

We disseminate these best practices in various ways. The website listed at that site, all of the best practices are available free of charge and can be downloaded for us. The video can also be ordered from this site.

Other ways that we disseminate best practices include technical meetings. Just two weeks ago, we assisted with a meeting in Chicago where we had approximately 170 industry participants, and we reviewed many of the best practice documents and had technical experts there to assist in disseminating that information.

And, of course, our annual safety summit. And I need to touch on this meeting because it is such an important gathering that addresses beef safety challenges. We host this meeting annually, and our next one will be in March of 2009, and this really is again a family meeting. We have created an atmosphere for very open sharing across all industry segments. It's a time for information sharing in very small group settings, hands-on

training and technical sessions if you will. A lot of information is transferred in those two days.

We also include research updates. We bring in researchers to share with us the latest data and information that's been collected from all of the research that goes on over a 12-month period, to share with us the very latest information and then talk about how we can apply it on a daily basis.

We also talk about emerging issues. It's essential with all the time that we focus on *E. coli* O157:H7, that we don't take our eyes off emerging challenges, things like MRSAs, C. difficile, just watching the research and bringing experts in to talk to us about some of those other issues to ensure that they don't become challenges for us regarding the safety of U.S. beef products.

The one segment of the farm-to-fork continuum I haven't touched on is the consumer, and they are the last segment of the beef safety chain. And, through the use of Check Off dollars, we do conduct a lot of consumer education programs, and we also do outreach at retail and food service and are

continually conducting research in the field to get an understanding of consumers' perceptions of beef safety.

The websites on your left is a screen shot from beefitswhatsfordinner.org which contains a safety tab, and it has extensive information for consumers about everything the industry is doing to address beef safety.

The beautiful picture of the burger there on the right is part of a new program that we've just developed called safe and savory at 160 degrees. We found through some consumer research that there are few consumers who understand that raw ground beef products need to be cooked to 160 degrees, and we also found that many had a misperception that cooking it to 160 degrees, they'd have a bad eating experience. So we came up with this idea of safe and savory at 160. It's a safe product, and you also have a really good eating experience.

As I said, this is a very new program. We're looking at ways to disseminate this

information possibly through family programs like the YMCA and PTA across the U.S. So we continually understand that consumers also play a key role and have a responsibility in handling and cooking our products properly, and we'll continue to work with that sector to educate them.

I've talked about the history of some of our programs as where we are current day and want to talk a little bit about our ideas as we continue to move forward and address beef safety challenges.

There's still a lot we don't understand about the on-farm ecology and epidemiology of *E. coli* O157:H7. Super shedders. Some of you have probably heard that term. We've done some research that shows that there are some animals in a pen who may shed incredible amounts of *E. coli* O157:H7. What do we do about that? Why do those animals shed all of that, you know, these large volumes of pathogens? There's a lot we need to learn there. There's much we don't know about current management practices. Could feeding practices be affecting shedding of these pathogens? There's still some

work and some knowledge we need to gain there.

As I mentioned, pre-harvest interventions. We have several that are currently seeking regulatory approval but we need to continue. Once those are approved, they need to be optimized and improved, and we need to find more tools and we'll continue to focus on that.

Processing interventions. We need to continue to evaluate them and understand if they're optimized and also is there new technology that needs to be implemented in the processing arena and emerging issues. Again, we'll continually track those emerging issues to ensure that there aren't new challenges that we're missing.

We also have the need for a true process control tool, and you heard some of this discussion yesterday but we feel this is a role that BIFSCO could play in beginning this discussion of how do we develop something that's a true process control tool, and we actually have some researchers in the room who are going to share some information, a little bit, about some research that they've done.

But BIFSCO has done such a good job of bringing experts to the table to talk about new ideas that this is a role that we could play and begin this discussion.

Something else that we've been discussing is the development of a food safety objective. At this point, we do not have a true target for *E. coli* O157:H7. Zero, we would all love to eliminate the pathogen, but I think we all know that that's unattainable. So what is the true target? And that's something that we want everybody in the farm-to-form continuum to weigh in on those discussions from pre-harvest through to the consumer groups and that's something that as we move forward here that we'll be leading that discussion in the development of a food safety objective.

Outreach and training has to continue to be a focus. Through the annual beef safety summit, our producer leaders are committed to continually funding that. Technical workshops are needed. I had a discussion this morning with Dr. Kelly about how we could partner with some of the education and

training that she's doing and bring in some of our experts to continually enhance that training.

We'll continue to focus on best practices and add new knowledge and information there, and BIFSCO.org, we hope to turn that into one stop for beef safety information, research data, et cetera, and we'll continue to develop that website. So continually check that website for new updates.

In conclusion, when I look again at this text from the HACCP final rule from 1996, I begin to look at where I fit in this continuum, and it's really interesting because my husband and I actually operate a cow-calf operation in Minnesota. So I'm at the very beginning of the continuum. We start, you know, we calve baby calves every year, and we take the responsibility very seriously in following beef quality assurance techniques and animal husbandry, in ensuring that those animals are in their optimal healthy well-being at all times when they're in our care. We take that very seriously as we think about our operation possibly being a fourth generation family operation, you know, if our young

sons decide to follow in our footsteps and make a living in production agriculture, we want to ensure that we've been good environmental stewards and have an operation that's viable for them to take over in a few years.

In my job, I kind of fit in the middle of the continuum. I'm very fortunate to work with industry thought leaders who are consistently challenging and thinking about what we're currently doing on an every day basis and how we can improve that, thinking about what we need to do in research, thinking about how we train and educate to do a better job of addressing these safety challenges.

And I also fit at the very end of the continuum. I'm the mother of three young sons, and I fully understand my responsibilities every time I produce a meal for them and that there are things in my control that I need to properly handle and cook my food, and there are things that I can do to reduce food safety hazards.

So it's an interesting fit for me as I think about this continuum and my responsibility,

and I understand and take all of those responsibilities very seriously.

So I certainly appreciate your time. I look forward to further discussion of how the beef industry can continue our commitment to beef safety. Thank you.

(Applause.)

DR. ENGELJOHN: Well, thank you. At this time, are there any questions or suggestions for enhancing or improving anything that you saw this morning from the two presentations?

OPERATOR: If you'd like to ask a question from the phone, please press star and 1.

DR. ENGELJOHN: We have an individual over here. If you could give us your name and affiliation.

DR. ACUFF: Gary Acuff, Texas A&M University. Thanks, Michelle. I think BIFSCO, you know, has served the industry well in terms of promoting food safety, and also NCBA has funded quite a bit of research, and so I just want to briefly mention some of the things that we've done.

Actually this was initially funded by USDA.

You know, you can historically non-detect a particular indicator over a period of time, and that may indicate that your process is in control, but it also might indicate that the organism is not equally distributed, that it's stressed, that your methodology is not working well, that your sampling plan's not effective. You don't really know. You just know that you're not detecting it. Hopefully it's because your process is in control.

One of the things that we've been working on is trying to develop tools that we could use at specific critical control points in the process to show actually how much reduction you're getting by critical control point and thereby build it, help you come up with a sum of reductions that would help you get to a food safety objective. If we're going to have a food safety objective, you have to be able to add up your reductions to get to that point.

So Dr. Dickson from Iowa State and I have worked in collaboration now for several years on trying to develop a list of surrogate organisms that

are non-pathogenic but that represent the kill that you would get or the growth that you would get with *Salmonella* or O157:H7, and we have a group of about five or six, five, and they've now been donated to the American Type Culture Collection. So anybody can get them. You just have to contact ATCC and request those organisms, and we've used those.

Well, now here's the rub to the situation. Whenever I've used these in Texas for testing, I've gone into plants and convinced the inspector that I can come in and inoculate the neck prior to a CCP and then go through the process and measure at the end, see how much reduction we're getting which would indicate how much *Salmonella* or O157:H7 we're reducing. I've had luck with that. Jim, on the other hand, has been blocked by inspectors who say no, no, no, you can't come in and inoculate.

So there's some inconsistency there. You know, if we're going to actually validate CCPs, using a process like this, then we have to have some help from FSIS in terms of allowing us to come in and do some inoculation so that we can measure an

accurate reduction. And the only way we're going to come through with a validate, verifiable process is to be able to show exactly how much reduction we're getting at each point in the process, so that when we add that up the end and meet ultimately a food safety objective.

So is there anything you wanted to add to that, Jim?

DR. DICKSON: No.

DR. ACUFF: Okay. So I'm a better salesman than Jim, you know, with the inspectors. So --

DR. ENGELJOHN: Thank you, Drs. Acuff and Dickson. We appreciate that, and FSIS definitely will be getting in contact with you. We are focusing as we go forward on validation because we believe that's an area where we have to refocus. And so I think that would present some opportunities that we need to discuss. So we'll move forward.

We have a question up front.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I actually have a couple of questions.

Karlease, I was wondering, do you keep

names of all the people that attend the training sessions? Because I see on your slide that you said something like 375 people in 20 states attended.

DR. KELLY: I don't know how to turn this on.

MS. NESTOR: Conducted 22 regulatory education sessions in 20 states where there were 375 participants.

DR. KELLY: Yeah. What we do is we ask people to sign up, and very much like this meeting, some do and some don't, and then when they come to the meetings, we ask them to sign in. Right now we have a file, a paper file with a large, you know, number of all this information. It's sitting in a file. So if we need to gather that information, we can, but this year, one of our focuses is going to be on following up and finding out if after people have attended these sessions, did they actually learn something, was it actually beneficial to them? So we're going to convert that into scannable form so we can have more information.

But our purpose is really not to track the

names of the people that attend, but we could get that kind of information possibly.

MS. NESTOR: Well, I'm not interested necessarily in exactly who. It's just I went to the one in Newark, New Jersey, and as you know, that area of the country has the most small and very small plants, and there was one other guy there. There was a woman who sat behind me, but I think she might have been a wife of one of the presenters. I'm not sure. So if I had not been there, there would have been one person.

I can also say that, you know, while the presenters tried to do the best job they could, basically all they could do was read what was on the slides and couldn't answer any questions. I mean I asked some of the most common questions that people have about this, and they didn't have the answers. So I would hope that you would start to keep track of that, you know, the questions that can't be answered because obviously everybody can read what's on the PowerPoint slide.

DR. KELLY: We actually do collect those.

After every session, we get a list of the questions and we feed them back to the Policy Office so they might go into the development of future resources as well as Q&As, and we do realize, you know, as much as we try to, you know, maximize the scheduling of these sessions, there are some times when we don't publicize them as well as we should or we pick a date or a time that's not necessarily convenient for people in the area. So we're trying to do better with that.

DR. ENGELJOHN: I'll take one more question in here before I go to the phones, because the phones are working today, and I want to give them an opportunity.

MS. NESTOR: I actually had a couple of more but --

DR. ENGELJOHN: Could you pass it over? Yes. Thank you.

MS. KOWALCYK: Barb Kowalcyk, CFI. One question that I had, and it's more of a suggestion, is while the educational materials that you have are great, the one thing I found that was lacking is

what do they do with the data that they get back from the testing, you know, I mean the whole key to process control is in tracking the data over time, and I know you referred to a process control tool. But it is going to take a quite a bit of education to teach not only the inspectors but also the plant operators, you know, how they will use that data to effectively monitor their control.

And the other thing, I do have some questions and I can certainly speak to you privately, but in terms of collecting the sample, you know, do any of your programs actually define what it means to take a random sample? Most people think, you know, I just randomly pick a number out of the air. Well, everyone has an inherent bias. There's way to actually do true random sampling or to the best we ever can get there, and also you really didn't touch on stratified sampling and the role that possibly could play in developing a sampling plan.

DR. ENGELJOHN: Do you want to address that, Michelle?

MS. ROSSMAN: As far as the use of data, I will tell you that in our best practices, we do have text in there describing what they should then do with the information that they get from their testing programs, and I'd be happy -- we can walk through some of those best practice documents, and I can show you where some of that text is and how we try to educate them on what to do with the information.

MS. KOWALCYK: That's great, but again as you said earlier, people are very visual learners. It would be great to show them what a control chart looks like and how you would actually implement that in your daily practice of updating that and how you would actually interpret a control chart.

DR. ENGELJOHN: Great. Operator, are there any questions from the phone?

OPERATOR: At this time, I have no questions from the phone.

DR. ENGELJOHN: Okay.

MS. BUCK: This question is for Michelle. My name is Pat Buck, and I'm with the Center for

Foodborne Illness, Research and Prevention. And my question is about this safe and savory at 160. As an educator, and I am a teacher, I'm very interested in how we're going to get those food safety messages out to 300 million people. And what is your plan to either partner with other people within the meat and poultry industry? And what is your plan to partner with other non-profit NGOs like us or like others to convey those very important messages?

MS. ROSSMAN: That's a great question. As I mentioned, we have just developed this program based on consumer research that we did, and we are right now evaluating our best ways to get that message out, and I'd love to have a conversation with you later because we have put together a list of organizations who we see as targets who could help us to get that message out, and you may be the perfect partner. So I'd like to have that conversation with you.

MS. BUCK: Well, thank you.

MS. ROSSMAN: We understand it is a huge challenge --

MS. BUCK: Yes.

MS. ROSSMAN: -- and we have very limited dollars on the consumer education programs that we do. So we're always looking for ways to disseminate that information.

DR. ENGELJOHN: Okay. In the back. Thank you.

MR. CORBO: Tony Corbo, Food and Water Watch. I wanted to follow up on a comment and assertion that my colleague, Felicia Nestor, made yesterday about the, it seems to be contraction in the industry among small and very small plants and what is causing that. I know that she was criticized for using FOIA-ble information on testing data to make that assertion, but the Agency on an annual basis submits data to Congress, and I just wanted to give you the latest information I have, that between FY 2001 and FY 2006, there's been a decline in the number of small plants by 242 plants or a 10 percent reduction, and among very small plants, the reduction has been 357 plants or about 11 percent.

Karlease, in your outreach program, have you identified what is causing that? And as contrast, the number of large plants in that same timeframe has gone up from 350 to 359. What is going on?

