UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

+ + + + +

FSIS PRODUCT TRACING RELATED TO *E. coli* O157:H7 IMPROVING PRODUCT TRACING OF FOODS

+ + + + +

March 10, 2010
9:00 a.m.

U.S. Department of Agriculture
South Building, Jefferson Auditorium
1400 Independence Avenue, S.W.
Washington, D.C. 20250

MODERATOR: MR. ROBERT TYNAN
Deputy Assistant Administrator
Office of Public Affairs and
Consumer Education

USDA: MR. JEROLD MANDE
Deputy Under Secretary
Office of Food Safety

FSIS: MR. AL ALMANZA
Administrator

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

FSIS PRESENTERS:

DR. DAVID GOLDMAN
MS. JUDY RIGGINS
DR. DANIEL ENGELJOHN

PUBLIC COMMENTERS:

MEL KRAMER
JAY WENTHER
NANCY DONLEY
SCOTT GOLTRY
JOHN GRANICH
JOHN MUNSELL
FELICIA NESTOR
CHRIS WALDROP
PATRICIA BUCK
BEVERLY EDWARDS

I-N-D-E-X

AGENDA ITEM	PAGE
Welcome	
Robert Tynan, Deputy Assistant Administrator Office of Public Affairs and Consumer Education	5
Opening Remarks	
Jerold Mande, Deputy Under Secretary Office of Food Safety	8
FSIS Role in PulseNet	
Dr. David Goldman, Assistant Administrator Office of Public Health Science	13
Current FSIS Policy Implementation	
Judy Riggins, Deputy Assistant Administrator Office of Field Operations	40
Issues for Future Discussion	
Dr. Daniel Engeljohn, Deputy Assistant Administrator Office of Policy and Program Development	61
Public Comment Session	
Robert Tynan, Deputy Assistant Administrator Office of Public Affairs and Consumer Education	96
Public Commenters:	
Mel Kramer, EHA Consulting Group	100
Jay Wenther, AAMP	103
Nancy Donley, STOP	107
Scott Goltry, AMI	109
John Granich, FoodTRACE	114
John Munsell, Foundation for Accountability and Regulatory Enforcement	117

I-N-D-E-X

AGENDA ITEM	PAGE
Public Commenters: (cont.)_	
Felicia Nestor, Food and Water Watch	121
Chris Waldrop, Consumer Federation of America	125
Patricia Buck, Center for Foodborne Illness Research and Prevention	127
Beverly Edwards, Deloitte & Touche	129
Closing	
Al Almanza, FSIS Administrator	131
Question and Answer Session	133
Adjournment	

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

(9:10 a.m.)

MR. TYNAN: Good morning.

AUDIENCE: Good morning.

MR. TYNAN: Thank you. All right. Thanks for coming to our FSIS public meeting on Product Tracking Related to *E. coli* O157:H7. I also want to welcome some of the folks that we have on the telephone that will be participating by teleconference, and I will be the moderator for today's meeting.

I'm Robert Tynan. I'm the Deputy Assistant Administrator in the Office of Public Affairs and Consumer Education, and it's a pleasure to be here with you today.

Before I get to the gist of the meeting and introduce our first speaker, I wanted to go over some logistical information which is always important when we have a large group participating.

Restrooms, if you need to take a break, they're located in the South Building. They're located at the end of each wing, and the ladies

room is, if you find the ladies' room, usually the men's room is all the way down the other end. So Wing 5, which is out the door and to the right, is closed. On Wing 4, it's been just newly renovated, and there's a men's and ladies' room there. Wing 6 and 7, going the other way, if you prefer to take a left as opposed to go to the right.

We have about a 15-minute break scheduled during the session. That will be coming about 10:30. If you feel a need to take a break, please don't hesitate to do that sooner if you need to.

Food and beverages are not permitted in the auditorium. Water is allowed, but we ask you to please take your plastic cups and whatever with you as you leave.

There is a cafeteria here at the South Building. It's located between Wing 3 and Wing 2. So the sticker for those of you who came in as visitors, that sticker will be needed to get into the cafeteria and out of the cafeteria after the meeting is over.

We'll have staff outside in the

registration area, you saw them all probably as you came in, that will be able to assist you if you have any questions or need anything at all.

I will also be managing the public comment period that's stated on the agenda. That will be later on this afternoon after our speakers are finished. I have a list of those that have pre-registered. We have some that want to make a public comment that are on the phone. We'll start with those. If you want to make a public comment, if you could please see our folks outside in the registration area and put your name on the list. So we'll do the ones that are pre-registered first, and those of you that decided today you wanted to make some public comments, we will address those at the end.

We're going to be allotting in that public comment period, we'll probably be allotting about four minutes based on the number of people we had registering for comments. So you'll have about four minutes to capture the main points that you want to make regarding product tracing, and then as

you all probably are aware, we have a vehicle for submitting written comments after the meeting. Those comments will be due May 7th, and if you look on our website, there is a link that gives you some information on how to submit those comments officially.

And, again, if there's any questions or issues that you need some assistance with, please don't hesitate to see our staff out in the registration area. They're excellent, and they've done this so many times they can help you in any way you need.

But thanks again for joining us today. We're looking forward to a good meeting, and I will now introduce Mr. Jerry Mande, who is our Acting Under Secretary for Food Safety for some opening remarks. Mr. Mande.

MR. MANDE: Thank you, Robert, and thank all of you and good morning and welcome to our second public meeting on product tracing.

Almost one year ago, President Obama established the Food Safety Working Group. Health

and Human Services Secretary Kathleen Sebelius and our USDA Secretary Tom Vilsack were given the honor to co-chair that Working Group. So on behalf of Secretaries Vilsack and Sebelius and the Food Safety Working Group, I want to thank you for being here to participate in this important meeting on product traceback.

Food safety is a high priority of this Administration, as evidenced by the Working Group and its accomplishments already. But there is still much more to do.

The Working Group identified improving our ability to trace contaminants back to their source as a high priority in our July 2009 Key Findings Report. As you may recall, we held a joint meeting with the Food and Drug Administration here last December that was focused on improving the system for tracing food products and ingredients related to illnesses, especially during an outbreak.

We asked for and got your input on what's working right in our system, where we have gaps,

and ways we can improve.

I am thankful you are all here today as this discussion continues.

The work here today is important. It's work that's vigorously supported by both the Secretaries and the President, and as Secretary Vilsack has said, we must do everything we can to reduce the number of foodborne illnesses, hospitalizations, and deaths to zero.

Our focus at this meeting is our product tracing efforts for Shiga toxin *E. coli* O157:H7, and more specifically, how we trace back to suppliers when the Agency gets positive test results from its routine testing program. We will share with you our latest thinking on how we can strengthen our traceback efforts, and we will explain the role of PulseNet regarding FSIS positive test results.

PulseNet, which was co-founded by the food safety agencies in Government, including FSIS and CDC, and which I had the privilege when I worked at the White House to announce with

President Clinton, is a prime example of what we can accomplish when we all work together. The national network of public health laboratories combined with epidemiology enables federal agencies to detect and control outbreaks of foodborne illnesses rapidly, a key goal of the Working Group.

Finally, we will share with you our thoughts on next steps. I especially want to thank and appreciate Dr. David Goldman, Judy Riggins, and Dr. Dan Engeljohn for being here to speak and present on these topics today.

The discussions efforts to improve food safety don't stop here. They continue. We also want to hear from you. We have set aside ample time today for comments, and I encourage you to submit comments in writing to us as well.

I appreciate and share your dedication to food safety, and I know we all share a commitment just like the Secretaries and the President to reduce foodborne illnesses and preventable deaths from foodborne disease as low as we can.

Thank you very much.

(Applause.)

MR. TYNAN: Thank you, Mr. Mande. Let me take you through the agenda very quickly. It's a very simple, straightforward agenda that you all have. So our opening remarks, Mr. Mande made those. So we've already gotten into our agenda, but the first presentation will be related to the FSIS role in PulseNet. That will be Dr. David Goldman who is our Assistant Administrator in the Office of Public Health Science. We're allowing about a half an hour for each of the presentations.

The second presentation will be the current FSIS policy implementation, and that will be Ms. Judy Riggins. She is the Deputy Assistant Administrator in the Office of Field Operations.

And after that, we'll take a little bit of a break so that you can think about some of the topics that were discussed, and after the break, we'll have another discussion related to issues for future discussion with Dr. Dan Engeljohn. Dan is the Deputy Assistant Administrator in the Office of Policy and Program Development, and that will

conclude our presentations for the day, and we'll begin the public comment period after that.

We're hoping to have closing on the meeting at approximately 1:00, maybe a little bit sooner.

So with that, I'm going to introduce Dr. David Goldman. As I mentioned earlier, he's the Assistant Administrator in the Office of Public Health Science. He's formerly the Director of the Human Health Sciences Division at FSIS. He's a family practice and preventative health public health physician, and he's a member of the Commissioned Corps of the United States Public Health Service.

With that, I'm going to introduce Dr. Goldman.

DR. GOLDMAN: Thank you, Robert. It's a real pleasure for me to be here this morning and present on behalf of the Office of Public Health Science.

The first thing I need to do is acknowledge Dr. Emilio Estaban who is here in the

1 audience from our Athens Lab. He is our senior
2 science advisor for lab services, and he, in
3 conjunction with the Outbreak Section of the
4 Eastern Lab in Athens, were instrumental in
5 preparing this presentation. So I want to thank
6 them for that.
7 What I hope to do as the slides suggest
8 is to do several things today in fairly rapid
9 order, and this presentation I think is fairly
10 straightforward, but if you have questions, there
11 will be time for technical questions I think at the
12 end of all the presentations.
13 So I want to start out by talking about
14 how FSIS interacts with and participates in
15 PulseNet. As the slides suggest, I then want to
16 discuss briefly a review of *E. coli* O157:H7
17 isolates that were collected by the Agency during
18 calendar years 2008 and 2009 and their
19 relationships with PulseNet clusters. Then I'll
20 turn to a case study that will illustrate the role
21 of subtyping and getting to the source of
22 contamination, and then I'll end up with a couple

of sort of miscellaneous slides to bring you updates on some of our current activities, specifically our efforts to develop a test for non-O157 STECs and then also how we, in the public health community, is using M L V A or MLVA as a subtyping method.

So as you just heard from Mr. Mande, PulseNet is a collaboration that's existed for about 15 years now. All of the state public health labs and all the federal labs are members of PulseNet, and there are daily uploads to PulseNet, to the PulseNet database of pulsed-field gel electrophoresis or PFGE patterns, most of which are associated with clinical cases, that is, people in the community who are sick with a certain foodborne illness and get tested and have a culture which confirms a pathogen; that pathogen isolate gets subtyped via PFGE and that gets uploaded to PulseNet. But there are also food samples, and we'll talk about the importance of having food samples in PulseNet.

So this is just a general outline of the

process flow for either a clinical specimen or a food sample. They are received in the lab that's going to do the culture and confirmation. They do serotyping when it is appropriate. I say as appropriate because, for example, there's no serotyping of *E. coli* O157, but for *Salmonella* isolates there is serotyping, and importantly, the PulseNet database is segregated according to serotypes. So, in fact, there has to be a serotype identified with a *Salmonella* isolate before it can be uploaded to PulseNet.

Then the isolates in the cultures in those labs are processed for PFGE, and the image is uploaded after some quality control efforts are undertaken to the PulseNet database. And then CDC will assign a pattern name if there doesn't already exist a pattern name for the isolate pattern that's just been uploaded.

So just briefly, PFGE really reflects the genome or DNA that is present in a bacteria that has been isolated, and that's the so-called fingerprint, which is a term that's used and

perhaps a little bit misused, but it does reflect the DNA that's present in that bacteria.

So I want to talk a minute about how we, the public health community, look for matches in the PulseNet database. For each pattern that's uploaded, there becomes an expected number of patterns of a given pattern in a specific timeframe or geographic area, and that's what we call the historical background. And if the number of patterns or their geographic occurrence exceeds that historical background, then CDC will designate that event as a cluster, and I'll talk more about what a cluster is in just a little bit.

Once a cluster is designated, though, then the awareness of all the participating laboratories is heightened, and they begin to look for matches to that cluster. And so, in particular, imagine some of the state public health labs who do a lot of different sorts of laboratory analyses. Once they see a cluster that's been designated, they're more apt to prioritize the pulsed-field gel typing of a given isolate in order

to determine whether or not it matches the cluster that's just been named by CDC.

So we use the terms match to indicate that the patterns one to another are indistinguishable. You may have heard that term as well.

So when a food isolate is found to match a clinical cluster, that is a cluster of illness patterns, this is reported to CDC epidemiologists. So in addition to just uploading the pattern to PulseNet, there's an active communication to CDC. And then CDC decides, based on many factors, whether or not to investigate that cluster.

There is also the possibility that in a particular state or in a couple of states that are contiguous, there is what we would call a geographic cluster. So there's a cluster of patterns that have arisen from clinical cases in a fairly narrow geographic area, and those are often reported to CDC, and they may be given a cluster code designation once the epidemiologists, either at the local level or nationally, are able to find

a link between the cases.

Other considerations for designating a cluster include unusual age or sex distribution of the cases, and so, for example, if there were a cluster of patterns and they all happened to be from female patients, or they all were among the elderly, then that would get some special attention and may result in a cluster designation.

The other thing I want to mention here is that the CDC is developing an algorithm of sorts or rule set to help determine when a cluster should be investigated. There are many, many clusters that are identified, and it's a matter of prioritizing among those clusters and weighing various factors. And so the CDC in collaboration with the food regulatory agencies is developing this SOP of sorts.

So FSIS monitors the patterns that exist in PulseNet and, in particular, when we upload a food isolate, we undertake our own review of the PulseNet database. We have staff who are trained on PulseNet techniques, both in the lab as well as

the database itself. They are trained in the application of the Bionumeric software, which is an aid to the investigators to help us recognize clusters and patterns, and so our scientists in the Outbreak Section of the Eastern Lab are actively involved in this investigation.

And, again, any time we upload a food isolate to PulseNet, there is this act of collaboration with CDC.

The last bullet refers to the fact that there is a fairly standard search lookback, if you will, of any patterns that may be associated with a food isolate that's just been uploaded. And so it occurs at various levels, but we do undertake this review ourselves, and the variability of the 30, 60, 90 days really has to do a lot with the frequency of the pattern so that if it is a common pattern, then the lookback is a little bit shorter. If it's a rare pattern, then we'll look back further into the database to see if we can find any matches.

So just to summarize this section of the

presentation, as I just mentioned, the search for PFGE pattern associations occurs at various levels. We do our own as I just mentioned. The CDC is actively looking at this as well as the state participants. They're always looking at the PulseNet database, and there's something called the PulseNet web board, which is an area where more free text sort of communications can occur between investigators.

It's important to say that ultimately, all associations between and among patterns must be confirmed by CDC.

Let me now move to this two-year review of positive isolates that I mentioned just at the outset.

So in calendar years 2008 and 2009, FSIS tested each year of those two years, approximately 11,000 ground beef samples, for the presence of *E. coli* O157:H7. That's the MT43 program for those of you who keep track of our program codes.

During that two-year period, there were 82 samples that were confirmed positive, and the

PFGE analysis was conducted each and every one of those samples. We've been doing that really since the beginning. So it's important to reiterate, for every positive sample, we conduct the PFGE analysis and upload that to PulseNet.

The last bullet refers to the fact that if there are additional epidemiological investigational samples that are collected during an investigation, those follow the same sort of sample flow that I outlined earlier and are uploaded in a similar way.

This is probably one of the most important slides in this set. During that two-year period, again calendar years 2008 and 2009, CDC-PulseNet identified 94 clusters associated with *E. coli* O157:H7. During that same period of time, as I mentioned earlier, there were 82 random ground beef positive tests in our verification program. Of those 82, there were 18 instances in which those isolates were found to be related through PulseNet to existing clusters or outbreaks as defined by the CDC. Of the 18, there were 13 independent events,

and I'll have a line listing in just a minute, and I'll tell you about what I mean there.

The collection of food isolates during these clusters, that I'll get to in just a minute, may have occurred during or after the outbreak cluster date range, but never before the identified cluster outbreak.

I want to make another point here. A cluster may include a food isolate and not be an outbreak, or on the other hand, an outbreak often is a cluster of clinical cases without a food isolate. So it can occur in different ways. The essence is that you need a epidemiological link in order to associate the patterns.

So just a few points about the timing of things here, and we'll come back to this first point later, but the time between collection of a sample and one of the plants that we regulate and its posting to PulseNet can be as quick as seven days, but sometimes it takes up to several weeks, and I'll explain some of the variables that impact that timing.

Cluster definition is a little bit subjective, and this comes directly from the PulseNet director at CDC, but generally back to my earlier description of a historical baseline, any aggregation of patterns that occur in a 60-day period that exceeds 2 times the expected frequency may be considered a cluster and often is considered a cluster. That's not a hard and fast rule, but that's just a rule of thumb.

The pattern name may change as the knowledge of the pattern evolves. What I mean by this is that during an investigation, we've had the case in the past that there was consideration of whether a pattern with a one band different, for those who are familiar with that terminology, should be included in the cluster or not, and sometimes depending, as the investigation unfolds, that determination is made. So the pattern name may change as a result of that determination.

And then the frequency of the PFGE pattern in the database is quite variable, and again we'll show you that in just a minute.

So in this next slide, and I'm glad you can see most of that. I don't have a pointer, but I want to orient you to the columns here. As I mentioned earlier, there were 13 independent events. So you see that in the first column. The commonality means the number of times that pattern was uploaded to the PulseNet database. Again, this is the two-year period, 2008 through 2009. The timing refers to when the collection of the sample was done in the FSIS regulated plant, and you can see, with one exception, they were all collected during the cluster date range, which is the second from the last or far right column there.

The classification refers to whether this was an outbreak, ultimately defined as an outbreak, or whether it remained a cluster, which means that the source of the contamination was never found.

The collection date again is the collection in the plant. The OSEL date, the Outbreak Section of the Eastern Lab, refers to the date that it was received in our lab, and I'll talk about the timing there as well in just a minute.

And then the upload date is the date that the OSEL scientist actually uploaded the pattern into PulseNet.

The cluster date range, of course, often is defined or probably always defined in retrospect because we don't know when the last case was until the outbreak or the cluster is defined as being over.

The last column is the cluster size. You can see there's quite a bit of variability there.

I want to explain a couple of things before we move on from this slide, and that is that you can see event 8, there are three kinds of separate entries there, and for event 11, there are four separate entries. The reason for that is that FSIS, I think many know this, analyzes five subsamples. So for every sample we receive of ground beef, we divide it into five subsamples. If one of those subsamples is positive, it's considered a positive, but in some instances, we have multiple subsamples that come up positive, and in each of those cases, we have determined that we

should analyze each of those isolates separately, conduct a separate PFGE on each in the event that there are different patterns contained in a single sample. So that's why you see those multiple entries for events 8 and 11 there.

The other thing I want to point out is if you look at events 1 through 4 and add 7 to that, they're all part of the same cluster. And a couple of points to make here. This was a big cluster. There was a long date range you see there, almost five months. Eventually, if you look at event 7, at the time we looked at it, there were 406 uploads to the PulseNet database. So it's a very common pattern, and I just wanted to point out that relatedness between those five events there.

Okay. The next series of slides, I'm going to tell you something about the timing of the processing of these samples. So in this slide you see just the two columns highlighted here, the collection date and the OSEL date. Again, that's the date it's received in the Outbreak Section of the Eastern Lab for processing.

Really, the variability here is fairly minimal. It says five to seven days. So a lot of the variability, and even the fact that it takes that long has to do with the fact I think most people recognize that we isolate O157 or we analyze samples in all three of our field service labs. The Outbreak Section obviously is in Athens. So if there's a positive sample in Alameda or in St. Louis, that isolate has to be shipped to the lab in Athens, Georgia, for processing. So that's probably the biggest factor in terms of the five to seven days it takes for it to be received in the Outbreak Section of the Eastern Lab.

In the next slide, this is meant to depict or highlight the time it takes from receipt in the Outbreak Section of the Eastern Lab to the upload into PulseNet. I said earlier, there was a little more variability here, and I want to try to explain a little bit of this. When it's received in the Outbreak Section of the Eastern Lab, they actually have to regrow the pathogen. They get what's called a slant, and they actually have to,

you know, regrow the pathogen first. Then they have to run the gel, which usually takes parts of two days to do. Not all gels are perfect. Sometimes gels have to be rerun, and then there is a final step which is very important, and all the gels are reviewed and certified, so to speak, by CDC before they're posted. So that explains the variability in the time to upload there.

The next slide is just again to highlight the fact that the frequency with which a pattern is present in the database is quite variable, and I think these are the extremes in this particular review.

In this next slide, again just to reiterate earlier discussion about clusters, the cluster really varies most by time but by geography as well and by the frequency with which a pattern exists or some combination thereof. So the clusters are quite variable, and you can see here as well the date range for many of these clusters is quite long. In fact, in most cases, it's at least a couple of months, which is pretty typical

of the clusters.

In this example, it's meant to show that, you know, the outbreaks and cluster sizes vary quite a bit. I don't want to generalize about this, but it's not always true that an outbreak is going to have more uploads to PulseNet than a cluster, but if you think about it, clusters tend to be smaller meaning they are not solved. The source of contamination is not found because there's less data there to be analyzed or to be reviewed. If there are fewer cases, then there are fewer interviews done, fewer food histories obtained, and there's less data on which to base or generate any hypotheses about the cause of the contamination.