DR. KELLY: I think that is a really good question. It is something that I would like to look into. At other public meetings, we've learned that FSIS is doing more with data, and I think that's one of the things that I want to follow up on, is to find out, you know, what is happening? What is the cause? And is there something that we should be concerned about? And if so, what should we do about it?

So it is something I'm interested in and following up on.

DR. ENGELJOHN: Tony, I would just say we as an Agency will be looking into the issue of that. As Karlease said, it's an issue that we need to have a better understanding for. So we've noted that, and we'll put that on our agenda. Yes.

DR. HOLLINGSWORTH: Jill Hollingsworth,

Food Marketing Institute. We represent the retail food stores, and my question is directed to Michelle.

As you know, our concern for O157 is not just in the meat supply. It's also fresh fruits and vegetables, and I thought I heard you say that there were no approved pre-harvest interventions. I wanted to get that clarified, but also if you could give us some update on where is the industry with approval of the pre-harvest, the vaccines, probiotics, feed additives, because all our focus is let's get O157 out of the food chain, not just worry about getting it out of the ground beef at the point of production, but let's work on the cattle.

MS. ROSSMAN: There are no approved pre-harvest interventions. Right now, sodium chlorate is in front of FDA for approval, and there are two vaccines as well as another technology in front of USDA trying to gain approval. We are working with them in a coalition with other meat associations who represent all sectors of processing and production to expedite that process.

It's my understanding that next summer we would expect to have approval to go to the next step of approval, which would be large-scale trials in the field to get a real handle on efficacy in large trials, and then the next step would hopefully be approval.

I'll tell you, it's been a very long, frustrating process. It's really a new thought process applying interventions to a live animal that may have an effect on public health. So it's been a real education process, and we're not there yet.

I know I've been saying for many years, hopefully next year we'll have a pre-harvest intervention, but we're not there yet, but we are very actively working with USDA and FDA to get approval.

DR. HOLLINGSWORTH: Well, anything we can do to help that, we would like to participate.

DR. ENGELJOHN: This is Engeljohn. I would just say on that matter, FSIS has weighed in that in terms of those kind of pre-harvest interventions that could take effect, it's our belief that any

reduction is an effective tool as opposed to striving to get a significant reduction. And so there is a difference in thought process there that I think that we're all working through, and so that's one of the issues that I think that we've overcome to some extent.

Any other questions in the room before we move onto the next presentation?

(No response.)

DR. ENGELJOHN: Any issues or questions coming in from the phone, Operator?

OPERATOR: If you would like to ask a question, please press star and 1 on your touchtone phone.

DR. ENGELJOHN: And I'll just remind those of you that are in the room that we don't have a scheduled break, and so I would just suggest that you can get up and get your coffee or take a break as you need to, but we'll go forward with the presentation and get in public comments as well.

We have a question here.

MS. NESTOR: Felicia Nestor, Food and Water

Watch. First, I just wanted to say that I really appreciate the BIFSCO document on the guidelines. You know, when I was looking to make comments on the N-60, you know, the cautionary comments are in the BIFSCO document. So I thought that was really good.

And this question, I'm not sure if it's appropriate now or, you know, I hope it's answered sometime today by FSIS or the industry. When I was in Chicago at the industry meeting, a small processor got up and said, you know, when we find a positive, you know, we all have the responsibility to identify all of the contaminated product and get it off the market. Now, obviously that processor was under the impression that FSIS was going to be involved in that and that there is a goal of identifying through trace back and trace forward all the contaminated product, and that is not the case. And some consumers are under the impression that that's the case. At that public meeting, no one corrected the woman and said, no, we really don't try to do that.

And so I hope that today you make it clear

that that currently is not a goal of the regulatory program.

DR. ENGELJOHN: This is Engeljohn. I'll answer from the policy perspective of the issue for what we do today, which is for every FSIS positive or an AMS positive or other state lab positive that react to, in terms of pursue as a sample result that we're responding to, as if it were our own. There is a trace back. So that goes back to the product affected by that production lot that's represented by that sample and a determination made as to whether or not additional product is affected as well as to the supplying establishments. And that's what our STEPS database is intended to accomplish which is to go back and do a look at the production practices in place on the day on which that product was produced.

So from the product that's in the FSIS chain, for which a sample is represented by an FSIS equivalent sample, that does occur.

For the results associated with industry testing results, there presently is not a mechanism

in place in which the Agency follows up with the supplying establishments. When a slaughter establishment, a trim fabrication establishment or a grinding establishment or at retail finds a positive, that mechanism is not in place. It is a mechanism for which the Agency is looking into a process by which we could follow up on those positives, but that is not the case for the industry testing results. It is only the case with the FSIS ones.

MS. NESTOR: Okay. Just to be clear, tell me if I'm wrong. If FSIS finds a positive at a plant and the grinder identifies one single supplier, FSIS will go within several days and take some follow-up samples at the supplier, but there's no attempt to go back to the supplier that day and say Lot X was tested positive. Where else did you send all of the Lot X? Am I correct about that?

DR. ENGELJOHN: And the issue is when we find a positive, we identify that the production lot represented by that positive is microbiologically independent. So it's the data associated with that,

whatever the plants may have in terms of segregating that production lot from others. So that investigation is made, and then that makes a determination as to whether or not a recall is necessary to pull additional product out of the marketplace that may have been affected by that production sample because the lot may not have been properly identified.

At the same time, FSIS goes back to the supplying establishment and looks to see whether or not there's evidence on that day that the production process for which the lot was positive for would indicate that there's reason to believe other product is affected. So in that case, product moving from the supplier to the receiver would not necessarily be affected unless there's evidence that the product should be linked to it.

So the circumstances are that an immediate determination is made about product associated with a sampled lot.

MS. NESTOR: Well, I've done a FOIA, and I'll be looking at those records.

DR. ENGELJOHN: Okay.

MS. NESTOR: So we can go over it then, but if there are two suppliers, the name is put into a STEPS database, and if that plant's name comes up twice within 120 days, then the Agency goes back, right? So in the case where you have FSIS testing finds a positive with two or more suppliers, there is no immediate sampling done and no attempt to trace forward.

DR. ENGELJOHN: The issue related to follow up sampling is the one looking at current production practices, but in every case where there's a positive and the suppliers are identified, there's an 02 procedure back at the supplier in every case.

MS. NESTOR: Which means -- an 02 procedure is when FSIS goes and look at the plant records to see whether the plant noted that there was probably a problem with that production lot.

DR. ENGELJOHN: It looks at the production process to see if there's evidence that the production was properly processed that day.

MS. NESTOR: Right.

DR. ENGELJOHN: That is what they're rechecking and doing an investigation for.

MS. NESTOR: And I asked Ken Peterson at one point, when you go to the grinding plant, do you ever find that the grind plants' records indicate that there was a problem, and he says, no.

DR. ENGELJOHN: Okay.

MS. NESTOR: Okay. The records are basically not very helpful.

DR. ENGELJOHN: Okay. Are there other questions in the room before we go to the next presentation?

(No response.)

DR. ENGELJOHN: Okay. I'm going to give you an overview of the trim sampling compliance guidelines and the discussion following that, and we'll entertain until noontime, if there are questions that come up, related to that, or we'll move on with the agenda depending on what kind of response we get to the presentation that I make.

For those of you who don't know me, I am the Senior Strategic Risk Manager for the Agency.

It is my responsibility to look into what risk management practices we need to have in place to control public health related risks associated with the products that we regulate.

In the outline I'm going to give you today, we're going to go through the purpose of the guideline, the guideline's content and then next steps that I envision that the Policy Office would be pursuing with regards to this guidelines. And then we'll provide an opportunity for public comment on issues related to the guidance document, things that can be done to improve it or enhance it, things that we need to consider, and then as I can, I will provide clarification to any of the issues that you might raise during the discussion.

The purpose of the guideline was to first of all address the adverse events which are related to *E. coli* O157:H7 in both calendar years 2007 and through today in calendar year 2008. We had identified that the controls for O157:H7 are not adequate to protect public health and that we need to put in place additional control measures to

reduce risk.

Part of those adverse related activities are associated with outbreaks for which there's human health associated with raw beef products in both years. Prior to calendar year 2007, there were no reported human-related illnesses associated with the beef products for which we had a recall. But last year there were a record number in terms of those directly associated, and then we've had some as well this year.

In addition, we do track the percent positive rate in the verification testing results that we get from year to year. The testing results have been on the increase. Last year, at the end of the fiscal year, we were at .20, which was the level that we had been maintaining in ground beef for the prior couple of years, and by the end of the calendar year though, we were up at .37, nearly .4 percent by the end of the calendar year.

So far this year though, in comparison, for ground beef where we had .20 at this time last year, this year we have .40 in terms of our percent

positive rate. And we heard some information yesterday that it may be our testing methodology that may be contributing to this. The Agency does not believe that to be the case but it obviously is an issue for which we need to further assess whether or not the methodology does have an impact in terms of the percent positive rate.

For beef trim, we started this program in March of 2007. Our positive rate at this time last year was .42 in beef manufacturing trim versus today it's .71 in terms of the calendar year through October 7th. So we believe that there's an increase in terms of the indicators that we have for positive product getting through the slaughter operation, through the trim on fabrication operation into the grinding operations.

So the purpose of the guideline then was to provide information about what we think is appropriate design for sampling and testing programs. Our primary focus was on beef manufacturing trim because that's the opportunity at which industry has put in place, for the most part

in the large operations, 100 percent testing of all production lots associated with manufacturing trim.

From our checklist that we conducted last fall, in which we looked at production practices within the beef sector, not all operations or testing beef trim, but the large operations we believe to be, in fact, testing 100 percent of the production lots that go out the door.

We also wanted to provide information to assist in the development of the programs to assess adequacy of process control. Indicators other than O157:H7 could and should be used to indicate process control and from the questions that we asked from our checklist, identified that establishments generally are not at least documenting that they're looking at other microorganisms than O157:H7 or necessarily having production practices in place that would identify their systems are well controlled.

And then we wanted to provide some guidance in terms of sampling and testing programs that could lead to reductions in contaminated product, meaning

that testing alone as we've heard before, and that the Agency firmly believes testing cannot be used to put safety into the system. It's an indication of whether or not the system is working, but any effective system has to have a feedback loop so that there can be continuous improvement in that operation.

We did identify principles related to statistical process control for O157:H7, and I'll walk you through the primary principles that were in this document. We did identify the contamination during slaughter dressing is reasonably likely to occur even under good manufacturing practices. In the Agency's Federal Register documents in which we've told industry that we believe they need to reassess beginning in 1999, 2002, and again in 2005, and more specifically in 2002, the Agency said that we could not see how a slaughter operation could operate without at least one critical control point to address O157:H7 because we, the Agency, believe that O157:H7 is reasonably likely to occur in that operation.

The second principle was that contamination should be minimized to the maximum extent practical, realizing that we're not working in a sterile system whereby the carcasses will not become contaminated. At this time, there are no practical interventions in place that can eliminate completely O157:H7 other than on the carcass irradiation, but that is not used in this country on beef carcasses, and so we are working in the mode of minimizing to the maximum extent practical the level of contamination.

Thirdly, the decontamination treatment should remove *E. coli* O157 to the maximum extent practical and to a non-detectable level. In the Agency's documents that published in the Federal Register in 2002 and 2005, we did identify that our goal would be to ensure that production lots of product going out the door in each operation that has, in fact, passed pre-shipment review, should be at a level in which O157:H7 would be non-detectable.

With that then, in order to ensure that, there needs to be some understanding about the capability of the slaughter/dressing operation

through validation. This is an area for which we think that the Agency has not focused on the content and degree of validation that occurs with production practices. It is an area for which we are refocusing and again getting at some of the issues raised earlier, in that there are mechanisms in place to demonstrate that production systems are, in fact, known in terms of their capability to address the level of contamination coming into operations.

It is the Agency's belief that contamination levels likely do change over the course of the year due to seasonality effects with O157:H7. Again, we believe that contamination is greater during certain months of the year than in others and that the slaughter/dressing and other production practices should be adjusted to address this greater level of contamination, and so operations should know the capability of their systems and adjust them accordingly and have data to support that their systems are, in fact, capable.

And, in addition, microbiological indicators of process controls should be

established. The Agency has stressed that we do not see how you can demonstrate your system is producing a non-detectable level of O157:H7 without testing for *E. coli* O157:H7, but we also recognize it is not the organism that you would use to demonstrate that you have process control. There are other indicators of process control that any effective HACCP system should be using in addition to the monitoring and verification that would occur on a day in and day out basis. And so the indicators of process control should be used to demonstrate that there's continuous improvement for reductions of contamination in the operation.

Another principle was that sampling and testing for O157:H7 should occur at a frequency sufficient to find evidence of contamination exiting the slaughter dressing operation. Our best practice guidance documents that we've issued, that we know at least the larger operations are following, is that every production lot is sampled and tested for *E. coli* O157:H7 using an N-60 methodology designed to find contamination.

The results of that testing then should inform the HACCP system. There should be a feedback loop whereby information from the trim manufacturing operation should feed back to the slaughter operation in those circumstances where positives are found, and investigations should occur to determine whether or not the system was operating properly.

Likewise, when there are contamination events or other failures during the slaughter dressing operation, there should be a feedback loop to the trim manufacturing operation to inform whether or not the contamination is there when it might not otherwise be indicated to be there, simply because of actions that occurred during slaughter dressing, and so there should be a feedback loop in both directions.

In addition then, the adequacy of the sampling testing program should inform whether or not you're able to detect those kind of system failures that are occurring either sporadically or systemwide failures whereby more contamination is getting through the system than what you would

normally find.

We also identified the principle that the high prevalence months for O157:H7 are known and should be addressed. This is an area for which the Agency clearly is looking for additional information, research related to this issue as to whether or not the months in which high contamination events occurring are changing. We've traditionally looked at April through the end of September, October as the high prevalence months, although in the Agency's testing program, we do find a fair number of positives towards the end of the fall into the end of the year.

Of course, we're looking at ground beef and frozen product, and there are other issues related to that, but in any case, the high prevalence seasons have been known in this country for some time, and we believe that controls should be put in place to address the higher likelihood that this pathogen is coming on carcasses to the slaughter operations and that the events for contamination may be occurring at a higher rate and contamination may

be at a higher level during these periods of time and that production practices should, in fact, be adjusted to address this higher expected contaminating event, and that the data should be present to show that, in fact, that process is controlled.

The Agency believes that the production operations should be controlling at the low prevalence rate in terms of percent positives and in terms of performance during the slaughter dressing operation.

We believe that the contamination may overwhelm these slaughter dressing operation such that more contamination is simply getting through the system, and in part, this is what we believe is happening during the high prevalence season months, and that we find more positives during this period of time indicating that more product is, in fact, contaminated perhaps at low levels, but every opportunity of testing is an opportunity to find the organism and to remove product from the system and then to adjust the system.

Trim testing and sampling for O157:H7 provides an indication of the adequacy of the prior control. Programs should be designed to provide high confidence that contamination is minimized and at a low level.

We identified the principle that sporadic positive test results are expected. A well operating program should be one designed to find positives and to address those positives, and a system should be articulated such that you know the difference between your sporadic rate that you expect at all times during the year and evidence that there is process control failure. We believe that a production process cannot operate properly if you can't identify a distinction between the two.

With this, then, we identified that multiple positive test results involving same source materials, which generally is what we're dealing with when we're talking about beef manufacturing trim, is evidence of a high event day. It could indicate that there is a systemic failure either developing or that has developed to adequately

control for the presence of O157:H7 and therefore the process is out of control.

In these circumstances, negative test results are suspect by the Agency whereby we would consider them to be false negatives and that insanitary conditions likely have occurred in that operation such that not only is the trim and the negative test on trim affected, but primal cuts and other products produced in that operation are, in fact, affected by that determination. This is in part the determinations that the Agency used in a recent recall from this past summer in which we declared that there were insanitary conditions and primal cuts in addition to manufacturing trim were affected by that decision.

From this, then, our testing results for trim and how we use them, FSIS did conduct a nationwide baseline survey in which we looked for the presence of O157:H7 in manufacturing trim available for commerce. The criteria were specifically established that we would only use the testing results from trim that had been released by

the establishment for the production in raw ground beef operations. This is not a baseline study to look for the prevalence of O157 on beef. This was a designed study to look for the prevalence of O157 on trim that had been produced in an effectively operating system as determined by each establishment and released for the purpose of using in raw ground beef.

Our results identified that the trim positive rate then was .68 percent of the samples that we tested were positive. Some of these samples were pretested by industry. The survey was done nearly three years ago, between three and two and a half years ago, and so it was at a time for which the larger operations were testing 100 percent of their trim for O157:H7, that many smaller operations were not, and today many small operations are not testing the trim as well. But in any case, at that time, the samples of available for raw ground beef production tested .68 percent positive.

So that is the percent positive rate that we found in this nationwide baseline survey.

Some, but not all of these samples were pretested, and we identified that. The Agency does not have information to identify how m any of the production lots we sampled were pretested.

We also had anecdotal information from industry that suggested that the average annual positive rate in pretested trim despite industry is between 1 and 2 percent, realizing that the rates are probably different in the low prevalent season than in the high prevalent season, but the average was between 1 and 2 percent.

So the FSIS then selected 1.5 percent as a guidance value for purposes of deriving a high event day criteria for identifying potentially false negative results. Again, it was important to identify a percent positive rate in manufacturing trim likely available for commerce in order to begin the process of discerning statistically anyway the difference between sporadic positives and those which might indicate that there is a systems failure because there is a high number of positives in like source product.

And, again, our production practices within the industry, and that has been accepted by the Agency, is that we have point source contamination generally when good manufacturing practices are in place, because there are same source materials used in the production of manufacturing trim and trim is segregated into individual units based on space and time, even though they have generally same source materials in them.

And so it was important to be able to discern differences as to sporadic positives or indications that the contamination rate is actually high.

For verification testing, then testing should be for both O157:H7 as well as for microbial indicators or process control. Although in the National Advisory Committee for Micro Criteria for Foods document on HACCP, that committee did identify that generally a HACCP system should not require end product testing if the validated safeguards in place are, in fact, effective.

However, with O157:H7 being an adulterant

in raw product and there are no interventions widely used that would eliminate this pathogen in raw products, then at this point in time, the Agency's belief is that microbiological testing of finished product in this case, manufacturing trim, is, in fact, a necessary component to ensure that adequate controls are in place for O157:H7.

Testing should occur at all opportunities where raw beef is handled prior to the sale to the consumer. Again this gets at the issue of ensuring that there is a non-detectable level of O157:H7 in raw beef as it goes through the system.

Each testing event provides added confidence that O157:H7 was present, if it is present at a low level sufficient to remain non-detectable.

The Agency in this guidance document then did provide some guidance to small and very small plants who, for the most part, are purchasers of beef manufacturing trim for use in their production practices. We do provide guidance to small plants in order to give them resources and to help them

make some decisions about how they can demonstrate that their systems individually are operating properly.

It's not enough just simply to rely upon the grant of inspection for product moving from one establishment to another. That grant of inspection is an evidence from the Agency that the system producing that product was operating in accordance with the system that that establishment designed. It is not a guarantee that the product is free of O157:H7.

And so the guidance that we provided to small plants was based on the premise that the source materials were tested 100 percent. Production lots were, in fact, pretested. So this would give minimum frequencies for testing assumed that these production lots were pretested, and then we provided guidance that there should be increased testing in terms of high prevalent seasons so that there can be added confidence that if low level contamination was getting into the system, that it might be found.

We segregated this into the four categories that were mentioned yesterday in that we have our inspectors collect information at least identifying on each sample form the production in that particular establishment on the day in which the sample is collected. And so we segregated it into those establishments producing greater than 250,000 pounds of product a day versus those who produce more than 50,000 but less than or equal to 250,000 a day, and then those that produce more than 1,000 pounds but less than or equal to 50,000 pounds per day, and then those that produce less than or equal to 1,000 pounds per day. This ranged from greater testing in the largest volume category to more than one sample per month, in the next highest category at least monthly, the third highest category then being at least once every other month, and then for those smallest operations who are producing product for which they're purchasing trim at least once a quarter.

The sampling guideline then as well identified that the establishments must define the

production lot which is, for the most part, a sampled lot. They're one and the same.

If the same source materials are present in other production lots, establishing microbiological independence is therefore essential, and so they must have a program designed such that a sample collection procedure can find point source contamination, and again our guidance is that this should be at least N-60. From our checklist that we conducted last fall, we did identify that there are many establishments using something other than N-60. In any case, we believe that at this point in time, N-60 is the gold standard that should be applied across the board on beef manufacturing trim.

The production lot size is a critical consideration. The larger the lot size, the greater the vulnerability for not finding O157:H7. It's the more product then is impacted by the decision of that sample.

The Agency's guidance is that it's best to collect the entire sample from each combo bin for a composited sample representing the lot. We know

that this is not the common industry practice, but we believe that it does reduce risk if, in fact, each individual combo bin is treated separately. And then if box trim is available, such that it's in 60 pound boxes or some other size box and is sent into commerce in that manner, then there should be samplings from one or more of those boxes or units in order to get a composited sample representing the lot.

It's important then in the guidance that we identified that you need to understand the lab testing method capability. FSIS analyzes 325 grams of a composited sample. There is a need to know the laboratory procedure that is in place within each operation because each lab can analyze things differently, and we know that industry for the most part doesn't specifically look for *E. coli* O157:H7. It's looking for generally a host of triggers or target genes or other components that would identify more than just O157:H7, but for which that screen is, in fact, including O157:H7, and we do consider this to be a more conservative approach than looking

only for O157:H7 because it is our belief that samples positive for O157:H7 likely are also positive for non-O157:H7 Shiga Toxin forming *E. colis* which is an issue for which the Agency identified that we are pursuing in terms of developing with ARS laboratory methodologies to, in fact, look for six of those particular components in the samples that we collect.

We also identified that there was industry practice that from an efficiency standpoint, some laboratories do, in fact, enrich samples and then combine those samples so that they're analyzing fewer samples for an efficiency measure but have also developed validating data to demonstrate that they don't lose any sensitivity or specificity with regards to their methodology.

And so in some cases, samples come in, are individually enriched and then aliquots are pulled from those samples. They're combined. I put composited here. I think pooled is probably a more appropriate term used by the laboratories, but in any case, that sample is analyzed. If it's

positive, then there may be a determination made to go back and look at the individual or enriched samples to find out which particular production was, in fact, positive and we heard yesterday that there may be some concerns about that process, but in any case, we would expect there to be some validation associated with that process. But it is one way to ensure some lab efficiency in terms of decreasing the number of samples analyzed but it also does present some risk with regards to product that may be released that actually might be positive but only tested negative.

In this case, going back and looking at the individual enrichment, it would not be considered retesting by the Agency, and I do want to stress that the Agency considers any retesting of positive product to be inappropriate, and we would not find that acceptable I think under any circumstance. So we do draw a distinction between further characterizing whether or not a sample is negative or not, but not first looking at a positive sample and then trying to provide that it actually was

negative.

We think the proper interpretation of the sampling and testing results for a well-designed program is critical for ensuring that false negative product is not released for use in raw ground beef.

Using the data the Agency has available to it, because the Agency has never received information from industry as to what the positive rate is for the trim programs for which they operate, so this would be the product for which establishments release into commerce as raw beef produced product, the Agency is then using the 1.5 percent as a guidance criteria, with that then some measures using statistical parameters can be identified to give us a 95 percent confidence level as to whether or not a production process is producing product at greater than that 1.5 percent positive rate that I identified as a guidance level.

In this particular case, the guidance document has a table in it that identified a variety of different positive numbers with regards to production lot sizes and to make a determination as

to whether or not there are more positives than what would be expected if the contamination rate was less than 1.5 percent in all those production lots.

With that then, if there were 55 individual production lots, these would be microbiologically independent production lots, through N-60 testing, for a given period of time, and again this could be in a day, this could be over the course of time, particularly for small plants, in this case 3 positives could indicate a systematic failure for control of O157:H7 in the source materials. Again, this is using the assumptions that the Agency provided on the data that we have since we have no other data to use as a guide. We did identify in the guidance document that each individual establishment should identify its criteria for discerning when product is, in fact, more than just evidence as having more than sporadic positives, in this case, the determination being made between sporadic and systemic failure, realizing that the industry uses a screening methodology that's looking more broadly, more conservatively from our

perspective, looking at more than just O157:H7, the positive rate would be expected to be higher and that that might be criteria that an individual establishment might use for its distinction between sporadic positives and those that evidence the process might be out of control.

We did identify that a properly designed raw beef HACCP system then would have feedback mechanisms to reduce the likelihood of systemic failure to control for O157:H7. Again, each positive event should, in fact, lead to an investigation to understand whether or not the production practices at slaughter/dressing were, in fact, properly applied as well as whether or not the trim testing results provide some evidence that the system might not be operating as expected. Again, this might be due to a combination of more contamination coming into the system or a particular failure of the system to prevent the contamination from getting out of the system.

Again, the document was written for the purposeful intent of looking at slaughter operations

that also fabricate the trim, so that there could be a very direct feedback loop between the two operations. However, this guidance is intended to also be effective for operations that purchase trim and that the individuals who purchase that trim and have a testing program in place on the trim or the ground beef would be providing feedback to the supplier so that there could be evidence built to demonstrate that the systems might, in fact, not be properly controlling for O157:H7.

In terms of next steps, these are the intentions of the Policy Office with regards to where we would like to go with the guidance document. We're here today to get verbal comments, but we are, as well, accepting written comments through November 17th. The intention is to get information that would inform this document so it could be good guidance for industry as well as for FSIS personnel so that when they look at a food safety system, they can, in fact, make some distinctions as to whether or not the program is actually designed to control for O157:H7. This

would be at all points in the production process, and this would be looking to see if there is a feedback loop between slaughter, between trim manufacturing, between primal cut develop and bench trim, between that and mechanically tenderized steak operations and then with grinding operations.

We believe that the document then can serve as a useful tool. We're looking for your input as to how to enhance it and improve it so that it is, in fact, appropriately articulating what a good operating system should be reflecting, and we also think that it's necessary through the public comment to help ensure that we have an understanding of the controls for O157:H7 throughout the raw beef operations as well as what the Agency does for its controls, and that it's critical to have consistency and uniformity where practical in terms of the design of the sampling and trim programs.

It is our intention to update the guidance with the input that we do get and then to issue it as final guidance after we've fully assessed the comments and reviewed it.

If we were to use this document in terms of a compliance guideline, we obviously would post it to the webpage. We're asking for comment on it now. The Agency would continuously update it as new information is presented that we need to consider.

We also think that it would serve as a useful tool in terms of training, particularly for our own employees but through some of the activities that Karlease identified through outreach for industry as well.

And so with that, I think, Mr. Almanza, I'll just ask if there are any questions or comments from the audience, and we'll start there.

Yes, we have a question out here.

MS. HATCH: Yes, my name is Michelle Hatch. I'm with Greater Omaha, and I'm also a microbiologist. I have a question on more of the data. Do you plan on taking the data at all and breaking it down into I guess different components in order to not have it so broad for future references in order to get past some of the old data that's being utilized from 2003, 2004, so that next

year in this type of meeting or things like that, in moving forward, we can actually have a certain set year of when we'll actually have some good comparisons is what I'm referring to here.

DR. ENGELJOHN: Okay. Well, I can say with regards to the baseline data that we had, this was from data that's now more than a couple of years old, and so the Agency has identified, it is our intention to do, as continuously as we can, baselines, and so one of the issues would be for the Agency to consider what are we doing with regards to baselines. Is there a way that we continuously have a statistical baseline such that we're not doing them once every 5 years or every 10 years because again recognizing this baseline data is actually from a couple of years ago.

So there is the intention to do that, but presently we have that number. It's the only number that we actually have for a baseline on beef manufacturing trim.