I want to highlight these three particular events. Two of the three are examples of events in which the collection of a sample happened to coincide with the beginning of cluster date range, and I don't know this to be true, but it's possible that the upload from the food isolate may have been the first entry in this cluster, but

these are the three in which again two out of the three, they occurred at the beginning of the cluster date range, and in one the collection of the sample was just after the beginning of the cluster.

So this is those three events again. In each of the three instances, there was no contamination source ever found. In two of the three, the cluster sizes were, actually in all three, the cluster sizes were very small, and in two of the three, they were infrequently seen in the PulseNet database. So this is just to kind of reinforce the point that these are small clusters. They were collected early in the cluster date range, but these particular events were not ever concluded in terms of the contamination source.

Now, I'm going to move, as we move toward the end, to the case study. You see at the top, there are two events listed for event 9. If you think back to the original line listing, that first entry was not listed there, and I'll explain why it's listed here, but that first entry, the

collection date of 5/7 was actually an OPEER retail ground beef sample. So it was not even part of the MT43 program but rather the MT05, but that was part of this investigation. So that's why I've shown this here, and I'll explain how it eventually fell off this line listing.

In the next slide, this shows the fact that during this particular investigation, which did lead ultimately to a recall, that both FSIS and the New York State Department of Health sort of independently concluded that there was both a clinical isolate and a retail ground beef isolate that seemed to be indistinguishable according to PulseNet, and the match was reported on the very day that the pattern was uploaded. So it was recognized immediately.

And in this particular case, the food isolate originated from, as I mentioned, the routine sampling which was part of the retail program, not our MT43 program. And this was the first food isolate associated with the cluster. So that the event that's highlighted with the

collection date of 5/7 is the first food isolate that was initially associated with this particular cluster.

As the investigation unfolded, it was later determined that that particular isolate was not part of the outbreak. So it was part of a PFGE, a PulseNet cluster, but through the use of MLVA, and as I said, I'll mention more about MLVA and its use a little bit later, it was determined that this particular isolate, again the ground beef isolate collected by our OPEER program investigators, was not part of this outbreak.

So this slide now focuses on the second entry which again was depicted earlier on the line listing of these events. In this particular case, this entry refers to a routine ground beef sample, again part of our MT43 collection program, from an establishment. It happened to be a small grinder that produced product from where it says same source material, that refers to the same source material as the retail sample that was collected earlier had.

Then you can see that there was a review by PulseNet, and this was identified as an apparent match to the cluster that was being investigated and then was later confirmed.

It's fortunate when there is a food match because it helps with traceback, so even in the case where we were initially concerned with the ground beef positive from a retail sample, it allowed the Agency to begin its traceback activities even though ultimately that particular sample was not shown to be part of the outbreak.

If there's not a food match, the regulatory agencies are left to rely on case control studies or other epidemiologic studies that the CDC or the states do to draw conclusions about the source of contamination. So that's why I said it's good for us when there is a food match because it helps us in our investigation.

Just to finish up this particular example, the CDC performed MLVA and determined again that this isolate from 5/21, which again was a routine sample collected at a grinder, not part

of the investigative activities, but rather just a routine sample, was a match by this MLVA, but then again the MLVA confirmed that the first supposed match was excluded based on the MLVA results.

As part of the investigation, and this does happen fairly frequently, the Outbreak Section did receive product from the source meat producer as part of the investigation, and those particular samples were found to be negative in our labs.

So the conclusion here is that the only food sample ultimately associated through this outbreak investigation using both PFGE and then ultimately MLVA was from a grinding establishment that used source product from a single source.

This final slide here is just an overview mostly about the timeline that I've already outlined for you. The product is sampled at an establishment. I think everyone knows that in nearly every case, but not in all cases, the product is held while the sample is being processed, and then, you know, usually about day five or six, *E. coli* O157:H7 is isolated in one of

our labs and, of course, if the product has been held, then the company decides how to dispose of that, but it doesn't go into commerce, and then if it's in commerce, then we usually proceed with some discussions about recall.

And then you can see later the upload of the patterns to PulseNet and then the activities that occur subsequent to that, the ranges from 8 to 100 days really is meant to convey that there is an ongoing review activity that occurs once patterns are uploaded to PulseNet as I mentioned earlier.

So I'm going to end up here with a few of the miscellaneous slides. We've had discussions from time to time about non-O157 STEC methods development. I think most people are aware we've been working with ARS, the Agricultural Research Service, for some time to help us develop both a screening and a confirmatory method. We're at the stage of still trying to get a screening method that will work in our labs, and I'm not going to go through all this data, but as part of this method of validation and method development, the method

development on the ARS side and the method validation kind of on our side, we did look at some historical archived isolates called lysates, and we tested the PCR probes against those lysates, and you can see the data kind of speaks for itself. What I want to point out here is, and this is kind of a current state, the probes that were provided and developed by ARS do not seem to work very well for O111 and O145. They seem to work fine for four of the six serotypes but not for those two. So we are continuing to try to get a method, a screening method that will work for all six of the serotypes that we've identified previously.

And I want to draw your attention to the last bullet there. There were three samples, representing about 1.3 percent of all the 224 we tested, in which we found through PCR the O antigen, the stx which is the Shiga toxin gene and the eae or intimin gene. So if you had to draw any conclusions from this work, you might say that we might expect to find one of these serotypes in roughly 1 percent of the samples.

But I want to mention a very important caveat. This is just PCR testing. We don't have an organism. We have not gotten to the point of isolating an organism. So you can't really say, and we don't know for sure whether, in fact, all of these determinate, the O antigen, the stx and the eae, came from the same organism, were contributed by different serotypes, different organisms, and even whether they were necessarily from live organisms. So there are lots of questions yet, but I wanted to update you on that.

And then finally, just very briefly about MLVA because I know this has been a point of much discussion, MLVA is a complement to PFGE. It is not and never will be a substitute for PFGE. It is another method of subtyping, and you see the actual name there, multiple locus variable number tandem repeat analysis. It is a different way of subtyping that can be of assistance. So if there's a very common PFGE pattern, MLVA can be employed to help distinguish among those very common PFGE patterns, and it helps us in other ways.

On the last slide, you can see some of the ways that it might be used. So you can take some isolates or some representative isolates. Another approach is to take all the isolates in a cluster and conduct the MLVA as part of the effort to define the cases in a cluster or in an outbreak I should say.

I do want to point out that FSIS is now conducting MLVA on all O157 isolates as a proactive measure, so that in the event it's needed during the course of an investigation, it's available to investigators.

So with that, I will conclude my presentation, and I'll be around later for questions or comments.

MR. TYNAN: Thank you, Dr. Goldman. I appreciate you clarifying that. For us non-scientists, that was a pretty clear presentation.

I just want to clarify something, that we're not taking questions at today's meeting, either between the presentations or during the comment period. We will allow for comments. If

you have some questions, they will have to be folded sort of into the comment period, but we will not be responding to those during this meeting. So I just want to clarify that so that there's no misunderstanding in how we will be proceeding.

Let me take us to the next presentation on the agenda, and it has to do with the current FSIS policy implementation, and I have Ms. Judy Riggins. She is the Deputy Assistant Administrator in the Office of Field Operations. She's responsible for the day-to-day operations, the administrative policy enforcement issues related to our field inspection programs. And with that, Ms. Riggins.

MS. RIGGINS: Okay. Good morning. This morning I'm going to talk to you about what we do, the actions that we take in a routine FSIS positive for O157:H7 situation, and before I go through the current thinking on our new approach, I wanted to kind of walk you through very quickly, describe what our inspectors currently do with regard to O157:H7 positives so that you can see the contrast

between what we do now and what we are contemplating doing.

And this information is found in our FSIS Directive 10010.1. So if you want to review it at some later time, that's the reference.

I'm just going to walk you very briefly through what our inspectors do.

At the time of a presumptive positive, our inspectors are instructed to inform the plant that the sample is, in fact, presumptive and that they will be coming back to them at the point when the product sample is determined confirmed to be positive to ask for some additional information. This prepares the plant for gathering the information that we're going to ask them for.

At the time that the sample turns positive, we then have the inspector provide information to the District Office, and it consists of this information, the name of the supplying establishment, supplier lot numbers, production date and the name of the supplied material, and any information that can be used to identify that

storage or that source material that was used in the making of that particular ground beef lot, the source materials for a confirmed positive that are from a foreign establishment, and there's a whole series of information that we collect on the foreign establishment.

We also at that time, at the time of the confirmation, the inspector writes a noncompliance record, and we do give the plant time to respond to this noncompliance record. We give the plant time to determine what it will do to properly dispose of product, and in the meantime, while this information is being relayed to the District Office, that information is then entered into our step system by the District Office, who has this particular plant in its geographical area.

Once the information is entered into the step system, and this is a system that captures all the information about source supplier plants, the districts that have plants in their geographical areas where these suppliers are located are also contacted, and this information is relayed to them.

The inspectors in those plants who did receive product then are asked to also gather additional information about the product, what was used, how it was used, how that plant then made sure that there was control of that product, where did it go, so that we can track it back and determine where all of this product that was from the same source material may have gone. And we keep tracking it back and tracking it back until we find it.

With regard to the NR, we then have the inspector at that plant conduct an O2 procedure wherein he or she will review all the records that are related to the processes that were used in the production of that particular implicated lot, that adulterated lot, and we determine whether or not all of their HACCP and prerequisite program and other components of their food safety system were, in fact, executed in the manner prescribed in their procedures.

At the plants that were identified as supplier plants, we have the inspectors collect follow-up samples. For large volume plants, we

collect 16 samples, and for small volume plants we collect 8 samples, to determine whether or not there is still an indication that product that's being produced by that plant is, in fact, being produced in insanitary conditions and product would be rendered adulterated.

So that's kind of a thumbnail sketch of what we do with regard to a positive currently, and our inspectors are continuing to traceback to determine information. So we don't ignore information. We do traceback to all possible sources.

Now, I'm going to walk you through our current thinking, and I want to acknowledge the work of the team that actually developed this current thinking on a new method for our EIAOs to conduct. I want to thank Catherine Rockwell, Jennifer Webb, Lisa Volk, Bill Shaw, Evelyn Mbande, Joan Collins, and Teresa Taylor for the work that they did on this method, and with that, thank you.

So this first slide basically talks about

the purpose of the new methodology. We believe that we can improve our work that we are doing, we can improve on our inspector's method. It is not to replace the inspector's method. They will continue to conduct their responsibilities in plant, but this is a new thought process that we are considering, that would be used by EIAOs at the time of the presumptive positive so that we can get more detailed information at an earlier time. And it provides our EIAOs with a new thought process at the point when we have a presumptive positive for either raw ground beef or raw beef trim.