The other data that we have then relates to our annual percent positive rate and so we look at

that on an annual basis. The Agency has tied the percent positive rate that we find in our regulatory testing program to the Healthy People 2010 Goals so that we know, as was mentioned at the beginning of the meeting yesterday, what the contribution of ground beef is to the public health burden. We haven't yet built in the measure for the contribution of trim to that. So there will be the intention of looking at all of the components that are used for raw ground beef, not just beef manufacturing trim. One of the National Advisory Committee recommendations to us was that we should be looking at head meat, cheek meat, low temperature rendered products which we presently don't have built into a baseline study, and we really don't know what the contribution is on those percent positive rates. So there are a number of things I think the Agency is looking at to see what is the best reflection of the percent positive rate in products available for production, and the Agency previously hadn't considered a baseline study to actually identify what is the prevalence of O157 on

carcasses before the interventions which I think would also be an important thing for us to look at.

So there are a number of things that we're considering.

Any other questions? Yes.

MS. ROSENBAUM: Good morning. I'm Donna Rosenbaum from STOP, Safe Tables Our Priority, and I also have concerns about the baseline studies, and I appreciate the fact that we're here studying sampling and studying what's been done so far. I think the problem is that we're two to three years behind the ball here with what's already rolling down the track and being done. And it would have been nice to have a meeting like this in 2004, 2005. We can't do that. We can't go back, but in looking at the data that you've got and what you're basing things on, I have to agree that I'm very concerned that the variable of the prevalence rate is so important in informing the whole system, that without that data, we don't see how you can build an accurate system around it without knowing that at the very beginning.

So I think while you want to take what you've got and run with it and do the best you can at the time, I think you've got to do more than think about getting baseline data. You have to have good baseline data now, going forward, continue it. This organism evolves and changes over time as do industry practices. You're going to have to continuously be monitoring for this organism in trim, in ground beef, to have real good information that's informing your systems.

And without that, we're a little unsure of how you can base judgments and inform the system at this point. You know, taking a 1.5 number at this point is a little bit like a rabbit out of the hat. We don't know what it is and that variable is so important for the system. So you really have to move very quickly to get as much information as you can to inform the system to put something in place that's going to be effective over time.

DR. ENGELJOHN: Thank you. And I think your points are well taken. We recognize that, and we certainly are looking at ways that we can get at

that in a shorter timeframe than what normally occurs for us, which is to design a study and operate it for a year and then have that data.

So continuous baselines, ways to look at the industries positive rate to inform that as well would be one thing for us to consider that we have never done before. So, thank you. We'll certainly look into that.

Yes.

MS. KOWALCYK: Barb Kowalcyk, CFI. First of all, I want to say I was happy with a lot of the things that I was seeing in the document. I think it's going in the right direction.

I did have a couple of concerns. One is I think there needs to be a better definition of what microbiological independence is. It seemed awfully vague to me, and I'd like to see much clearer and more concrete definitions because this is going to be critical in determining what product gets diverted and what product doesn't, and I just think that the document is a little vague, and I'd like to hear more thoughts on that.

The other thing is if you go back to your slide where you have the testing for process control where you had that little chart, and it said you have something like, for plants that produce more than 250,000 pounds a day, you're going to test greater than 1 per month, and I believe if I recall correctly from the compliance document, that there's, I think it's Table 1, FSIS had said that in order to determine if a process was out of control, you'd have to see two or more positives out of 24 samples.

Now, I understand that based on what you said, Dan, this is assuming that the product had already gone through process control sampling, but earlier, it's not in the document to me about that because based on this table, my initial reaction was it could take somebody three years to figure out that their process is out of control and as a consumer, that's unacceptable. You know, it needs to be very clear that this will not provide adequate feedback on process control in a timely manner, yet throughout your presentation, throughout the

document that's what you said the point of this testing is, is to provide an assessment of process control and I think most people would agree that, you know, if you're doing testing once, four times a year, it would take you six years to figure out that your process is out of control.

DR. ENGELJOHN: Thank you. I appreciate that, and I will say being one of the principal authors of the document, that the document is a compilation of multiple things, and there needs to be some clear distinctions very distinctly between a slaughter fabrication operation that has control at that point and then different guidance perhaps developed for those who receive that product and how they would use it as well as for grinders.

So it has a mishmash of all that's contained within it, and I think your point's well taken. We can definitely work on that issue. And we'd welcome any written comments on that on how to improve it as well.

MS. JOHNSON: Do you want to check the phone line, Dr. Engeljohn? Check the phone line as

well.

DR. ENGELJOHN: Oh, yes. Before I take this next one in the room, Operator, are there any questions from the callers?

OPERATOR: At this time, I have no questions in queue. If you'd like to ask a question, please press star and 1.

DR. ENGELJOHN: Are there individuals on the line?

OPERATOR: Yes, we have about 16, 18 participants.

DR. ENGELJOHN: Wonderful. Okay. Thank you. Thank you. Yes, Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Dan, I've got a question about how involved the Agency is going to be in these programs. You know, reserving judgment about whether or not we can support the process control aspect that you've proposed, I mean it's my understanding that inspectors have not been very involved at all in making sure that plants are following up on a positive and, you know, once you have multiple

positives, that gets to be another level of analysis and then you also have the feedback loop between the slaughter floor and the trim floor which, you know, that product is going to be on the trim floor. I don't know what it is, maybe two days later or three days later, and so, you know, I guess my question is has OFO agreed to allow the inspectors to participate in this and have you started drafting any instructions that inspectors will be, you know, following when this is in place?

DR. ENGELJOHN: Thank you. This is Engeljohn. What I would say is that within the Agency presently, we recognize that the systems we put in place have really not focused upon this systems approach other than for the most part our EIAOs looking at our food safety assessments, to look at the overall food safety system, and so the individual employees in the plant every day have been tasked with looking at plant data but there's a great deal more that needs to be done than just looking at the data. And so the systems we have in place presently aren't designed actually to address

it as comprehensively as what they could be but I can tell you that we are working on a couple of policy documents that are going through the clearance process which gives the internal program areas the opportunity to comment but, but for the most part, we are focusing on slaughter/dressing and those activities there, as well as in those operations that have trim fabrication as part of that slaughter operation, how then the two operations need to be looked at as a system which isn't specifically what we would do today in a very defined way. So that would be in the form of a policy document that is under development.

If it does issue, and I think there's merit to it, but we certainly will work that through that process, there will need to be a very strong training component with that as well, and if that policy moves forward, clearly it would have the buy in of all the program areas within the Agency.

So from our perspective, we recognize we need to focus on a more systemic approach in plant every day as opposed to relying upon the food safety

assessment specifically to identify problems, and so that is an area that we are, in fact, focused.

Yes.

MS. HATCH: Yes, Michelle Hatch with Greater Omaha. Yes, I don't kind of want to take away from that piece of it, and I just want to say that as safety and being a U.S., you know, resident and everything, we have the safest food basically in the United States and we got that from everybody in this room coming together, and first of all, I just want to make sure that nobody loses sight of that. So that means that somewhere along the line, FSIS, the industry, the consumer groups, everybody has come together to make that happen, and we just need to make sure that everybody knows that it has been a collaborative effort in making that happen because, not one industry or group, and that has solely been able to do that and make this a process, and so it has been a collaborative effort among everybody.

And I think that, Dr. Engeljohn, that, you know, the FSIS in the districts, we have a really great district actually in the area that we are,

that really uphold a lot of what's been up here on these bulletins and the PowerPoints, and I think it's more about the unity of going across the districts, and I think probably in Karlease Kelly's outreach programs, that it's a matter of gathering information as to which districts are actually doing better in conveying the messages from Washington and utilizing them in your outreach programs to the other districts, would be just a recommendation.

DR. ENGELJOHN: Thank you. I do want to also just touch on that. I agree that there does need to be a good working relationship at the plant level with the inspection force, and the inconsistencies across district lines is always an issue that I think we tackle on a day-to-day basis.

I will say though that we do know that there are differences in the levels of control amongst the establishments, and coming up with at least some minimum level of what we would expect for everyone, not on a regulatory format at this point in time, but at least getting all operations up to having programs in place that at least are

demonstrated to be effective is something that we will continue to strive for, and I think it does point out there are differences amongst establishments. There are poor performing establishments for which the Agency is focused and it's not focused just to put our resources there and continue to get them there but it's to ensure that those establishments actually develop their programs into effective food safety systems and that's a focus I think that we need across the districts we have a need to put a little more effort. So thank you.

Yes, in the back.

MR. DANIELSON: Thank you. Dean Danielson, Tyson. Dan, and I hope everybody, you know, everybody did hear you, training, things as we learn, we implement things and develop new things to address the new learnings and training is a very difficult task across multiple companies, multiple plants and FSIS. I mean this is a very complex matter that we're talking about, not only just how to go out and cut a piece of meat off, but then as

these reviewers or EIOs go in or company people, as we go review raw material suppliers and our auditors, it's very, very complex, the lab methods that are in place. How do you look at validation data and assess that within the process that's there. Is it legitimate? Is it, you know, is it -- I use different slang terms, but is it worthless or is it not very good. So it's very challenging to get people up to speed and to get them.

I've got an anecdotal story here for you, Dan, and just last week, this was in FSA, we were having in one of our plants, the EIAO, this is the first time in history, in my history that this ever happened, the EIAO went to the laboratory to review laboratory procedures. This never happened before. That's an outcome of new learnings and trainings, and then interestingly enough, the EIAO observed that in our procedure, we had a modification in the enrichment process than what the manufacturer had in their prescription. And he saw that. This is great. I mean a great observation that was made, an astute observation with my auditors doing raw

material suppliers, I would expect them to see the same thing, and so then he drove us through the process of showing us -- show us your validation to support this alternative enrichment process and we did have that, and it was an improvement over, from our standpoint, for validation.

But I make that as an observation. It's the first time this ever happened. I think it's very good when you guys go into the plant, and for everybody else to listen to this, it's a long complex process and it takes a lot of training and education and intuitive people to go in and look at these things that are going on and the more exposures that they have to them. It was heartening to me to see that type of an in depth analysis take place rather than, you know, don't take this too hard but the NRs we get, a piece of paper that's not signed or a date that might be out, you know, those types of things that come out of the FSAs that are more, you know, mundane than a true interpretative observation of a process validation difference, that's good stuff. We all need to be better at

that. So I'm heartened by that. My people got all excited when this happened. I thought it was great. I thought it was great. Thank you.

DR. ENGELJOHN: Thank you. I appreciate that. Anytime we get that anecdotal information, it's helpful.

I will say at least from a commitment from the Policy Office and the Agency, we are trying to put out policies that have delayed effective dates so that there is, in fact, a training component built into them so that before they're implemented, there actually is an understanding of the intent and that we're actually on the same page both our own employees and the industry as to what we're trying to do. How we teach somebody to think is a different issue. I think that we can learn a great deal from you in terms of the audits that you do, the types of things you look for to help inform us. It is an area where I think we need to focus more, and I'm glad our employees are stepping up to the plate. So thank you for providing that. Yes.

MS. KOWALCYK: Barb Kowalcyk, CFI. I just

wanted to play off a comment that he made, and this is a very complex issue, and I really think that, I just want to reiterate the point that I made yesterday is that FSIS really needs to provide plants with the technical assistance so that they can develop sampling plans.

I'd like to take it even one step further because I don't think -- you're going to have to have some sort of oversight on the development of the sampling plans and the implementation of the sampling plans because, as the gentleman just pointed out, garbage in gets you garbage out, okay. So you need to have a good robust sampling plan that's implemented correctly so then you can generalize and interpret your results. And I don't think that the inspectors have the capabilities or the time actually to do those activities. So one thing that we have advocated for is that sampling plans for the plants should be certified or approved through some mechanism either by FSIS or by an independent third party. And that will make sure that you're really achieving the goals that you want

your microbiological testing programs to achieve. So that's the one comment.

The other comment I'd like to make briefly since I know there's others waiting is I think really there needs to be more discussion and focus on the fact that in recognizing that you can't have a one-size fits all sampling plan, you really need to talk more about the power of your testing programs, and make sure that they're again -- it's a way to evaluate whether or not they're meeting the objectives that you've set forth.

DR. ENGELJOHN: Okay. Thank you. Yes.

MS. ROSENBAUM: Donna Rosenbaum with STOP again, and I'd like to take a comment a little further again on the testing program and on the prevalence rate, and reference that in terms of the overall goals of this program. So I have a comment and a question.

I understand and we support the notion of differentiating between and having to have a system differentiating between total system overload with contamination rates indicating that something has

really gone wrong versus there being a low level sporadic rate that will be background and that we'll never be able to get this to zero.

However, there's a difference between saying that and then taking the position that that level that you've set it at, that you know that there's sporadic rate of is okay, and this is a lethal pathogen. This is just about the second now most important toxin to man, and we need to have a system. I would like to know whether it is a goal of USDA in setting forth this plan to drive that number down over time, and if so, we'd like to see that much more thoroughly implemented throughout the guidance document.

DR. ENGELJOHN: Okay.

MS. ROSENBAUM: And we saw some comments yesterday that indicated that some people in the industry are looking at it that way, but we'd like to see that reflected in the USDA material so that we're not, you know, 10 years ago after HACCP started with standards that are not being driven down, that have kind of just set there and set in

place. Especially with this pathogen, if you're looking at this pathogen, it's going to be necessary to do things and acknowledge that it might be very, very small and incremental over time, but we do need to have something in place that drives it down.

DR. ENGELJOHN: Great. I appreciate that. I will say the Agency does have its strategic plan posted. It is available to look at, and it is designed actually -- it doesn't have a specific performance measure in it for beef trim. It's specific at this time for ground beef, but the Agency has a number of other performance measures that we're working towards, and they're built with the intention of having continuous improvement. They are not set at a level and they stay there. They're actually built so that we're constantly trying to drive down the rate that we have.

So it is one way to articulate it, but clearly we haven't articulated that in a manner that you can see that. But I will say the way that presently our risk management programs are designed, they are designed to identify what we believe to be

the current practice and then to set a level that's going to drive that down further until the point at which we know that there needs to be some substantive intervention in place perhaps to take it to that next level. We don't think we're there with O157, and so there is the design to continuously lower that. We'll better articulate that.

I think you have a follow up.

MS. ROSENBAUM: Would you consider setting a time. I don't know what that time would be, but something that everybody would agree upon, whereby a year after you -- the anniversary date of every year after you release the compliance document and it's complete or you're setting some type of standard, to go back and revisit it so that it's not just arbitrary out there, well, when we get to it, we'll do it. I think that should be set forth in the plan from the very beginning.

DR. ENGELJOHN: Okay. I would agree, and I think it's responsible that we have -- as I said, we would continuously update them, but we will put forward an action plan that does, in fact, put some

measures in there. It's also important for the Agency to know that the guidance we put in place is effective. And we do need input on that as to whether or not what we've constructed will be effective, and then as Karlease mentioned with our training, it's not good enough just to deliver it. You actually have to have a measure of success. Is it working?

So I agree. An effective program would design an action plan to get at that, and we'll do a better job of articulating it.

Yes.

MS. BUCK: This is Pat Buck from the Center for Foodborne Illness, Research and Prevention. And one thing that I think is kind of important as you're putting this plan together is something that the gentleman brought up just a little bit ago, and that is the need to have the types of training that's actually going to be hands on. Too many people have to learn -- I mean I'm a teacher. Too many people only learn a complicated and detailed operation like what you're asking them to do by

hands on training, and that one on one training would then, of course, I think drive your inspection force as well as the people working in the industry to realize that this is really crucially important that we do this correctly. So I would encourage when you're putting your plans together, the other thing I would encourage you to do, is make sure that the plans are then being implemented because I have heard from too many different sources that these HACCP plans get written and then as soon as the inspector walks out the door or they know FSIS is not coming back, that the plan goes into a drawer and is not followed correctly.

Now I do not think that happens with the industries that are committed to food safety, but I do think that that does happen, and we need to weed out people that abandon good food safety protocols. Thank you.

DR. ENGELJOHN: Thank you. Our session goes until noon, so I'm going to keep you here until you stop asking questions. It's not an encouragement to stop asking questions, but I do

want your input. We do want to improve the documents we put together.

If I could, Operator, are there any questions on the phone?

OPERATOR: I have no questions in queue at this time.

DR. ENGELJOHN: Okay. Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Someone's comment reminded me about -- well, a number of comments have reminded me about the issue of consistency and, you know, I really think that the Agency needs to put in place a constant practice of evaluating the extent to which the policies are being enforced in a consistent manner. I mean in the last several months, I've heard about plants that had FSAs, you know, different plants of the same company, that used the same plan in different districts and the plan is acceptable in one district and not in another. And that's really ridiculous.

Anytime I hear anything from an inspector, you know, I reach out to inspectors all around the

country, and too often I hear that a policy in one area of the country is not being followed in another area of the country. We were talking yesterday about the definition of fecal. Supposedly that was, you know, in a written document as early as, you know, prior to HACCP and I was hearing about changing from inspectors years into HACCP.

Dan, you and I had a discussion a while ago about the Tech Center and the instruction that was being given to inspectors when they go for training, you know, when they would ask, what do I do if I go back to my plant, and my supervisor tells me to do something other than what I've learned in my training, and what they were told is follow your supervisor. And we came up with some kind of process where anytime there was a difference between a supervisor and an inspector, that conflict would get elevated and a determination would be made.

I just heard recently, and I'll probably be coming to you with the detailed privately, about a plant, again, the inspector has Tech Center instructions, and the supervisor said we're not

doing it this way, you better do it this way. And apparently, you know, he got OFO signoff on that.

So that kind of inconsistency and, you know, regulation by location just really from a consumer standpoint is really just not good enough.

DR. ENGELJOHN: Thank you. Barbara.

MS. KOWALCYK: Barb Kowalcyk from CFI again. Two things that I think would improve the sampling and improve the document that I'd like to see added is, one, you know, one of the things your sampling plan ought to do is minimize bias and this is either where you're talking about industry or FSIS sampling. People inherently will want to do better if they know they're going to be tested. So if there is some way to kind of blind the plant workers to the fact that a test is going to be occur, it would be very beneficial to do that, and I know, I think I've brought this up previously privately with people with FSIS and I know it's difficult, but I think there are ways that you could get around that, so the plant doesn't know when FSIS is going to be taking a sample. Even when the plant

itself is doing testing, I would think that they would want to in some way blind their workers to the fact that a test is being taken ahead of time because you really want to get as representative a sample as possible.

Along that same line, I think that there needs to be more discussed about stratified sampling, the whole idea, and you do touch upon this in the document which I think is good, but the whole idea that if you just take your N-60 or whatever N you choose, right off the top of the combo bins, it's really not being representative, and I think that both FSIS and industry to think about ways that you could actually stratify those combo binds to effectively get a better representation of what the lot is really like, and I think there probably are ways that you could do that. You just need to -- I think it'll take sitting down and really working it out and looking at the whole process to determine how you could achieve that.

DR. ENGELJOHN: Okay. Thank you. I will say that to the extent that we need to make clearer

sometimes why we make the policy decisions that we do, O157:H7 being an adulterant does create some circumstances in which we've pulled samples, and we don't pull samples in a manner such that there's a likelihood that products have been released into commerce. So we have some restrictions, but we certainly can look into other things to get at the issue of being less announced or less -- a process by which we can look at that, and I don't know what that is, but we certainly can look at that.

On the stratified sampling, I would say the Agency, again from a policy perspective in terms of where we're going and Dr. Esteban mentioned yesterday, we're looking at some other things in terms of what we could do to do our job different and perhaps better. I think we recognize that pulling those excision samples is a time consuming process which if there were tools available to do it differently so that we can get at perhaps more of a representation from within the combo bin, using the tool that would get external surface tissue only, and there are tools available that industry's

actually using in some of their own establishments, might not be commercially available yet, but we're looking into what can we be doing to sample it different.

So new technologies on that is something we're always looking at to improve our opportunities. And I would say that we look at differences in our verification testing program when we're just doing our normal verification check versus when we have reason to go in and do a more thorough evaluation. It does present the opportunity to collect samples differently, perhaps collect more samples in a particular production lot in order to get better information about that process, and there is less notice given on those. So there are some opportunities to look at how we can sample differently.

So thank you for the input, and if you are going to put that in your comments and have some suggestions that, too, would be helpful.

Jill.

DR. HOLLINGSWORTH: Dan, if you could just

help me understand a little bit on this small and very small plant frequency chart that you have, am I correct in assuming that that is the frequency for small plants that receive trim and boneless beef that they intend to grind and their frequency of every one, two or three months is based on the fact that the incoming product, the source material they receive, has already been tested. So this is actually a second test.

DR. ENGELJOHN: Yes.

DR. HOLLINGSWORTH: I wanted to check on that. And secondly --

DR. ENGELJOHN: I'll just answer that first.

DR. HOLLINGSWORTH: Okay.

DR. ENGELJOHN: Yes, the document actually explicitly does say there is a presumption that there was 100 percent testing of all the source materials elsewhere, being the first thing. And that as the Agency recommended, we think that the receiver should test the product at that level and have a program in place on the finished product

perhaps, if they're grinding it as well. But we realize there are practical considerations particularly for small and very small plants in terms of what they can afford to do and the information they have.

I also just want to point out that because it is the design of many programs where O157 testing is the only check that's in place in terms of the process, and we believe there should be other process controls in place to give real time information about the production process. So the O157:H7 testing isn't the only thing that's occurring. It's occurring for a specific purpose of looking for O157, not looking at their process specifically. Okay.

DR. HOLLINGSWORTH: But so that is a second test that's done on pretested product?

DR. ENGELJOHN: Yes.

DR. HOLLINGSWORTH: Yes. Okay.

DR. ENGELJOHN: Every opportunity to test we think should be taken. Okay. At retail as well, okay.

DR. HOLLINGSWORTH: Well, we'll talk about that. And then I guess since this only applies to those plants receiving this pretested product, this would not be the chart that would apply to a small or very small slaughter operation that's also generating trim itself.

DR. ENGELJOHN: We think that that operation should have a program in place to address their trim as well, and our recommendation is 100 percent of the trim should be addressed, whether it be from their own production or bench trim that they're pulling in from primal cuts in some fashion. If it hasn't been pretested, any systems approach, then they need to have in place a supplemental program.

DR. HOLLINGSWORTH: Okay. Thank you.

DR. ENGELJOHN: I'll let you think for a moment but I will say that Mr. Almanza I think is of a like mind that in order to beat the lunchtime crowd, we might let you go to lunch and then come back and then finish the afternoon earlier. So it's 11:00 now. I suggest that we, unless you have more

questions, and I'd love to have your input. You can talk to me as well off-line, but I think we'll break. I think we gave you an hour for lunch, and so if you could be back here at noon, then we'll start the afternoon session. Okay. Thank you.

(Whereupon, at 11:00 a.m., a luncheon recess was taken.)

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

(12:00 p.m.)

MR. ALMANZA: So the presentation is going to be Draft Labeling Policy Guidance for N-60 Testing Claims for Boneless Beef Manufacturing Trimmings Concerning *E. coli* O157:H7, and doing the presentation will be Rosalyn Murphy-Jenkins. She's a Senior Technical Advisor on Labeling and Program Delivery in the Office of Policy and Program Development.

The staff has primary responsibility for the development and delivery of USDA policies and programs on food labeling, food standards, and amenability used in the safe production of meat, poultry and egg products distributed in domestic commerce and exported from the United States.

She has been with the labeling and consumer protection staff for the past 33 years -- 13 years. It can't be 33. She's only 34. (Laughter.)

MS. MURPHY-JENKINS: I wish.

MR. ALMANZA: And deals with general food standards and labeling issues with a primary focus

on international labeling issues including import/export labeling and country of origin issues. Rosalyn.

MS. MURPHY-JENKINS: Thank you, Mr. Almanza. I wish I was 34.

Good afternoon, everyone. And I will be presenting today on the Draft Labeling Policy Guidance on N-60 Testing Claims for Boneless Beef Manufacturing Trimmings for *E. coli* O157:H7.

As we all know, labels for meat and poultry products are to convey truthful and not misleading information. As Dan mentioned yesterday, we posted web guidance, draft web guidance. It was posted yesterday afternoon for the labeling of N-60 testing claims and, of course, as a result of it being a draft, we are welcoming comments. The guidance is in draft form. So it will be revised, after the comment period, and I'll mention that a little bit later, after the comment period, we'll put it in final form so that those establishments wishing to put this voluntary claim on labeling, will have some guidance in how to do that.

We recognize that this is a food safety issue rather than traditional labeling issues. Labeling claims do come into our office for review and evaluation but this type of claim would be reviewed in a different manner, and I'll give a little bit more information on that.

How did this all come about? The Labeling and Program Delivery Division received a few requests for label claims bearing N-60 testing claims. We had not seen any of these types of claims before, although there was documentation presented to support the claim submitted by the establishment. The Agency recognized that this draft guidance or some kind of guidance needed to be provided to the industry to provide a framework for how these labels can be applied to products and it be truthful.

An establishment may submit such claims as long as they can demonstrate that these claims are truthful and not misleading.

Although the product would be sold to retailers, these types of claims would not appear on

retail ready packaging or those products sold directly to consumers.

To provide a little bit of background, I think it was also mentioned in the Federal Register notice, or alluded to in the notice, that N-60 labels are intended to provide information to a receiving establishment about the supplier's HACCP system and the testing that that supplier does, in lieu of certificate of analysis, we recognize that these certificates of analysis are not being properly transferred with the products through distributors.

And we also want to be assured that the claim asserts that these raw beef components were produced under an integrated control program between the slaughter dressing operation and the trim production operations and that the product has been tested and that that testing was done by a particular sampling method.

Of course, in evaluating these types of label claims, there are specific conditions that need to be met. As with all labeling claims, the

labels need to be submitted for approval. This type of evaluation would be a little bit different than what we do in our traditional label evaluations. It would be more of like a technical review where we would have an ad hoc committee gather together technical experts from the Agency to review the information, and as I walk through what's included in the guidance, you'll see that there is quite a bit of documentation that should be submitted as part of the labeling application and that would be reviewed by this ad hoc committee.

As I said, the label submittal would have to include certain information besides the documentation. We would expect the label to also bear certain labeling information and, of course, we expect that our FSIS personnel will be developing instructions to verify that the claim is truthful when an establishment applies it to their labeling.

As far as what type of information would appear on the label, in addition to what is normally expected on a label that is applied to product at an establishment, a statement would need to be on the

label to convey that the testing was done by the establishment. Here's an example of something like derived only from ABC Company's N-60 Tested and Passed Beef Trim.

The label would also need to include a statement about whether the testing claim is specific to the label container or whether multiple containers are involved in a particular sample production lot. There's a couple of examples there, N-60 negative for 2,000 pounds, and as I said, this would not be expected on consumer size packages, consumer ready products. So also a statement of limited use, such as not for consumer labeled product.

The beef trim for N-60 tested products, and then various containers of tested trim, if they are mixed together to form a particular formulation, the N-60 label would also need to state that the final product was tested before it was combined with other tested trim, other tested trim that may bear an N-60 label, but that that combination, that final product was not tested. If that final product was tested,

then the label could also state that as if N-60 tested twice under a sampling program or any other appropriate qualification to convey that information.

In terms of documentation needed to support the label claim, of course, all the beef trim used to produce the product would have to originate from carcasses slaughtered at an official establishment with at least one validated intervention for *E. coli* O157:H7.

The documentation would also have to include that the N-60 tested claim would be supported by -- that the product was actually tested, and it could be either via a screen type method, using a FSIS method or an equivalent method for *E. coli* O157:H7 analysis, and then a statement in the HACCP plan that the testing was incorporated.

The sample collection methodology would also indicate that at least 60 randomly selected samples are analyzed and at least 325 grams of the product is composited and tested.

If any of the product tests positive, then

the documentation would also have to include that the lot represented by that sample was diverted from the ground beef operation. An example here is the positive lots are diverted to cooking or other further processing that will destroy the pathogen.

And then a description of that would need to be included by the establishment in the documentation that that property was properly disposed of.

There would also have to be evidence that there would be no re-sampling, no collecting of another N-60 sample of any production lot that tests positive.