We hope that it will help us to identify affected product in beef suppliers where the contaminant most likely was incorporated on the source materials used to produce either the ground beef or obviously the trim at slaughter.

The notice also provides instructions to our District Office for managing the information gathered during a product traceback. And that's important because the communication that has to occur among District Offices in order to make an

effective transfer of information is important, and it must be done in a timely manner.

So at the point of the presumptive positive, we know that presumptive usually, based on the methodology that we're using, it takes about 48 hours for the confirmation to occur if it does confirm positive, and we know in a majority of cases, that it does confirm positive.

So at that presumptive stage, we intend to send an EIAO to the plant where the presumptive positive was detected, and we intend to identify all affected product and the potential suppliers earlier in the process and to respond more rapidly to protect the public health.

The EIAO is to determine whether a sole source supplier or multiple suppliers produced the source materials in positive raw ground beef product or in trim. And within 48 hours of being notified of the presumptive positive, our EIAOs are to first collect information and report investigative findings in accordance with our AER reporting system, document their findings to a

series of questions that I'm going to walk you through that are in Section A and Section B of our new methodology, and then they are to use the decision tree that's been developed for them to determine which questions apply to a particular traceback situation because we want to make sure that we have covered all of the possibilities that could occur in a situation where product has become adulterated.

The EIAOs are to prepare a memorandum to the District Manager, the Deputy District Manager, and the District Case Specialist to inform them about the summary of their results of investigations and to recommend further action. Again, that's important because the information has to be conveyed quickly to our District Office so the District Manager can make decisions about what the next appropriate step should be.

EIAOs are to communicate with the District Office to ensure that all necessary information has been collected regarding the findings and are to discuss any issues that need to

be clarified that may warrant further follow-up.

So then with regard to the actual thought process that we're contemplating using, we have a separate set of questions, one set for traceback for originating slaughter establishments and grinders of source materials derived from the slaughter establishment, and then a second set that will be used in instances where we have grinders of source material from cattle that's not slaughtered at that establishment. That means that I'm a grinder and I've received trim, okay. So we have two sets of questions. We know that some of the plants are obviously producing their own trim, and we have to make sure that we're covering all of the instances that could occur.

We also have developed a decision tree which is in this slide to make the decision making, especially in a time where our EIAOs are expected to gather information quickly, to kind of streamline their thought process and help them to distill that information and come to a logical conclusion.

So we're expecting them to provide the following for each source material that's used in the implicated product lot. First of all, the supplier lot numbers, the production dates, the name of beef components that are used in the production of the implicated lot, and then the amount of beef component that was produced in pounds.

And once they determine that information, we're then going to expect them to gather the following information using these questions to guide their inquiry, but they will not be the only questions that could be asked by an EIAO because their thought process should lead them to ask the next logical question once they receive certain information. So these are example questions that are expected to be used to guide their inquiry.

What information does the establishment have about the slaughter, dressing, and fabrication of their source materials?

What were the results of the establishment's sanitary dressing and process

control procedures that are included in their HACCP plan, their sanitation SOP, their GMP or other prerequisite programs for the production day in question?

Were there any process changes? Were there any changes in the process for the production period in question, such as a new process or a procedure introduced, a new intervention being applied or a non-routine event?

Are there any documented failures by the establishment or by inspection personnel of the establishment's sanitary dressing and process control measures for the production period in question? So we would expect them to look at any event changes, any zero tolerance failures, any NRs, any improper sanitary dressing practice events that could have occurred.

We also expect them to look at the generic *E. coli* testing programs. What were the results of their generic *E. coli* testing program on that production run? Do the results for the time period in question indicate a loss of control? And

if so, we also want them to understand what did the plant do in response to that, if anything.

Then with regard to *Salmonella* sampling, what category is the plant in? Are they in Category 1, 2, or 3? Is a sampling set currently being conducted by FSIS? Does the establishment do its own testing? Do the results indicate a loss of control? Is the plant using its *Salmonella* testing to make any decisions? And if so, how do they use it?

Does the establishment have *E. coli* O157:H7 verification testing programs during slaughter fabrication? Was sampling performed during the production in question? If 100 percent testing of all trimmings is not designated and controlled to ensure ready-to-eat processing is not conducted, what is the rationale?

In other words, we're going to be looking at their hazard analysis decisions that underpin their current processes.

Did the establishment receive positive test results? Do results indicate occurrence of a

high event period? A high event would be a day on which they had done their own *E. coli* O157:H7 testing and found that there were a significant number of lots, a significant number of combos, that were positive for O157:H7. What decisions did they make regarding those positives? What did they do about primal and subprimals that were produced in those high event periods? And do sampling results provide a clear definition?

Other questions that we've been asking are, are any of the source materials associated with the positive test results used in the production of other raw products? If yes, name the products produced so that we can traceback.

List whether the products are intact or non-intact. Were the source material on the same production lines or food contact surfaces of source materials implicated by the positive ground beef test or by the trim test? Are interventions or other processes used? We're going to be looking at their interventions to determine whether they were actually executed in the manner prescribed. Were

they using the appropriate concentration, the appropriate temperature, the appropriate duration of time, the appropriate pressure, the appropriate pH, all of those parameters that make a difference in whether or not it was an effective application.

And are all products under the establishment's control, or have they been shipped? Of course, that's a very important question for us, whether adulterated product has actually been shipped in commerce.

Then the next set of questions, Section B, is with regard to traceback for grinders, those who have actually received the product but who are not producing trim at their facility.

We're going to expect the EIAO to determine who the domestic suppliers are, the establishment name and establishment numbers, what source material information is on hand at the grinder, the supplier lot numbers, production dates, name of the beef components that were used, the number of pounds that were used.

We're then going to expect for foreign suppliers that we will gather the same information, who was the foreign establishment, the number and all other pertinent information that would have come with that particular shipment that was used in the production of that lot that was found to be adulterated.

We're also going to gather additional information on the foreign product, the health certificate number, the production date, the shipping marks, the date the imported product entered the country, and name or description of the supplied source material because we're going to have to trace to find out who else might have received that product.

We're also going to ask what information does the establishment have of the source materials? What were the results of the establishment's processes that are included in their HACCP plan, GMPs, SSOPs, or other prerequisite programs for that production date?

We're also going to gather information on

whether the establishment implemented any decontamination or antimicrobial interventions for that production period in question at that grinding establishment.

Does the establishment implement controls that are more rigorous during a high prevalence season, April through October?

Does the establishment have purchase specifications that require the establishment to conduct validated interventions during slaughter or fabrication, testing of carcasses or trim, for O157? Because we want to know what are they requiring of their suppliers and on what information are they basing their hazard analysis decisions.

Do the source materials used in the production of ground beef have a certificate of analysis? Are they receiving a certificate with each shipment?

We're also going to look at any process changes at the grinder. Were there any changes in the process for the production period? Such as was

a new process or procedure introduced? Did they have new employees or new equipment? Was there a new intervention that was applied or a change in the application method of the current intervention? And was there a non-routine event that may have affected the product?

Upon review of the SSOP or other prerequisite programs and all associated sanitation records, we're going to ask for the time period in question, were there any documentation that indicated that an event occurred that would distinguish between the time period in question and other production periods? In other words, was there some very distinctive event that occurred that would have resulted in adulteration of product or breakdown in their food safety system?

SSOP noncompliance records that would have indicated insanitary conditions that occurred, or SPS noncompliance documented events such as improper employee hygiene or equipment failure that might have occurred that could have resulted in the adulteration.

We're also going to ask does the establishment have an *E. coli* O157:H7 verification testing program? Was sampling performed during that period in question? Did the establishment receive any positive test results? If so, how did they use those positive test results? Did they indicate a systematic cause of breakdown of systematic control for that period? And did the establishment take appropriate corrective action?

With regard to rework, we're going to ask whether the plant uses rework. Is there any carryover product or any other evidence of overlap of production periods for the production lots in question?

We're also going to ask, are there any source materials associated with positive tests used in the production of other raw products? If yes, name the products produced and list whether the products were intact or non-intact. Were the source materials all on the same production lines or food contact surfaces of the source materials implicated by a positive ground beef or a positive

trim results? Are interventions or other processes used by the plant that would have accounted for or addressed pathogens on that product? And are products under the establishment's control or have they been shipped? Because we're going to need to follow through to track that product to wherever it might have been shipped.

Then we go into a description of the District Office's assignments or requirements because we want to make sure that the District Office understands what needs to be done. We're expecting the District Office to assign the EIAO to conduct the traceback, and after the presumptive positive, we're going to expect -- actually, this will be done within the first 48 hours at the time of a presumptive.

So when we're notified about the epidemiological information, if there is any, we're going to expect that we will actually deploy the EIAO at that time. And if multiple suppliers are involved, the District Office in whose area the original positive sample is detected is expected to

contact the Districts where we know the product originated, those suppliers. If we have four suppliers, five suppliers, it doesn't matter how many, we're going to ask those District Offices to deploy EIAOs to those plants and to also conduct the same type of inquiry so that we're sure that we're gathering all of the information about every supplier that would have contributed product that went into the making of this particular ground beef finished product.

We're going to expect that the District case specialists in each District will gather all of the information from each of the EIAOs who will have been dispatched, and we will have a District case specialist to prepare an AER that will summarize all of the information that will have been gathered. So we have the information from the original grinder establishment as well as all of the suppliers to that grinder, and make sure that all that information is an AER and is readily retrievable.

It's important that we document

everything in a clear and concise manner and that we have an adequate record of that occurrence so that when we are looking back at what happened, we're not fragmented. Part of our issue now is to make sure that our documentation is in our -- note system which is where we actually house all of the enforcement information. So we're making sure that we're clear in our directions to the District Offices about documenting that information.

And the very last slide, I think I've summarized everything that has been said here, the very last slide is another flow chart which describes all of the activity and kind of synthesizes it for our EIAOs as well as our District Office personnel and our case specialists especially who are going to have to be the ones to actually gather and document, make sure that all the information has been adequately documented for each event.

With that, I will close, and Mr. Tynan.

MR. TYNAN: Thank you, Judy. We're a little bit ahead of schedule, and given that this

is a large building, I think we probably ought to use that to start our break sooner than later. What I would suggest is that we come back not at -- I'm going to make an adjustment in the schedule, not at 10:45 but maybe 10:50, give you another 5 minutes. The cafeteria, those of you who are having a caffeine attack and need their Starbucks, it's out the door, to the right, at Wing 3. So if you want to grab a cup of coffee, but please be back here promptly at 10 minutes to 11:00. Thank you.

(Off the record.)

(On the record.)

MR. TYNAN: The next presentation on our agenda is issues for future discussion, and that's Dr. Dan Engeljohn. Dan is our Deputy Assistant Administrator in the Office of Policy and Program Development. He manages staff that develop the regulations and policies associated with inspection procedures, data analysis, performance standards, strategies, and things of that nature. Dan.