If multiple operations within one establishment or multiple establishments are involved in creating the production lot for N-60 tested trim, for example, if a slaughter processing operation establishment produces the trim, or the trim is derived from another establishment, which was also tested, or has a N-60 claim on it, then we would expect that the documentation would describe how the establishments communicate and how that

would be recorded regarding the slaughter/dressing performance and trim test results, how the would be made available to FSIS personnel for review at each establishment, and then how that information would be used to investigate and adjust the HACCP system to ensure that the system is adequate for control.

Additionally, a written protocol addressing the criteria used by the establishment requesting the approval of the N-60 label, to identify an acceptable number of sporadic positives from a trend towards a systemic failure to control *E. coli,* for example, those high event days, that this criteria would need to justify how to discern when one production lot is or isn't microbiologically independent of another when same source materials are used in individual production lots. That protocol would also have to describe the decision making for that product disposition. The lot represented by the N-60 sample has been diverted from the raw beef operation and then how this information would affect microbiological independents of a production lot.

The documentation would also have to include a description of how the approved label will identify the specific production lot that's tested. For example, through a lot code or a lot identification number.

As I said, we posted this draft guidance yesterday afternoon. It is indeed draft guidance for review and comment. So, of course, either today verbally or through written comments, we encourage you to submit it to the e-mail address I have there, and the comments will be accepted through November 17, 2008.

Once we get the comments incorporated into some final guidance, then if we adopt the program or the Agency institutes this program, then we would suggest that you submit your label application, in the usual manner, those few that are familiar with that, it's also outlined in this website here, and we would evaluate whether or not the information that's submitted is enough to justify the product is labeled in a truthful and non-misleading manner.

I understand that because this review is a

little bit different than what we would do in normal situations of label kind evaluation, it may take a little bit longer, but we would, of course, try to expedite it in a way that would be acceptable to those establishments that are submitting for approval. Thank you.

(Applause.)

DR. ENGELJOHN: We have some microphones. I don't know where the microphones are. Okay.

MS. MURPHY-JENKINS: And as I said, because this is going to be a collaborative effort among Agency officials, in your questions today, either Dan or I will comment.

UNIDENTIFIED SPEAKER: This is just an observation. I know that it came up before that the perception and my perception also as having used the previous and the current FSIS methods, that the method has improved. When you say something that's been shown to be equivalent to the FSIS method, I would encourage you to actually say that it has to be equivalent to the current MLG method. A lot of things are in the marketplace, a lot of different

tests that were validated by AOAC or other agencies against methods previously in use by FSIS, not the method currently in use.

And I think in the interest of keeping quality up and making sure the testing is equivalent, that the MLG Guidebook version be specified.

MS. MURPHY-JENKINS: Thank you.

MS. ROSENBAUM: Donna Rosenbaum from STOP. I have a couple of comments.

First of all, I appreciate the opportunity to write in comments. I would like to request because of all of the detailed information that's going to go into comments that are meaningful, that you perhaps consider giving a couple of weeks additional time because I would personally like to have the transcript of this meeting to be able to prepare comments, and I've been taking notes but I can't write that fast, and there's a lot of things to think about in preparing these comments and we'd like to make them as meaningful as possible, and I'd like to see everybody in the consumer sector as well

as the industry sector be able to use the information that's coming out of this meeting informing very useful comments for you. So I think it would be very helpful to have that transportation before we got into that process. That's number one.

Number two, I would like to see also some definition in the sampling method. N-60 in and of itself when you just say N-60, as far as we're concerned, you know, it means different things to different people because it has so many variables involved in how it's applied, and N-60 in and of itself it not a sampling method. It just demands a certain number of samples being taken. So if you're going to do something based upon a label with something on it, I think you need to call it something more definitive than just N-60, so that it has a set plan behind it and a set number of points that everybody will know has to have been met to be able to call it that and have a label applied to it.

And in mind with the Safe Food Coalition comments that we gave yesterday, I personally, and I think the Safe Food Coalition, would be much more

comfortable with it being labeled as testing under a certified sampling plan versus specifically N-60 because again, that might be subject to each plant and each process in each plant and it might not be appropriate. Different things might be appropriate for different plants.

MR. GOLTRY: Scott Goltry, AMI. I think, one, we appreciate the ability to comment on this and the draft guidance document, you said it was going to be coming and it's here, so we are able to comment on this N-60 labeling document which we appreciate that.

But I think also you need to understand or take a look at the risk of what is really being done now with not the ability to put labels on boxes that they have been tested to a N-60 or equivalent program, and how that's gone through the distribution system. Basically that information is being passed on through bills of lading or invoices to the first point of shipment and then from there on it's up to the brokers or distributors to pass that on to some of the small and very small

grinders.

Also I'd like to have you consider how product coming from Canada, trim that is destined to be ground down here would also fit under this kind of N-60 labeling or something equivalent like you mentioned, that would fit into that whole scenario.

I think it's a good idea that it is a voluntary situation or system, but to me I think there's a lot of like has been said earlier, there's a lot of devil in the details, and your risk group or whoever's going to be put to task to understand this situation, I think they need to understand that there's a lot of this information in here that's already being done and to have this great carrot to help the system identify what's N-60 and not N-60 I think could be problematic and over burdensome.

MS. MURPHY-JENKINS: Maybe it pays to be 34. Thank you. (Laughter.)

DR. ENGELJOHN: This is Engeljohn. I did want to follow up. I did get one question earlier about whether or not the N-60 label could apply to the ground product, an operation that may, in fact,

be controlling product from slaughter to trim to ground, all the way through to the retail store but not to the consumer. And it's certainly is our intention to allow for that. So if you have some suggestions for how to incorporate a ground component onto this, we as well would find that to be something probably that would be of benefit to industry.

Again, the whole purpose here being to find a way to get at the issue of not having information transferred with product through the distribution channels. So if that's something that would be of value to industry, we certainly would entertain developing that further as well.

MS. JOHNSON: Anything on the phone, Dr. Engeljohn? On the phone line.

OPERATOR: If you'd like to ask a question, please press star and 1.

(No response.)

OPERATOR: At this time, I have no questions in queue.

DR. HOLLINGSWORTH: Jill Hollingsworth,

FMI. Since this is a voluntary program, is there going to be any difference or significance or is FSIS going to address product that is labeled or is not labeled differently even though it may have gone through the exact same process? I guess I'm not clear on what will be distinctive about the product that is labeled if it's a voluntary label versus the product that is not labeled but may have gone through the same process, or is there any difference?

DR. ENGELJOHN: This is Engeljohn. I would respond by, I do see distinct differences between this and what's happening today and perhaps into the future, in that product produced under this system is one for which as Rosalyn mentioned in her presentation, is an integrated system whereby the Agency itself will be providing training and instruction to the FSIS employees in the plant to actually verify that the criteria is being met for the labeling claim program.

So there will be a specific focus on the actual interaction between the performance at

slaughter and the performance at trim, looking at the program to see that it is, in fact, being followed and those conditions being met. So that's a specific focus on a labeling claim process whereas today the inspectors are looking at a verification program for the system but not necessarily looking to verify that the pieces are tied together between the feedback between the slaughter and trim.

So we would view that as certainly being a more robust mechanism for the control. Again, it gets at the issue of feedback. It gets at the issue of us specifically verifying that activity and then the purchaser of product of who would be receiving this product would at least have additional information about the production process that is occurring at other establishments for which they may not be able to get as much information about the control program which is an argument that we've heard from particular the small and very small plants who feel they don't have the ability to get information about the production process, and certainly aren't able to get it on a routine basis

whereby today they may or may not get a certificate of analysis. They may or may not get information on the bill of lading, and they may or may not be able to get information from the processor about their production practices.

So we would certainly see it as a more robust mechanism for an integrated control in a more comprehensive food safety system. So we would see differences there and particularly for an establishment that was purchasing only this kind of product, labeled as such, would and could perhaps handle that product differently than one who doesn't have as much information.

MR. GOLTRY: A follow up, Scott Goltry, AMI. In your first bullet point, you mention that labels would be truthful, convey truthful and not misleading information.

MS. MURPHY-JENKINS: Uh-huh.

MR. GOLTRY: I think the intent of this label is to be truthful about was the product properly sampled for N-60 or another method, equivalent to that, and did the product test

negative and is the product in the box or container that product that was actually representing that sample. It sounds like we're going far above that to turn this into a total food safety evaluation and there are systems in place to already evaluate those food safety systems.

DR. ENGELJOHN: And I would just comment that again the issue at getting at more standardized approaches to this, one of the components and one of those bullets was that we're specifically looking at the decision making process within the plant on how they discern the difference between sporadic positives and those that could lead to evidence, the process is out of control, whereby they would control negative production lots differently on days in which they have that evidence. And that isn't something that's built into a very focused verification activity that we have today. So this would standardize that to a great extent across those plants that are using this label.

So we do see that it is a comprehensive look at the food safety system for which there's

feedback and we don't, we don't see the value in testing and not doing anything with that data. In fact, that's just a test and divert program that actually would not function as a mechanism to inform the system.

We believe this would provide greater control in place to get information back as to whether or not this system is working properly and is it adjusted appropriately.

MS. BUCK: This is Pat Buck from the Center for Foodborne Illness. Are we talking about a lot more resources to put this type of labeling in place not only for the Agency but also for the industry at large? Is this a serious resource problem?

DR. ENGELJOHN: From my perspective, Engeljohn's perspective about the design of the program and how it would be implemented is that, as I think Scott from AMI said, many of those in industry have programs in place that aren't as structured such that we, the Agency, are verifying them.

This would be a change in the inspection

procedure. So as we mentioned in one slide, it would entail a special training program whereby our inspectors in these plants would be provided instruction and training on how to verify this program. So that would be a change there.

I would see there would be an investment in training holistically across the board on this particular issue.

For those in industry, obviously it does change a bit from what they're doing. I would see that the reliance upon certificates of analyses and those quarterly follow ups or monthly follow ups that plants are doing today probably would not be as necessary. I think that's an intense activity that industry tries to comply with today but it isn't working well.

As far as resources in the Washington Office, we do have technical teams that we would be pulling together that would be reviewing this as the labels come in. So I think we've anticipated what we need to do. Our intention is not to have these applications for long periods of time. We recognize

there's a public health benefit in our opinion to this approach. So I think we would put the resources to it. We have the technical capability to do so.

I think the bigger issue though is if, in fact, we adopt a label along these lines, it is a matter of getting that information out, training on it, and then making sure that we're verifying appropriately.

There's, in the back.

DR. HARRIS: Joe Harris with Southwest Meat Association. Going along with Scott Goltry's comments a moment ago, it seems like that the current draft policy goes so far beyond what a current COA would include, that is it's a whole new program. It is not something that could be done in lieu of providing a COA. There are a lot of underlying things that would be implied by one small label statement, and I would be concerned that the usefulness of this is going to be extremely compromised by having so many strings attached to one small label statement that it's not going to be

worthwhile for processors to go through all of the things that they're going to have to go through for this label claim when a lot of the things they're already doing anyway. But now they're all being tied to a single labeling claim.

So we would caution that there is just too much being implied by one label statement.

DR. ENGELJOHN: I appreciate that. I will say again from the Dan Engeljohn policy perspective, the certificates of analyses today are of little value frankly in terms of how they're used and being used by industry. I think that in terms of reliance upon them and the information that they're intended to imply to the industry, particularly those who are purchasing the product is not as robust as it needs to be, and so I think today I think there is some evidence that it's a paper exercise which needs to be strengthened.

Are there any questions from the phone?

(No response.)

DR. ENGELJOHN: If not, I think we'll move to the next presentation.

MR. ALMANZA: Our next presenter is Dr. Barbara Masters. Dr. Masters is a senior policy advisor at Olsson, Frank and Weeda. Before joining the firm, Dr. Masters served as Acting Administrator and then Administrator for USDA FSIS from March 2004 through January 2007.

During her tenure as Administrator, she worked to establish -- no, she established a solid infrastructure of science-based policies and data analysis which have helped to reduce foodborne illness and product recalls. Dr. Masters.

DR. MASTERS: Thank you, Mr. Almanza. Certainly I think this has been a good opportunity to have a lot of dialogue and discussion about *E. coli* O157:H7 and sampling and a lot of things that have been going on both with the industry and some of the training and some of the things that have been happening in FSIS.

I don't think I have anything new in my presentation, but I think what is unique and different about the presentation that I have is that it does relate specifically some learnings from 2007

and 2008.

I want to thank my colleague, Dennis Johnson, who assisted me in putting this together as well as some of those in industry who may or may not know they assisted in putting this together.

This presentation focuses on some specific illnesses. We know that in 2007, there was at least nine beef related outbreaks. We acknowledge there may have been more but CDC reported at least nine beef related outbreaks, five multistate outbreaks which we're going to focus on three.

And we're focusing on these three because we had specific information that we were able to obtain the data on particularly related to the source involved in these outbreaks related to the raw materials.

We also will acknowledge that the illness information is based on unofficial preliminary reports that may be incomplete.

So being consistent with how CDC would present this type of information, we're going to focus on Grinder A, B, and C, and Grinder A was

involved with 36 illnesses, B 47 illnesses and Grinder C, 52 illnesses. So clearly these were large outbreaks in 2007.

We had go, as we've talked all the last day and a half about assumptions, and you always have to rely on underlying assumptions. These outbreaks all were the result of grinding operations, and they were traced back to grinding operations, and the root cause, if we look at these grinding operations, we do not believe, we made the assumption that the grinding facility was not the root cause. Their practices were not the root cause per se, that they purchased product that was contaminated, and it was contaminated to a level such that it did lead to illnesses.

Certainly we heard some things over the last day and a half, 2007, was it anomaly? We talked about process control at the slaughter floor. That's where it all happens. So we are looking at the suppliers. Did they have process control levels? Dr. Engeljohn talked about clearly if you're exceeding your process control at a certain

level, all of a sudden your interventions aren't working anymore. So what happened that these suppliers in 2007 to these illnesses, we don't know, but we do know in these cases their products reached the grinders, and once it reached the grinders, there's basically virtually nothing the grinders can do.

Mr. Biela talked about, he had a program in his facility, cold chain management, looking at suppliers of incoming product, those kind of things, but once he gets the product, he has that product.

And so we're saying, our assumption is the inquiry should focus on the ultimate suppliers of that product. Those are our assumptions.