DR. ENGELJOHN: Thank you and good

morning.

I'm going to walk you through a bit of the history of where we've been with O157:H7 and the design of our verification program to be protective of public health and then end with current thinking for which the Agency is in the process of developing further for next steps, and I believe that you have copies of this presentation. If not, I know that they'll be made available to you.

Next slide.

First, I'm going to make sure that it's clear that you understand the Agency is, in fact, looking at how we develop our food protection strategies differently now than what we had in the past. We are, in fact, now operating within the Food Safety Working Group that Jerry Mande mentioned in his opening remarks, and we have a very specific charge in which the federal agencies responsible for food safety are to work collaboratively in terms of developing an overall strategy to be protective of public health and

1 responsive.

2 And so the three primary principles for

3 which are, in fact, developing our food safety

4 strategies relate to preventing harm to consumers

5 as being our first priority. Secondly, we need to

6 do this through systems in which we are able to

7 work from good data and that we're conducting

8 analyses of those data to influence how we move

9 forward, and that we have effective enforcement

10 strategies in place.

11 This is particularly important from the

12 perspective that the Agency, FSIS, is, in fact,

13 undertaking its new Public Health Information

14 System, which is set to begin this calendar year in

15 terms of deployment to the field. And it is

16 specifically designed to gather new and better data

17 about what's happening in all the operations that

18 we conduct inspections in, such that we are able to

19 discern whether or not there are changes or

20 potential changes that might affect the food safety

21 system sooner than relying upon illnesses to drive

22 us to those operations or to have other information

from the outside that indicates that there has been a problem at an establishment.

And then finally, the agencies are to work together to ensure that we are, in fact, identifying outbreaks sooner and responding so that they're stopped, and this is important as well in the sense that identifying the source is becoming a more important issue as we move forward in that attribution as to what caused the individual to become sick, which food, becomes a critical issue for the agencies in terms of developing risk management strategies.

I want to remind you that the Agency has been driven since 1997 on the Healthy People 2010 goals. We still as an Agency here at FSIS adhere to meeting these goals. We've been successful in many cases of moving towards achieving the goals by the target year of 2010, but I'm going to focus today on *E. coli* O157:H7 because it is the topic of this public meeting, and it does demonstrate that we've had what we consider to be tremendous success in reducing human infections for this particular

pathogen since we began tracking our changes in our food safety strategy in 1997.

The baseline year 1997 identified that 2.1 individuals were infected with *E. coli* O157:H7 from all food sources per 100,000 population, and the goal was to halve that by the year 2010. The tracking of this particular performance measure is through the FoodNet data, which is a collaborative effort between CDC, public health partners in the states, FSIS, and FDA. In 2008 the human infections were at 1.1 per 100,000 individuals.

FSIS has been working very hard at trying to better attribute what foods are, in fact, causing people to get sick and, in particular, the foods that we regulate here at FSIS which includes the meat, poultry, and processed egg products.

We do use our verification testing results in a way in which we associate that with human infections to identify an attribution estimate. We have worked with CDC on this in terms of the methodology, and we, the Federal Government, as part of the Food Safety Working Group, are

1 specifically looking at how we can better design
2 attribution models to have more confidence that we
3 know which foods are, in fact, causing people to
4 get sick. But because we do have a robust dataset
5 related to ground beef samples, and our
6 verification testing program of approximately
7 11,000 samples each year, we have developed a model
8 in which we associate with the bullet that has the
9 two asterisks by it that approximately .34 cases
10 per 100,000 are directly attributable to ground
11 beef products.
12 So, for FSIS, we look at not only this
13 overall number of getting it down to below 1 by the
14 year 2010. That's for all foods, but presently we
15 believe that .34 cases per 100,000 are directly
16 associated with the consumption or handling of
17 ground beef products. This is based on, in part,
18 the volume adjustments that we have to our
19 verification testing data and which we place more
20 emphasis on larger volume production operations and
21 positives that we find in those establishments
22 because the exposure to human public is greater

because of the greater volume of product that's produced.

So we do track this from year to year, and from our data, we would identify that the attribution to ground beef has, in fact, been decreasing over the last couple of years.

Now, to get at the policy milestones, to remind you where we started, so that I can give you a perspective about where we're going, in 1994, primarily in response to a large outbreak associated with food service consumption of ground beef, the Agency did declare *E. coli* O157:H7 to be an adulterant in ground beef product. This is the product closest to the consumer. It was the product that was causing individuals to become sick, and so our initial policies were focused specifically on ground beef and only ground beef was considered to be adulterated if found to be positive with *E. coli* O157:H7.

We were challenged in court on this particular issue, and fortunately we were supported in the court decision that our adulteration

determination was, in fact, valid and appropriate. Some of the reasoning behind that adulteration determination was that thorough cooking by the consumer is less than what is required for food safety, and so even though thorough cooking would under normal circumstance render this contaminant to be rendered safe, thorough cooking by the consumer of ground beef products was such that that is not necessarily the case, and the court agreed that that is, in fact, how the consumer viewed this product.

In addition, the pathogen is particularly virulent in that it's different than other pathogens that we typically would find in raw products, and that again, thorough cooking would not render this product to be safe. And so this, plus other determinants, the Agency moved forward and was successful in maintaining that it's an adulterant in raw ground beef products.

In order to stimulate the industry to gain active control over this particular contaminant -- this was pre-HACCP in the sense that

we had not yet issued our HACCP regulations that shifted focus to the establishment to ensure that they, in fact, were controlling the food safety hazards that are appearing in the meat products that were being produced. This particular issue came about before HACCP, and the Agency began a verification testing program directed at half of these 5,000 samples being at retail operations and the other half being in the federal establishments, but we started with 5,000 samples directly associated with ground beef products.

In 1997 the Healthy People 2010 goals were published and put in place, giving the agencies a roadmap in terms of designing risk management strategies that, in fact, could be protective of public health. Even though the outcomes were based on human infections and we, the regulatory agency, do not regulate people on how they behave, we do regulate the products that they, in fact, are able to purchase. And so this set in motion a charge for us to design risk management strategies that would drive down the potential

exposure of the public to various pathogens in food products. We began that in 1997.

At the same time, the Agency initially began analyzing a 25-gram sample in terms of our analytical procedure at the laboratory. We determined that it was necessary to increase the sample size in order to have a greater likelihood of finding this contaminant which we believed to be sporadic in nature and when present would be at low numbers. The Agency changed its sample size from 25 grams to 325 grams. We do have on our webpage a chart that tracks our percent positive rate over time since the beginning of the program. There's a tremendous leap in terms of the number of positives that we found after we changed from the 25 gram to 325 gram sample. So we believe that that was a first important mitigation that was designed to have a better likelihood of finding contamination if it were to be present in products that we regulate.

Another significant event then happened in 1999 when the Agency also adopted a new

1 laboratory method which was aimed at selecting the
2 pathogen, as well as being able to better detect
3 that pathogen in a sample. So in 1999, there were
4 additional factors put in place to increase our
5 likelihood of finding this contaminant in raw
6 ground beef.
7 We also clarified in January of 1999 that
8 it no longer was a prudent risk management strategy
9 to focus simply on ground beef product, which was
10 the end product. The contamination we knew at that
11 time was occurring on the slaughter operation most
12 likely. It wasn't necessarily being introduced
13 throughout further distribution and that most
14 important place to mitigate this risk would be at
15 slaughter dressing. And so the Agency modified and
16 clarified its interpretation of the adulteration
17 determinations in 1999 and clarified that source
18 materials used for ground beef products would, in
19 fact, be considered adulterated if found positive
20 for this particular pathogen.
21 In addition also, products that
22 traditionally would not be used in ground beef

production, if, in fact, they were to be used or if they were to be used to make a non-intact product such as a mechanically tenderized steak or roast product, that product also would be considered to be adulterated. Again, creating a non-intact product changes the necessary cooking and handling instructions that the consumer would need in order to safely prepare this product. So we changed that procedure in 1999 and then began focusing on source materials and control of them to reduce the risk of *E. coli* being in raw ground beef products.

And our next significant event then occurred in 2002, in which the Agency formally began its STEPs process whereby we were beginning to track information about slaughter suppliers to operations in which we found a positive sample at a ground beef operation. This was our initial attempts at finding out what, in fact, was happening at slaughter operations to assess whether or not there was a systemic breakdown that could be leading to adulterated product getting into the marketplace.

It also was the period of time in which the industry collectively began looking for *E. coli* in trim. The Agency had not yet begun testing for trim up until 2002, but the industry collectively decided that in order to get a better grip over the control for *E. coli*, it was necessary for them to come up with some uniform or standard procedures in which they would begin testing trim before they released it to the Agency as a production lot that's ready to receive the mark of inspection. So testing of trim then began in 2002 on a wide scale basis by larger operations producing manufacturing trim.

Our next significant event would occur in 2004. This is 10 years after the Agency had declared that *E. coli* was an adulterant in raw ground beef and just a few short years after we had modified and clarified that definition to include source materials.

This put a focus then on the supplier. By this period of time, the Agency had been investigating and studying what would be an

appropriate verification strategy for the Agency to undertake that would supplement our raw ground beef verification testing program. And so in March of 2004, the Agency issued new instructions to our inspection program employees in which we began the process of collecting samples of manufacturing trim. This would be product that was produced by slaughter establishments in that slaughter operation. So our focus was to get a handle on the process control that was being delivered by the operation that was producing trim that would be going into the marketplace.

In 2007, the Agency issued another significant policy change. This was after a very large scale recall in which the Agency had found that we had previously conducted a food safety assessment in an operation, but that that operation had changed its production practices after that review had occurred and had not necessarily been picked up by the Agency in terms of a change in the operation. And so the Agency then for the first time issued a checklist survey to our inspection

program personnel in which was asked a series of questions about the production control practices in slaughter and further processing operations in which raw beef was being handled.

This was a first look by the Agency as to what was being produced, how much was being produced, and what were the interventions in place in those particular operations, and it included questions about verification testing, the types of pathogen reduction treatments in place, the number of suppliers that a particular grinder might be using, and it conveyed best practices that the Agency considered to be prudent for an establishment to be following if, in fact, they were properly controlling for this particular food safety hazard in raw beef products.

In 2008 the Agency then followed up with compliance guidance in a draft form in which the Agency specifically focused on N60 testing. This would be the testing protocol that industry was commonly using and that the Agency had adopted in terms of looking to see if we could find

contamination in production lots that would be produced under good manufacturing practices.

In essence, the Agency had determined that a N60 test, when conducted properly, would help establish the microbiological independence of one production lot from another, and that was the beginning of our focus on being able to discern whether or not a production practice was operating properly versus one that could indicate that there was a systemic problem.

This led the Agency then to identify some tentative criteria that we thought would be appropriate to use to identify when are too many positives too many, and again we expect the establishments to be using verification testing to identify whether or not *E. coli* is being properly controlled in their operations. We know that the interventions, applied during slaughter and dressing and during further fabrication, are generally not capable of eliminating this pathogen from raw product. There are interventions that are capable of eliminating *E. coli,* but they're not in

widespread use, and they're not mandated. Those would include high pressure processing and irradiation, as two examples.

In any case, the Agency was looking to see under good handling of the slaughter dressing procedures as well as through the trim testing program what would be an indication that same source materials that are traversing across conveyor belts and employees with the same knives and handling procedures could, in fact, be cross-contaminating one production lot to a next, but in any case, what would be an indication that there was a trend towards a breakdown in the process control from one production lot to another, and the Agency did identify criteria. At that time, we identified that for a production operation that was testing robustly, in this case 100 percent testing of production lots in 91 samples, if 4 or more samples were positive, that to the Agency was evidence that the control for this particular pathogen was above a level for which the Agency found to be appropriate under the circumstances of

1 looking at the positive rate that the Agency found
2 in its verification testing program.
3 So that was the criteria that we defined
4 in 2008 for a high event period. It was the
5 criteria that we said would no longer allow a
6 determination to be made that one production lot is
7 microbiologically independent from another, and it
8 also called into question whether or not primal
9 cuts or subprimal cuts, which typically would not
10 be considered to be adulterated with *E. coli*
11 O157:H7, would under certain circumstances be
12 considered to be adulterated because they would be
13 produced under insanitary conditions, in part,
14 based upon the accumulation of data that indicates
15 that the organism likely was present at a rate that
16 was above what would normally be expected.
17 The Agency also identified that we
18 believed that the establishments should be treating
19 the high prevalent season differently than the low
20 prevalent season. Do you know that the organism is
21 more likely to be present in live cattle coming to
22 slaughter during the months of April through

September, and that it would be appropriate for control procedures to be strengthened, particularly during that period of time to ensure that additional contamination is not getting through the slaughter dressing process as well as the trim operation.

We did have a public meeting that followed up that compliance guideline. We took comment on that, and we have been reviewing that since that period of time, and it forms the basis in part for what Judy Riggins mentioned in her presentation earlier today in terms of helping us to determine whether or not there was a breakdown in the production process when a supplier is implicated in a subsequent finding of *E. coli* at a grinding operation.

In 2009 the Food Safety Working Group was stood up, a year ago, actually at the end of this week, and the Agency identified some very specific items that we would be pursuing with regards to *E. coli*. They just represent the first things that the Agency would publicly be doing related to *E.*

coli, but we do recognize that there's a need to do more.

But in any case, in July, the Agency issued a new directive aimed at ensuring that our employees for the first time were actually verifying in a systematic way the slaughter dressing procedures to ensure that, in fact, cattle were being slaughtered in a manner such that their likelihood of contamination of those carcasses would be reduced and that the establishment had, in fact, in place procedures that would help them discern whether or not their slaughter dressing operations were operating properly.

That directive also identified that there was a need for the inspector-in-charge in that facility to relate the slaughter dressing procedure performance to the trim testing data in that particular operation because we believe there's a direct relationship between the trim results and the slaughter dressing operation, and so that was the first that the Agency put in place a mechanism to begin looking at the relationship between

slaughter and trim fabrication as an indication as to whether or not O157 was being properly controlled.

And then the second Food Safety Working Group initiative that was identified and initiated in July of 2009 was our bench trim program. This was a program that expanded our trim testing program from trim in a slaughter plant that directly produced that trim to an operation in further processing in which that further processing was generating trim that may be used in raw ground beef operations and, in many cases, were producing mechanically tenderized products and using the beef trim, the bench trim from those operations as an indication as to whether or not there's a likelihood that the mechanically tenderized product could be contaminated. So the Agency began that program in the summer of this past year and will continue to look at how we can further strengthen our programs.

Well, this leads us to where we are today. Judy Riggins, this morning, identified new

procedures that EIAOs would be following in terms of looking at getting back to the slaughter suppliers and making a more thorough assessment as to whether or not there was evidence of a breakdown in the production process that could have led to a positive in subsequent operations.

It was clearly a presentation to design to show that we're looking to see whether or not the establishments are controlling the slaughter and the trim manufacturing operations in a manner to have greater confidence that *E. coli* is not contaminating products that are going into commerce.

With that, we, the Agency, then have been developing new policies. These are under consideration. They have not yet issued, but they're in various stages of development.

The first is our N60 testing program. We have a very specifically designed program in which our inspectors are pulling excision samples. These samples do take a great deal of time to collect. Oftentimes, it's an hour or more per sample. The

intent is to be pulling very thinly sliced samples from the exterior surface of raw beef products. It would be those surfaces mostly likely contaminated. We know that there is a great deal that can be gained if we focus on improving the uniformity and consistency in this procedure. So we have developed new procedures. We have developed new training materials that would be directly tied to providing a visual of how to properly collect this sample. We still have some limitations as to how we can collect that sample in terms of randomness of it, and that there are some worker safety issues with regards to pulling samples deep down in a combo bin, but in any case, the random sampling is an important feature that we would have there.

But I want to also stress that the Agency has traditionally pulled a sample that is much larger than what is actually analyzed. When that sample arrives at the laboratory, our lab technicians then take that sample and trim it down in order to actually create the 325-gram sample that is analyzed by FSIS.

We believe there are some efficiencies that can definitely be gained from this, as well as removing perhaps some bias that might be injected into our system, and so we designed the procedure such that the inspectors would be pulling a 325 gram sample. And so we have some specific instructions that give better guidance as to the size of that sample, for the 60 pieces that they will be gathering that will amount to right at 325 grams, so that there isn't further work that would need to be done at the laboratory. Once that sample arrives, it would immediately be processed through our enrichment procedures and so forth, which would speed up our ability to analyze that sample faster.

So this would be a first step in terms of trying to get better guidance out on how our inspectors collect the sample. We also know that there is a need to ensure that industry is properly collecting their samples. This sample, the excision sample, the N60 samples are extraordinarily important in terms of identifying

1 whether or not a production process is working
2 properly or not, and so there's a need to focus on
3 ensuring that that procedure is being done properly
4 by both the FSIS inspectors and industry. So there
5 should be a focus as well by the Agency on ensuring
6 that our establishments know what we believe to be
7 a proper procedure and that they have the same
8 information available to them that our inspectors
9 would have.
10 We do have a new focus as well of
11 insuring that we're receiving public comment on the
12 draft compliance guidelines that the Agency is
13 developing. We consider these compliance
14 guidelines to be good guidance to industry on how
15 to meet our expectations for the policies that we
16 put in place. They are not regulatory documents.
17 They, if followed, would, in fact, help an
18 establishment to achieve the regulatory intent and
19 should not require additional validation because
20 we're providing you instructions that we believe to
21 be valid and appropriate.
22 But we also believe that there's a need

for public input. And so we have this year made the determination that we will be changing our process specifically on all of our compliance guidance. We will issue them in the form of a *Federal Register* document which will provide a comment period associated with them. We will make those documents available on the webpage. If necessary, we'll mail those guidance documents out to industry, in particular, if we think there's a need for small processors to have them in their hands to review. There will be a comment period for which we will analyze those comments and respond as to how we believe we need to address the issues and then issue follow-up compliance guidelines that will be put on the webpage, along with an accounting for how the Agency responded to the comments that we received.

Those that we have under development that should be in their final stages, being readied for issuance, would be one that the Food Safety Working Group put on its agenda for us to issue, and this would be a focus on pre-harvest controls for beef

slaughter operations. There's a great deal of research that's been done on pre-harvest interventions that can be applied by industry today. They're varying degrees of efficaciousness with regards to those treatments. In any case, the Agency believes that reductions of this pathogen coming to slaughter is an important control feature that should be addressed and that is available to the industry.

And so we've summarized the research on this particular issue with regards to pre-harvest intervention and will make that available for comment but to industry so that they can have some guidance as to what's available to them in case they don't know.

We've also put together a follow-up to the compliance guideline that we had on beef trim N60 testing from a year and a half ago and for which we already received public comment from a public meeting. This will be another opportunity to comment on this particular guidance document. It provides additional information on how to, we

think, properly address and interpret the results from a properly operating N60 program, and it will have specific guidance in it as to define what is a high event period.

Again, we think a high event period is critical to the operations in terms of knowing when is your operation indicating that there's a trend towards a systemic breakdown. And in the operations today, our best guidance to industry is, there should be 100 percent testing of all manufacturing trim and other components used in raw beef production and that that data should be used through statistical process control in order to ensure that the establishments are, in fact, properly operating.

So this guidance will be available to you for comment again.

We do have a series of three guidance documents developed on laboratory test kit validation. We recognize that there are a large number of test kit manufacturers out there producing kits available to industry that

supposedly are faster and more accurate than FSIS testing or other available testing methodologies, and to some extent, that's true, but it's also important that there is some identification as to what, in fact, constitutes a proper test that is specific and sensitive enough to be able to find *E. coli* at low levels.

And so we've put together what we think is good guidance to test the manufacturers themselves, to small establishments who send their products out to be tested by a laboratory. This would give guidance to them as to what kind of questions they think the laboratory should provide them in terms of response so that they have that on file in their food safety operation.

Again, this will be available for comment, but we believe it will be extremely helpful because of the large variety of differing testing methodologies that are available, and that could potentially be providing false results to the establishment that they're relying upon.

And then validation overall, for the food

safety systems, is the next phase that the Agency is looking at in terms of ensuring that establishments know what their systems are capable of achieving and that they have data to demonstrate that those systems are, in fact, working properly. So this would be follow-up guidance on general validation for all operations.

On the next slide then, other additional *Federal Register* documents that are under consideration and development, we have announced that we consider traceback into the federal system has been hampered and in many cases stopped at the retail level because of inadequate or just bad record keeping that occurred at retail operations. And so the Agency has identified in the December public meeting that we had on traceback that we were intending to pursue a regulation that would make very specific the types of records we think that retail operations, as well as the federal establishments, should maintain in order to be able to facilitate quick identification of what products were used, when and who did they come from, and so

1 this would be a regulation that the Agency has
2 under development.
3 We also agree that hold-and-test is a
4 prudent policy that should be in place in terms of
5 the Agency being able to make a determination that
6 product is not adulterated before we put the mark
7 of inspection on it. The testing results are
8 absolutely essential to know in terms of whether or
9 not that production lot likely is contaminated with
10 an adulterant or not. And so we agree, and we also
11 know that industry has asked us, to pursue hold-
12 and-test, and so we are working on ensuring that we
13 have a policy put in place that would, in fact, put
14 this as a policy related to all the sampling the
15 Agency does for items that would constitute an
16 adulteration situation if we were to test for a
17 particular food safety hazard.
18 And then labeling of non-intact meat
19 subjected to mechanical tenderization. The Agency
20 has identified, since 1999 when we issued our
21 clarification policy as to what would be considered
22 adulterated if found to be contaminated with

O157:H7, that mechanically tenderized meats do, in fact, present increased risk over those intact meat products that likely would receive thorough cooking that would render that product safe by the consumer.