So let's walk through our individual grinders from 2007. Grinder A had many, many suppliers, but they had three common suppliers during that period of the outbreak. They had a Canadian slaughter establishment, and it's the only establishment that we're specifically naming. It's Rancher's, and we did that only because in follow up to this establishment, FSIS did ultimately publicly

acknowledge Rancher's had testing issues, a Western slaughter establishment and an establishment that was providing low temperature rendered product which I think Dr. Engeljohn mentioned was something one of the Advisory Committees had suggested FSIS needed to look at differently in some of their baseline testing.

We have Grinder B, who also had various suppliers but FSIS did indicate in that case the likely source was Rancher's Beef in Canada, and they did that in a press release.

And then we have Grinder C who also had a variety of suppliers but they had four that were common during that outbreak period. Southwest establishment, South American country, a Midwest establishment and then an establishment that was providing treated trimmings, trimmings that had a lethality step applied to them.

So what are some common themes when we trace back? We talked about tracing back to suppliers a lot in the last day and a half. What are some common themes when we then took this

information and looked back at the suppliers?

Well, interestingly, none of these suppliers that we looked at had a high incident rate for *E. coli* O157:H7 in their own trim testing. I certainly don't want to suggest that just because you don't have a high incident rate, that that's an automatic, oh, no. Certainly somebody could be doing everything right and not have a high incident rate but certainly that should raise questions about what's going on. We talked about feedback loops to the system. So that's just one piece of information.

Two slaughter establishments had questionable process controls, and I say that from the perspective that one of them had not properly validated the use of lactic acid for their carcass intervention step, and I would say to you that this particular slaughter establishment was only using lactic acid as their intervention for controlling O157:H7 on the slaughter floor, and they were using it at 1.5 percent. Most of the journal articles and research articles out there suggest using lactic

acid, if you're going to use it to control O157, at at least 2 percent. And so this was the only intervention step they had on their slaughter floor, and they had not properly validated it.

Another establishment when you went back to look at their slaughter floor only was using hot water, which is a good intervention but they had not properly validated that on their slaughter floor. So questionable process control on slaughter floor.

Two of the establishments had questionable sampling practices. We talked about Rancher's. That's one of the suppliers at two establishments, and FSIS acknowledged that they were doing retesting. And one of the other establishments was not taking N-60 samples from the exterior slices which both Dr. Kelly and Ms. Rossman talked about. You absolutely have to take the exterior surface and that was verified by a third party audit when there was a follow up back at that particular slaughter establishment.

And only one of them said was using the treated trimmings, which is a positive finding, but

only one of them was doing that.

So that's the common theme of things that we have.

So we kind of summarized our learnings from 2007 that the suppliers in these cases had extremely low trim incident rates. In fact, some of them had no positives, when the industry average, and we had to put that down there as something, based on the draft compliance guidelines that FSIS had put out, at 1 to 2 percent anecdotally. So they were down at 0 or very low when the rest of the industry has had about 1 to 2 percent. That really 1 to 2 percent really is providing feedback to the slaughter floor, to the system.

So these establishments really didn't have that feedback loop to their system, which was allowing them to have deficiencies in their slaughter process, and again as we've talked in the last day and a half, your process control begins on the slaughter floor. That's where you're going to control *E. coli* O157.

So we move to 2008. Obviously there's been

multiple outbreaks in 2008, but there's really been three outbreaks in 2008. Retailer A, Retailer B and then the non-profit organization. The source for the non-profit organization has not really been conclusively demonstrated for that outbreak. So we're really not going to discuss it further here. We're going to focus on Retailer A and Retailer B.

Retailer A and Retailer B had a common supplier. We're going to call it slaughter establishment A, and I have to acknowledge, I don't have firsthand information for slaughter establishment A, and it's based on third party information. So if it's not 100 percent accurate, you know, when you're relying, when you're going to third party, it gets a little bit further removed. So I will state that up front, but what we have heard from third party information is that this slaughter establishment did not have any positive trim findings in 2007 or 2008 before these outbreaks. So again, none of their own establishment positives.

What we do know from the recently published

National Trim Baseline is that they did have positive findings in the FSIS Trim Baseline.

We have heard that their analytical sample size was 25 grams. We know the industry standard is 375 grams, and Dr. Esteban shared that the FSIS sample size is 325 grams. So we're looking at a different sample size used by this establishment.

And we have heard that customers who conducted testing on this establishment's product detected multiple positives when they acquired the product from this establishment.

We also have heard that for production at issue in the outbreaks, that this establishment made a decision to not operate all of their interventions.

So we would suggest that the learnings in 2008 are the same as that in 2007, that you have a supplier, again a supplier, that had no positives in their own trim testing when the industry as an average gets about 1 to 2 percent to use as their feedback loop. So this supplier, the slaughter establishment, did not have their feedback to their

system to detect what was going on or to use as feedback to their slaughter process. So again, you would begin to question what's happening in their slaughter process.

So how can you apply these learnings? We're not suggesting that testing should be mandatory, but if establishments are going to rely on sampling as feedback to their slaughter process, and again we would suggest it's a good thing to do, that that testing needs to be done in a way that it can, in fact, provide feedback to your system because as we've heard over and over again, that's where your process control has to begin. You need process control throughout the process, but it certainly needs to begin at the slaughter floor.

But for your sampling to be meaningful, whether you get negative results or positive results, you need proper sampling and laboratory techniques.

I don't want to suggest that a lot of positive findings don't have one meaning or that just because you get positives you should be

penalized, that positive results you need proper sampling and laboratory techniques, and you need that for negative results. It's equally important regardless of your sampling.

But I would suggest that in our case, what we found from our learning is that, in particular, a virtual absence of positives should clearly trigger a review as to the adequacy of sampling and/or laboratory results. Again, I think there are establishments out there that have clearly worked on their process enough that they do get a period of time for which they get no findings, but I think they would welcome a rigorous review of their process.

I think that should entail, is the sample being collected properly? Is it a surface excision? Are they getting a 375-gram sample or a 325-gram sample? Is it being properly enriched? Is the laboratory method adequate to detect all of the *E. coli*? Is it as sensitive as the FSIS method? And I agree, it's a good point that this gentleman made over here. We do mean the current MLG method.

Dr. Danielson mentioned recently that FSIS came in and looked at his laboratory methods and found a discrepancy. I think that's what we're talking about here. What is happening from a sampling perspective, and if somebody's getting all negatives, that should be a meaningful all negative. It doesn't mean it's wrong, but is it a meaningful all negative?

We would suggest for FSIS, we had access to data for a few of the outbreaks in 2007 and got some third party information for 2008, and we would encourage FSIS to go back to all of the outbreaks for 2007 and 2008 and look at all of the suppliers. Look at the HACCP records and the *E. coli* test results during the relevant period of the outbreak and focus particularly on those establishments that had all negative findings. We would anticipate there may be other plants that had all negative findings during those outbreak periods.

What was happening with their interventions on the slaughter floor? Were they operated as intended? For example, if they were using something

out of the FSIS Directive 7120.1, which is the directive that defines antimicrobials for example, were they using that as it's described or was it validated if they were using something different? We would encourage FSIS to go back and look at the sample methods. Obviously they can't go back to 2007 and see how they were sampling then, but certainly they could verify how those facilities are sampling now.

I have been in facilities in the last year and a half I can tell you. Not everybody does a good N-60 method. They should look at the laboratory method and ensure that they're using a laboratory method. They should have records for what they were using then. Was it a method that's a sensitive as FSIS and what are they using today?

Because again, our hypothesis is that process control at slaughter is essential to control *E. coli* O157:H7. Effective process control is based on validation of the process as well as ongoing verification. It takes both, and if an establishment is going to use testing as part of

their ongoing verification, that testing must incorporate adequate sampling and analytical techniques.

And if that's true, then we would suggest FSIS must adopt policies to address this, to minimize future outbreaks.

FSIS should emphasize at slaughter operations that serve as a source to the grinding operations. They should look at the validation of programs, the on-going verification, surface excision, and I think they've started to do that. You heard Dr. Kelly talk about her regulatory education program. What did they learn through their 65-07 and have they addressed all of that? If you read the 65-07 and what they found in their review, it was a lot of very small facilities, and so certainly Dr. Kelly talked about what she's doing for the small and very small plants on sampling, but what did they find from a verification and from a validation perspective, and are they ensuring that they're getting that information out to the small and very small plants and to their inspection

personnel to ensure that they had adequate in to make sure these kind of things are happening. I appreciate the perspective that Dr. Kelly and Ms. Rossman are working together to get the BIFSCO documents out there and to get the training materials out there, but if we don't get this information out there, we are selling ourselves short to make sure we are fixing some of the issues that we learned at least in the few outbreaks we followed up on to make sure we're not preventing future outbreaks.

We would also encourage FSIS to focus on trim testing rather than ground testing to test closer to the source. From our perspective, that actually eliminates that need for trace back. We talked about trace back. If you actually test the trim product, you are testing where the trace back would occur. So there is no need for trace back, and we would encourage FSIS to consider additional trim testing, and Dr. Esteban talked about the difficulty in getting some trim samples, but he also talked about FSIS' exploring new methods to ensure

they can better trim samples, and we would encourage that to continue so that they can get better trim samples at the laboratory and make sure that they're following through on that because then you eliminate that need for the trace backs.

So those are some of the things we would encourage based on our learnings, and if FSIS is able to follow up on the other outbreaks and get consistent answers, then we believe that that may assist them in moving forward with some of their direction. Thank you very much.

(Applause.)

DR. ENGELJOHN: Questions?

MS. NESTOR: Felicia Nestor, Food and Water Watch. That was great, Dr. Master. That's a very encouraging presentation. I have a couple of questions, and maybe this is for Dan.

The issue about deciding not to operate all interventions. If you had a HACCP plan, doesn't it specify how many interventions you use, and if you don't use all of them, you have not used your HACCP plan or can a person set up a HACCP plan that says,

you know, I may use any or all of these three interventions, and that would be one HACCP plan, and they would have the discretion during the process to --

DR. ENGELJOHN: This is Engeljohn. A properly validated system would have one for which they would know what the individual contribution is for the hurdles that they would have in place, and they would know that and they could adjust their system accordingly based on the consumer preferences. In this particular case, as an example, for natural or a process for which certain application of chemicals might not have wanted to be applied to the products, the customer may have requested that. In those kind of cases, we would expect that to have been validated.

So it's an issue for which a properly validated system would have addressed and would have known what the vulnerability would be for producing product that might get through the system in terms of O157.

MS. NESTOR: Okay. The only thing I just

want to make a comment that I mean this seems to suggest exactly what the consumers were advocating yesterday, which was a lot more information about where the contamination is in the grinding plants, you know, where it's coming from, which suppliers it's coming from. And I also would definitely agree with the recommendation of additional trim sampling for the same reason, because you're closer to the supplier and you can start identifying the problems.

DR. ENGELJOHN: I will just address that one particular issue on the trim sampling, and it's one for which we, the Agency, recognized that we needed to do. We began that program a year ago March. So it's now a year and a half or so old in terms of a program that we think added value to our overall determinations about the adequacy of the systems.

What's important to the Agency now is to look to make sure that we get in the number of samples that we actually schedule.

Because we have a baseline positive rate that we work from, the trim sampling program is one

for which we actually determine how many samples should we pull, based on the fact that we were looking for being able to measure a statistical difference in the positive rate. And so we were able to do that because we had a baseline value.

So the focus I think as we go forward, first of all, is to make sure we get the number of samples that we schedule, the number that we schedule is 3742 in a year. And so the question becomes are we getting that and making sure that we do, and then as recommended by Dr. Masters, is should we consider reallocating or perhaps adding resources to add more samples to get a better perspective about that, and I think those are the kinds of things that we certainly welcome your input on from everyone out there, but it is something that we are actively looking at as well.

MS. NESTOR: And I'm sorry, I do have one other question. Dr. Masters, can you explain again what you mean about common suppliers for your 2007? You said that these were the common suppliers, but there were additional suppliers during a certain

period?

DR. MASTERS: Yes.

MS. NESTOR: Are you saying that -- were these outbreaks a result of more than one lot of product, the result of production over a number of days?

DR. MASTERS: No. When you look at -- what you have to do when you start looking at an outbreak, you have to go then and see how many suppliers, these companies, these grinders supplied, had. So they might have had -- let's say they had 10 suppliers. Then you have to say what suppliers actually supplied the production during the period for which the outbreak occurred. Then you have to start looking at the common suppliers. You have to start narrowing your window down to the common suppliers that supplied during the period of the outbreak. And so then you have to narrow it down to see which suppliers were involved during the period of the outbreak. And so these were the ones that actually supplied during the period of the outbreak and the recall.

MS. NESTOR: Are you saying they were the only ones that supplied during that period of they were the ones that were common throughout the period?

DR. MASTERS: Okay. So Felicia's asking about the common suppliers, and so these grinders obviously have multiple suppliers, and then you go back to the recall and you see how many were involved in the recall and the outbreak, and you have to go back and narrow it down to common suppliers during the recall and the outbreak. And so they have multiple suppliers, but these were the common suppliers during the days of the recall and the outbreak event.

MS. ROSENBAUM: Donna Rosenbaum from STOP. This is a comment basically on your presentation, more for the Agency, in terms of I think we agree that, you know, more sampling is great, but you have a dichotomy here between sampling and then processes that when failed indicate HACCP failures, and I'm concerned. I see value in going back and looking at what went wrong in all those outbreaks in 2007 and

2008. What concerns me as a consumer is that we don't have more preventive, real time evaluation going on continuously that would prevent, be more preventative in nature than going back a year and half after something happened or two years after it happened and saying what could we have done better here. These themes and these HACCP failures should have been evident to the Agency at the time they happened and I think the Agency needs to look at why that didn't happen and then move forward with getting more towards a real time evaluation of those events.

DR. ENGELJOHN: There's a question here.

MS. KOWALCYK: Barb Kowalcyk, CFI. It's more of a comment. Barbara, I really enjoyed your presentation. I guess enjoy is probably not the right term, but I think it certainly emphasizes the need for movement towards consistent sampling and the need to put statistics back into statistical process control as we've been discussing for the past couple of days.