We think it's necessary to pursue mandatory regulatory action to put in place labeling that would require products that have been tenderized to be labeled. And so this is on our agenda for development.

And then finally, I wanted to touch on baselines because the Agency uses its verification testing program, to the extent that we can, to identify whether or not there are changes from one year to another in our verification tests. We fully recognize the limitations of our verification tests. They are, in fact, directed at establishments. In some cases, they're targeted at higher volume establishments than lower volume, or higher risk products than lower risk products. But still, the volume of samples that we collect provides us some limited information.

In order for us to make accurate, scientifically based decisions about whether or not there's a change in a particular prevalence or level of a contaminant in a product, we really do need to have scientific studies that would help us do that, and we do that in the form of national baseline studies. We do have funding specifically to address baseline studies, and we do do those baseline studies, but in a very non-timely manner I would say. When we issued our HACCP regulations, we had identified that we intended to routinely do baseline studies to establish new prevalence levels so that we could establish new performance standards based on those changes.

The Agency's intention is to look at our baseline study program, look to see where we can initiate new ones that have not been done, look to see which ones need to be started again for which we previously have completed, and whether or not we can come up with an ongoing way to identify ongoing prevalence levels in various pathogens so that we can more accurately identify whether a change in a

positive rate is, in fact, real.

And so we have identified a number of baselines related to beef that would, in fact, influence us with regards to policy development on *E. coli*. One in particular that is under consideration would be a beef carcass baseline study in which we will look at the level and type of contamination on the carcass immediately after the hide removal but before any interventions or evisceration occurs. The Agency has never conducted such a study, and unfortunately we're not able to identify whether or not there's a change in the type or level of contamination coming into the slaughter plants.

And so if we hold to the same design that we had for poultry and for hogs, we designed a two-sample collection operation in which we looked at our best indication of the level and type of contamination before interventions are applied, that would be most reflective of what came in from the producing operation on the farm, and then look again after the interventions have been applied.

This could be supplemented with a trim sample baseline repeat as well. We have conducted the trim baseline study in the past, but again it used a methodology for which we think there is some bias built into it, and so this would be an enhancement that perhaps could influence us as to the control that's in place in a slaughter operation, looking at pre-evisceration, pre-intervention, post-intervention, and then on trim.

And then our ongoing baselines in which we're looking at trim, we're looking at ground beef and a host of other products that could also include primal cuts or subprimal cuts. In any case, the Agency recognizes that these statistically designed national baseline studies give us the type of data that we best could use for attribution as well as for discerning whether or not there's a change in exposure of the public to a pathogen in the products that we regulate.

And so we are, in fact, committed through the Food Safety Working Group activities to focus on better baseline studies that can help better

identify what's happening with regards to the products we regulate.

And with that, I thank you.

(Applause.)

MR. TYNAN: Thank you, Dan. We're at the point in our agenda where we're going to take public comments. As I mentioned earlier in the session, that we're going to limit the comments to approximately four minutes. That's in order to make sure that everybody gets an equal amount of time to get their points made, and we think four minutes is adequate to get some of your major points in.

I would remind everybody that for those of you who feel that you have not been able to get all your points in, in the four minutes of the oral presentation that you'll make here today, you still have an opportunity to submit more detailed written comments. As I mentioned earlier, there is a link in our website and information on how to do that and submit official comments.

As I mentioned also earlier, we will not

be responding to the comments or the questions that you have today. If you have some questions or need some clarifications, if you could just build that into your comment period, and that will allow us to analyze those questions as well as the comments. So we'll put all of that together in our analysis of what we learned from the meeting today.

We're here to listen to what you have to say about all of the presentations. So it's important for us to get your feedback at this particular point. Again, if the four minutes does not provide, you still can submit some in a written format, and I'll go through the list of people who have preregistered to make comments in the order that they registered. We're going to take the phone people first. There are several that have been listening in by the telephone conference that will want to make comments as well.

One last point before I go to the comment period. All of the presentations are currently up on our website. So I know I've had a couple of questions about the availability of the materials.

They are up on our website currently. So those should be available to you. For some reason, if you have some issues with seeing those or pulling them down, please let us know.

Also, there will be a transcript of this meeting, and that will be posted, we're supposed to get that within about 15 business days. So we'll take a day or two to make sure that everything is appropriate, that names are spelled correctly, those kind of things. We don't change anything in the content, but just to make sure that things are attributed properly and that there wasn't some error in the recording. So about 15 business days, hopefully a little bit less, and I know all of you very often want to use the transcript in formulating your comments. So about 15 business days.

And with that, I'm going to go to the comments. I'm going to talk with Calvin, who is our Operator today. Calvin, are you on the line?

OPERATOR: Yes, go ahead.

MR. TYNAN: Thanks for helping us out

today. We have a list of callers. Could you go through the list for us. The first one that I have is Cristina Caputi, and I'm going to ask the commenters if they could introduce themselves, their name and their affiliation. Ms. Caputi.

MS. CAPUTI: (Garbled.)

MR. TYNAN: We're not hearing you. We're going to try and fix the audio. Can we come back to you?

Okay. Calvin, are you on the line?

OPERATOR: Yes, her line is open. That must be her phone. It's difficult to understand her.

MR. TYNAN: Where's Calvin?

MS. CAPUTI: I can hear you now.

MR. TYNAN: I'm sorry. Who's the Operator?

OPERATOR: Her line is open.

MR. TYNAN: Okay. But it's not very clear. So it's her phone?

MS. CAPUTI: I can hear you.

MR. TYNAN: Okay. Operator, why don't we

go to the second person, and we'll see if we can come back to Ms. Caputi a little bit later. I have Mr. Kramer.

MR. KRAMER: Yes.

OPERATOR: Mr. Kramer's line is open.

MR. TYNAN: Okay. Thank you.

MR. KRAMER: Yes. Hi, I'm Mel Kramer, President of the EHA Consulting Group. First, I'd like to thank you all for a -- meeting as well as the pdf PowerPoints online.

I have a concern that I'd like to express. In our economy, where local and state governments are feeling extraordinary pressure, a lot of state and local Departments of Health and Agriculture are having reductions in workforce, and the potential quality of their investigations which are fed into the system become somewhat questionable.

Case in point. There were three people who became ill with O157. A local sanitarian went out, identified a meat product. Two people were ill at one establishment. The third was picked up

at another establishment, and it resulted in a recall. There was no evidence in product testing. There was nothing at the plant that seems to have been awry.

The only problem with the -- of this outbreak or cluster was that it was another meat product from a different plant that was not picked up by the testing. The state only provided laboratory support, which there's no reason to believe that they did anything other than an exemplary job. And when PulseNet queried, there were two or three other cases and one of the -- that particular point on.

Whether or not with a full EPI investigation -- but with a more thorough investigation -- FSIS on the ground with the local health department, that second plant might have been identified, and it is very possible that it might have been the source of the illness.

I'd like to just put it out there that I think that as we go down the road of -- of time -- that public health has got to be maintained, and I

1 think that the federal agencies are going to have
2 to constantly pick up the slack as well as
3 validating the information that they are getting
4 from --
5 MR. TYNAN: Can I impose on you to speak
6 up just a little bit. It would help out with the
7 sound in the auditorium.
8 Mr. Kramer, are you finished?
9 MR. KRAMER: Yes, sir.
10 MR. TYNAN: I apologize. We had a little
11 trouble hearing you. So we're going to look
12 forward to having some written comments to be sure
13 that we captured everything that you said.
14 The next person that I have on the list,
15 Operator, is Sarah Slater. Is Ms. Slater on the
16 line? Operator?
17 OPERATOR: Her line is open.
18 MR. TYNAN: Ms. Slater?
19 MS. SLATER: I'm sorry.
20 MR. TYNAN: If you could speak up for us,
21 identify yourself and your affiliation, and speak
22 up as loud as you can to help us out with the sound

here in the auditorium.

MS. SLATER: I apologize. I do not want to make a public comment at this time.

MR. TYNAN: You do not. Okay. Thank you.

Okay. The next one I have on the phone is Jay Wenther. Mr. Wenther, are you on the line?

MR. WENTHER: Yes, I am.

MR. TYNAN: Please go ahead.

MR. WENTHER: Hi. I'm Jay Wenther, the Executive Director for the American Association of Meat Processors. First, I want to thank you for access to the presentation and the information that was provided and the opportunity to comment.

The American Association of Meat Processors -- FSIS product tracing for *E. coli* O157:H7.

We agree that FSIS -- speed and accuracy of the tracebacks to -- The Association encourages -- one of the two purposes of -- prevention of contamination -- establishment a pathogen exists --

The Association -- The Association appreciates the detailed information provided by Ms. Riggins' presentation this morning. In an effort to be fully transparent to stakeholders, the Association encourages -- to share further details and other statistic attributes that are required for tracebacks to occur -- establishment -- materials available for the Agency to allow tracebacks to occur. It seems as though there's some confusion about the specifics of where traceback can occur, the development of a question and answer document as well as other -- may be a means of clarifying some of these issues in an effort so that stakeholders can fully understand the process.

Furthermore, throughout the presentation, the Agency -- the Agency wants -- processors to know much more information that may be available to these processors as further processors that purchase products through distributors. The Agency may consider -- questions and ask further processor establishments and the other questions that are

1 asked to supplier establishments to provide
2 clarification.
3 The Association continues to encourage
4 the Agency to record the pertinent sample
5 information as outlined in Ms. Riggins'
6 presentation at the time the sample is taken, not
7 after -- Inspected establishments record a
8 variety of food safety related data throughout the
9 production of each -- and much of it may not be
10 fully utilized. We feel that the Agency should
11 follow this demonstration and this practice to --
12 samples.
13 The Association urges the Agency to
14 provide clear and concise information of --
15 documentation to further the objectives mentioned
16 in Ms. Riggins' presentation this morning.
17 The Association hopes that through
18 meetings and other activities, the Agency receives
19 valuable information and suggestions in order to
20 make improvements to the existing tracing systems.
21 The Association continues to request full traceback
22 efforts in an effort to determine the true source

of contamination and believes Agency's transparency that --

The new methodology presented today and future steps forward to improve the traceability systems that will better -- both consumers and industry stakeholders and we look further to understanding of how our member companies can -- to aid in this process. We will submit written detailed comments prior to the deadline as well. Thank you for your time.

MR. TYNAN: Thank you, Mr. Wenther.

I'm going to go to the folks here in the room. We have one microphone. It's over here to my right, your left. If I could ask you to come again to the microphone for your comments, as I call your name, and then again identify yourself, your name, and your affiliation.