And I think one point that you made that I

want the Agency to take particular note of is this whole idea that a virtual absence of positives tells you something. It tells you one or two things. Either their sampling plan is inappropriate and they're not catching contamination that's there or two, they've discovered some really remarkable intervention that has improved the process that much. Either way, you need to look into it, and it should flag something to both the plant and to FSIS that there may be a potential problem. You would not expect to go that long without having a positive in that situation. I just want to reiterate that point and I want to reiterate what Felicia said. This certainly provides justification for the things that the consumer groups have been asking for and that plants need to develop reliable, robust sampling plants that are implemented correctly and then use that data to draw accurate generalizations about the population so that we can prevent illness. As Donna said, we don't really want to find out a year and a half afterwards. If this is done continually, you would have caught this in the

process rather than after people have gotten sick.

MS. BUCK: Hello, this is Pat Buck from CFI. And I looked at your recommendations and I'm trying to piece this together in my mind. Is this something where you feel labeling for N-60 would be helpful?

DR. MASTERS: The question on the table is, is this something where I feel labeling for N-60 would helpful?

I think labeling for N-60 is a tool, and I don't think labeling for N-60 is really necessarily related to what we're talking about here. This is Barb -- as Dr. Engeljohn said, this is Dan Engeljohn from policy. This is Barb Masters. I personally believe FSIS already has the authority to verify what they're asking for in the program related to the N-60, and so I would suggest they're already able to verify the things related to N-60 label. And so I would suggest that the N-60 labeling is just a tool, and FSIS already has the ability and should, in fact, be verifying a lot of things that they're asking for around that labeling.

And so I'm not sure that there's added value to that label. It kind of gets back to Dr. Hollingsworth's question. Is there value added? If FSIS was already verifying those programs around that label, as I believe they have the authority to do, then I think the N-60 label could be a tool and is not necessarily an added tool. It's just a tool that people could choose to use. But again that's my personal perspective.

DR. HOLLINGSWORTH: Jill Hollingsworth, FMI. Thanks, Dr. Masters, for this information. I thought your retailer example was interesting since actually there were three retailers involved in these recalls. But one of the bullets you had on the retailer recalls was that the customers who conducted testing on establishment A's product determined multiple positives. And I'm curious as to what happened with those results. I mean, given that that product itself probably was diverted by the grinding operation, but was there anything done? Obviously the customer receiving this product knew something was amiss if they were getting that many

positive products, and is there any requirement that something be done? Is there any notification procedure? What should have or did not happen as a result of these customers finding all of these positives coming to them.

DR. MASTERS: Dan, do you want to --

DR. ENGELJOHN: This is Engeljohn. In this particular situation, of course, a part of this was a consequence of the investigation as to what happened. So it's part of how we find out these things. Part of the issue though is for the Agency to have access to information for which the plant is making determinations about various programs.

And so I would just respond by saying in this particular case, an investigation is what uncovered what we ultimately found out. The reality is that if, in fact, those lab results were affecting the food safety system, those would be the kind of records that we would expect to be on file at the establishment for which the inspectors would have access to and that they would be responding to in terms of asking questions about it.

There is a requirement for the inspectors to meet on a weekly basis with plant management to review testing results and to ask questions or to get further information. And so the process would have been if this had triggered changes in the program, then that should have been part of the overall food safety system. But it was discovered through an investigation.

MS. NESTOR: Felicia Nestor. I have a follow-up to that. Are the inspectors instructed once they have that work unit meeting to notify the D.C. office that the plant where they're working found a positive on X supplier plant's product?

DR. ENGELJOHN: This is Engeljohn. The expectation for the inspectors is that when they have questions or concerns about the data that they have, they may not be capable of determining the merit of the information but through their supervisory chain should, in fact, take steps to get answers. So the process would be that. There isn't a requirement today as we have discussed over the last day and a half, that individual establishment

data from another plant is actually informing the system. So our inspectors in a plant know what happens in that plant, not necessarily what's happening in another plant.

MS. NESTOR: So then USDA doesn't really have the ability to learn that two different grinders in two different parts of the country had a positive with a certain supplier?

DR. ENGELJOHN: This is Engeljohn. I would respond by saying that that may be the case today if, in fact, that information isn't made part of the food safety system at the establishment where that record would be reviewed. It's certainly an area for which we know we need to find some mechanism to address.

Are there any questions on the phone, Operator?

OPERATOR: Once again, if you would like to ask a question from the phone, please press star and 1.

(No response.)

DR. DANIELSON: Good information, and for

all of us in this business, that kind of information is valuable on lots of issues. If there was some type of opportunity that the Agency or however could share case studies with us more quickly than when they're occurring, we, every time we get this information, go back and look within ourselves and it helps. I mean if we have gaps, we need to fix them. If we don't know about them, we can't address them, and whether it's us or them or whomever, case studies of, you know, you've got the epidemiology associations to the outbreaks to the trace backs. I know there's a lot of confidential information involved, and it's a difficult process, but it's very valid information for all of us to push process improvements.

DR. ENGELJOHN: This is Engeljohn, and I would say we agree, and it is another area where we know we can improve and find a mechanism to get information out quickly.

DR. MASTERS: Thank you.

DR. ENGELJOHN: Thank you, Barb.

(Applause.)

MR. ALMANZA: Okay. Well, that's the end of the presentations. So we're going to open it up for any comments that anyone may have to end the meeting.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I have a question about a number of comments that have been made. It seems like a number of people are saying that you're more likely to find the pathogen on the external tissue which is the fatty trimmings, but if I'm not mistaken, Dr. Esteban, didn't you say yesterday that you found that it's more recoverable on the lean trimmings, so we've got this sort of paradoxical thing that you find it one place but you can't detect -- you're more likely to detect it at a place you don't normally find it?

DR. ESTEBAN: You're right. The current method detects a little bit less effectively or efficiently on fatty tissue than non-fatty tissue but it still has the ability to pick it up at very, very low levels. So it's not that it doesn't work, it doesn't work as nicely as it works with lean

meat. So again it's something we could improve on, but I think it's fit for the purpose right now.

DR. ENGELJOHN: Felicia, I did just want to follow up, and again I think it gets back at looking at our training materials and looking to see what our inspectors are doing. We don't know or at least I would say in the Policy Office, I don't yet know whether or not we are focused at only pulling trim samples or are focused on pulling fat samples. I know from the type of samples coming into the lab, you saw the variation that Dr. Esteban provided yesterday. It's an area for which we need to look at.

For us though, the most important thing is making sure we're getting the right tissue which is the exterior, exposed tissue to that contamination. So there is a need for us to look to see what's being done and to better standardize that amongst our employees.

MS. NESTOR: Okay. I have one other question, and this is about the compliance guidelines, the draft, and I don't have it in front

of me, but it seems to me that what is suggested in that document is that the Agency recognizes that N-60 is not sufficient to use for disposition on one lot of product because it doesn't give you a 95 percent confidence when there's not a 5 percent prevalence. But that if you were using N-60 in the context of process control, where you're going to have multiple lots tested, it can be reliable to tell you when your process is out of control. Do I have that right?

DR. ENGELJOHN: This is Engeljohn. I would agree with that concept. We think it should be an integrated system that involves more than just O157 testing. O157 testing is a mechanism to look at to see if O157 is there in the sample lot that you're looking at. We find N-60 to be a practical mechanism to do so and have accepted that. We think it can be vastly improved upon, but just reliance upon O157 is not sufficient. There should be other process control indicators demonstrating that the system is working properly and O157 should be one of those mechanisms to provide you additional feedback.

MS. NESTOR: So for the very small plants that are now strongly encouraged to do N-60 sampling, should they anticipate that coming down the pike is a guideline or recommendation that their use of N-60 on single lots of product is insufficient?

DR. ENGELJOHN: Well, again the guidance that we did provide to very small plants and particularly small and very small production volume plants was that for those operations that are purchasing materials, there is an expectation that that would have been pretested. So that provides one additional means by which they could choose to at least procure products that has an added value to it.

For those operations that are slaughtering the individual cow and dismantling it over time, well, there are other mechanisms that those operations can have in place. One is the process control that they have on their slaughter/dressing operations. We see value in having microbiological tests to demonstrate process control and we talked

about indicator organisms, indicators for the process, and we see value in O157 testing as a means to also demonstrate that over time, their system is controlling at an adequate level.

So we look at it holistically using the historic data, over time that your process is presenting what you intend it to present. That's how we would look at it. If the issue is, and we work with, in particular, the organizations involved with small and very small plants to try to get better guidance out there. They have presented us with some scenarios to specifically address, to try to get better, more specific information and that would be something that we intend to do very shortly in terms of making that information available.

We would welcome any input that you think we need to give to small and very small plants to help them with practical ways to demonstrate their processes or controls.

MS. NESTOR: Yes, actually I can think of one now. I've talked to a number of extension agents around the country, and a number of them

complain that they don't get the -- you were talking earlier today about, you know, post-dating the effective dates so that there can be training and people get up to speed. A number of them complained that they are not forewarned about a lot of these things, and then they just get plants calling them up and they really -- they have to learn while they're trying to help these plants that are undergoing FSAs.

DR. ENGELJOHN: I see Karlease taking notes, and she'll address the issue. How we can use our partners out there to better get information to them in advance to prepare them and perhaps work with them in a better say. So we'll take that.

MR. ALMANZA: Any more?

UNIDENTIFIED SPEAKER: Yes, this is just a rather short question. I'm very encouraged by all of the discussions today, but one thing that I'm wondering about, in particular as I listened to Barb Masters', you know, presentation, how are we going to adequately address the product tracing issues that are, you know, before us as we try and figure

out what to do with as a response to contaminated product? Is FSIS considering holding a public meeting to look at these product tracing issues?

MR. ALMANZA: We don't have that -- we don't have plans for it as of yet, but certainly we've committed to having public meetings to address these types of issues. So --

UNIDENTIFIED SPEAKER: Because I think, I think product tracing is intricately, you know, tied to the issues that we've discussed here, and I would highly recommend that you follow through on product tracing. Thank you.

MR. ALMANZA: Thank you. Any other questions? Barb.

MS. KOWALCYK: Barb Kowalcyk, CFI, and it's just really a comment, and I think that one thing that's important to remember, and I'm very happy, I can't state it enough, I'm very happy with the direction the Agency is going. I think it needs to be flushed out more. I think there needs to be some things that need to be clarified, but I do think statistical process control will lead us out of

this, but one thing that's important for everybody to realize, is that SPC is really about controlling variation and you cannot -- SPC cannot overcome a poor process, and I think the thing that struck me the most about Dr. Masters' presentation is that that one supplier in particular had a poor process, and I think it's important to realize that there is a distinction between the two. Donna touched on this, too. You know, you have the whole HACCP plan which outlines the process, and then you have statistical process control which will monitor the process, and if you have a poorly designed process, you cannot overcome that. Similarly, if you have a poorly designed sampling plan, you cannot overcome that. The data has been flawed and you really are not going to be able to determine -- you're really not going to be able to meet the objectives then of the microbiological testing programs.

So I think that those are two important points that the Agency really needs to understand and clarify in its documentation. Thank you.

MR. ALMANZA: Thank you. Any other

questions?

(No response.)

MR. ALMANZA: Okay. Then we'll close the comment part.

I certainly appreciate all the comments. We heard a lot of -- we have a lot of good information, and I think that as I said yesterday, this is one of those processes that is difficult but we need to go through them in order to be open and transparent as we've committed to doing, and to understand that there are different stakeholders and different viewpoints and taking all of those into account and trying to do or trying to move forward with the Agency, I'm certainly encouraged by a couple of comments that they see the Agency going in the right direction. But we're not finished. I mean this is just kind of the beginning, and certainly we appreciate all of the comments and information we were privy to over the last two days.

With that, Dr. -- or Dr., I almost promoted you. Our new Under Secretary -- Acting Under Secretary Beth Johnson.

MS. JOHNSON: Thanks, Dr. Almanza. I know who's making the decisions here. So --

Well, I really want to thank you guys, and I appreciate the fact that you've taken so much time out of your busy schedules to provide us with your comments and your insights and your thoughts over this last day and a half. I know that I haven't been here for much of it, but I did get updates from Al and from others and it sounds like it's been a very productive couple of days. So again I thank you very, very much.

E. coli has certainly been a challenge over the last year and as most of us know, over a very long period of time. I've been with the Agency almost seven years, and much of that time has been spent on monitoring, looking, asking questions, and focusing on what we can do more to control this pathogen.

Certainly these public meetings, too, are very important in the process. They provide us with a lot of great information, a lot of outside of the box thinking, that unfortunately those of you know

that, both inside and outside of Government know it's easy to get caught up in what's going on in those four walls and it's great to hear from you guys and hear what your thoughts are.

And we've had a few public meetings over the last month, one to discuss low dose irradiation and also some summits that we've had, and so those of you that have been here to comment, we really greatly appreciate that.

Controlling *E. coli,* like I said, is a very important public health concern, but it's also a very complex issue, and we all know that no one meeting is going to address all the concerns and all the aspects of this problem, and from the important discussion at this meeting today, we want to identify other priority issues and to develop a series of public meetings over the next year that we can take to further the discussion and also more importantly is to look at how we can take actions to move this forward.

Obviously the discussion is very, very important. We need this. We want to be transparent

and open. We also know that discussion doesn't get the job done and so we are looking to continue to work with you to do that as well.

Some of you know that, like I said, over the last seven years, I've been committed to working on food safety for the Secretary of Agriculture. I'm also a parent, and I have two young children, five and eight, and so this is not only an issue that I look at from a professional standpoint, but I also look at it from a very personal standpoint. And I certainly agree with all the efforts that folks both at FSIS and in the Agency, who take this very, very seriously to protect ourselves and our children and our nation, that you all, too, are very committed to reducing our risk of exposure to *E. coli*.

I want to thank you again for coming out to this meeting and for any of you that attended the raising claims, natural raising claims meeting yesterday morning, you've put a lot of time into helping us move forward with our policies and our regulations, and so again I thank you very much and

look forward to continued dialogue as we move forward on these important issues. Thanks.

(Applause.)

(Whereupon, at 1:45 p.m., 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 15, 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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