The first name I have on the list is Brian Cute, and I'm going to apologize in advance if I kill somebody's name. Brian, are you here in the audience?

Okay. The next is Nancy Donley.

Ms. Donley.

MS. DONLEY: Thank you very much. Nancy Donley from STOP, Safe Tables Our Priority. I appreciate having the meeting today, and we'll be submitting more formal comments later. These are just kind of in taking in with what's happening today, and there's a lot of information that was put out, but frankly, a lot of that information stimulated more questions in my mind than it did anything else, and I'd like to just encourage the planners of these public meetings, that they might consider having some sort of period after each presentation to just get clarification on issues where it would also help prepare written formal, written public comments as well.

The one thing I'm kind of taking away, that the general message of this is, and again it's because I can't have clarification, is that it looks to me as if the Agency is intending to gather a lot of additional information, and while I think that is very, very good, to traceback and get back down and understand a little bit more about what's

1 happening in the process of the production flow
2 that it gets to the final grinder, I didn't hear
3 anything today that really led to there being
4 additional testing, to be able to find out if there
5 is additional product that should have been
6 recalled, particularly in the case if there is, as
7 the comment was made earlier, about there being
8 unopened trim or source supplies that could be
9 implicated. It's not good enough to just
10 understand and traceback, if we're not doing
11 anything about identifying other potentially
12 contaminated product that has made it into the
13 marketplace and being able to recall it.
14 So that said, I look forward to listening
15 to everyone else's comments. One other just
16 specific thing that I really, really urge the
17 Agency to do, and I know it came up in Dan's
18 presentation, about where they'll be open to public
19 comments, is specifically high event days. I find
20 it just unimaginable that today, individual
21 establishments have the ability to name their
22 number as far as how many samples that they do that

1 come back positive, in determining if their process
2 is under control. So, hypothetically, you can have
3 one company that says, if I have one, I have three,
4 I'm not in control, but another one can say I'm in
5 control if I have less than 33 or 133. This is
6 something that just does not make any sense to
7 consumers. We are looking to the Agency here to
8 not just give guidance, but to set actual
9 standards, if you will, because actually this whole
10 idea of being able to have so many positives
11 doesn't even really fit in, if you will, with the
12 Agency's zero tolerance for *E. coli* in the first
13 place.
14 So anyway, thank you again.
15 MR. TYNAN: Okay. Thank you, Ms. Donley.
16 I appreciate it.
17 The next name I have on the list is Scott
18 Goltry. Scott.
19 MR. GOLTRY: Good morning. My name is
20 Scott Goltry, and I'm the Vice President for Food
21 Safety Inspection Services at the American Meat
22 Institute. The American Meat Institute was formed

1 in 1906, and our members process more than 90
2 percent of the nation's beef, pork, lamb, veal, and
3 a majority of the poultry produced in the United
4 States. AMI members continue to adopt food safety
5 practices to produce meat products which are safe,
6 affordable, and available.
7 During illness-related recalls in the
8 summer of 2008 and again in the summer of 2009, AMI
9 members discussed and shared possible learnings
10 regarding these particular outbreaks that had
11 connections to high event periods. The concepts of
12 bad -- events were reviewed by members.
13 As previously stated in comments to the
14 Agency, AMI agrees that each establishment should
15 develop or continue to use process control
16 procedures that are based on findings, corrections,
17 and possible tightened parameters of production or
18 disposition and react appropriately when they are
19 high in normal positive results.
20 AMI remains committed that the
21 predetermined number of positive test results to
22 describe a high event period for an establishment,

as previously mentioned by FSIS, has no basis.

Instructions in Directive 10010, Revision 2, to inspection personnel for verifications activities, *E. coli* O157:H7 in raw beef products are very specific.

Except in the case of high event periods, AMI is unaware if a change to the traceback follow-up sample procedure would have a significant improvement to public health.

Furthermore, regarding verification sampling, AMI would encourage the Agency to review ground beef production practices and sample ground beef products that are routinely produced by processing facilities.

Table 1 of the handout, which will be available afterwards, illustrates a number of ground beef verification samples at federal plants and the necessary follow-up samples taken by the Agency. In 2009 there were 35 federal ground beef verification positives that resulted in 492 ground beef and 940 ground beef component follow-up samples as a result of these ground beef positives.

This means there were 40.9 follow-up samples taken for each ground beef positive. This is an excellent example of the measurable outcome of Directive 10010.

Last year FSIS significantly increased the sampling frequency in high volume federal ground beef facilities, yet this focus on volume-based risk as well as improvements in testing method detection resulted in a 66 percent reduction of prevalence from .45 percent in 2008 to .3 percent in 2009.

Production logs sampled by FSIS were typically controlled by the producing company and not released into commerce until the laboratory verifies a negative result. On occasion, the manufacturer allowed the product to enter commerce before the test results were received from FSIS which would result in recall. The chart showing the number of recalls due to outbreak illnesses and those that were caused because product was not held pending analysis and had no analysis is found on Table 2 of the handout.

Additionally, a summary of the amount of federal import retail verification tests of raw ground beef that were not held and resulted in recall is found in Table 3 of the handout. FSIS has taken under consideration the petition by AMI that the Agency implement a system whereby product tested by the Agency must be controlled by the company until a result is known.

It is our belief that this action is an important part of managing food safety risk as is tracing and should be given the equivalent consideration.

On October 14, 2008, the Agency requested comments on draft label policy guide for N60 testing of boneless beef manufacturing trim. This concept would provide a means to improve tracing especially for boxed beef trimmings that have multiple destinations. AMI provided comments to this guideline and again will be included as part of our written comments.

In summary, AMI is unaware -- to support the need to change current policy regarding follow-

up sampling and inspection methods, except in the case of high event periods, encourages the Agency to adopt or support the control of product pending lab analysis, act positively to comments submitted by AMI regarding boneless beef sampling and testing labeling, and lastly, support representative sampling of ground beef by FSIS. Thank you for allowing me the opportunity to comment.

MR. TYNAN: Scott, I've met and talked with you so many times. I've never heard you talk that fast.

MR. GOLTRY: Well, you changed it from five minutes to four.

MR. TYNAN: Okay. The next name I have on the list for comments is John Granich. Mr. Granich, if you can come up to the mic, introduce yourself and your affiliation.

MR. GRANICH: I feel like I'm going up to American Idol.

MR. TYNAN: We have all kinds of hurdles in this business.

MR. GRANICH: My name is John Granich.

I'm with a company called FoodTRACE. Several of us have gotten together, some epidemiologists, some microbiologists, some database management people, and for the last three years, we've been privately funding a food traceability system.

We believe that food traceability is a triad that revolves around three things, product movement, people getting sick, and also testing.

Currently, in about 50 days, we're going to hold what we call a pilot test. We're going to have about 10,000 industry members come and join our test, and for 6 months, we're going to take all the product movement, we're going to store them in an essentialized database. We're going to take a system that we call for rapid identification of people getting sick and put that in there, and also a rapid assessment, put that data together, crunch it all up see where we can improve.

We welcome the FDA, the USDA, to come along and look at us. We want to see if we're doing it right. We've done this without a lick of government funding. We're not asking for any

money. So that should make it attractive to you.

I'm very interested in talking to you on the side a little bit.

Like I said, this test will start in about 50, 55 days, and about 10,000 people, in the produce industry, the retail industry, the repacking industry. We've already ran through two pilots, one where we took six months of product movement from Albertson's LLC, tracked their movements in our system, make sure our data would flow. We then did a live test with some produce, tracking it from a foreign country into the U.S. through a repacking facility, into a distribution center, 250 retail stores, and we're looking to bring meat into the fold and poultry and things like that.

So, anyway, you'll be receiving some written comments from us, and we look forward to your help in doing that.

We will ultimately provide, we believe, the Government a spot, basically have a geotactical plot that will allow you to hook a company, see

what test they've run, where those tests tracked the product movement, without ever leaving your office, and get a lot of those things done. Thank you much. Appreciate your time.

MR. TYNAN: Okay. Thank you, Mr. Granich. I appreciate it. Anybody that wants to give something away free, we always want to talk with them.

The next name I have on the list is Stic Harris. Mr. Harris, are you here?

Okay. Ms. Sarah Klein. Ms. Klein, are you here?

MS. KLEIN: I don't have a comment.

MR. TYNAN: Okay. John Munsell. John.

MR. MUNSELL: Yes, I'm John Munsell, and I'm the manager of the Foundation for Accountability and Regulatory Enforcement.

First of all, I want to commend the Agency for holding this hearing. I think it constitutes a remarkable improvement in the Agency's attitude towards traceback. So I commend the Agency.

I find it ironic in the last two years that the FDA, in spite of having inspectors in plants as infrequently as once every five to six years, still they have successfully traced outbreaks back to the spinach farms, pepper farms, -- peanut butter, et cetera.

In stark contrast, although FSIS inspectors are in every plant every day, the Agency typically fails to trace enteric pathogens back to the slaughterhouse of origin. And so if FSIS cannot accomplish tracebacks, as in the past, they have wanted to. And it's all because FSIS can trace animals with residue violations back to one solitary farm and aggressively post all evidence on the Agency website.

I recently created a PowerPoint which describes the overwhelming differences between a true HACCP program authored by Pillsbury compared to the allegedly science-based program that's authored by FSIS. And after I presented this PowerPoint to a stock show in Rapid City, a livestock producer stood up during the question and

1 answer session and stated that my PowerPoint would
2 make vegetarians out of meat eaters, and I
3 explained to him that more of these ongoing
4 outbreaks and recalls, they are what's reducing the
5 consumer confidence in meat, not my PowerPoint. I
6 also told -- that until FSIS develops the courage
7 to perform tracebacks to the slaughterhouse of
8 origin, that we're eventually guaranteed multiple
9 recurring future outbreaks and recalls, and since
10 the stock show, we have had more recalls.
11 So one reason tracebacks aren't
12 accomplished is because of artificial restrictions
13 mandated by the Agency, and let me give you just
14 one example. When inspectors collect ground beef
15 samples for analysis at USDA labs, inspectors do
16 not document the slaughterhouse of origin where the
17 meat originated until after the USDA lab concludes
18 that the sample has been confirmed as positive for
19 O157:H7, as Judy Riggins mentioned. This grossly
20 unscientific method of evidence gathering has
21 numerous drawbacks. One is it intentionally
22 obfuscates the evidence. Number two, it prevents

1 expedited tracebacks to the source of
2 contamination. Three, it insulates the source from
3 accountability. Fourthly, it sends all pathogen
4 liability downstream to the further processing
5 plants along with the previously contaminated meat.
6 And last but not least, this cover-up in prevalence
7 concerns.
8 So I'd like to show you just one easy
9 corrective action to prevent recurrences of this
10 public health debacle. I have in my hands here an
11 Agency e-mail dated July 26, 2002, that was sent
12 from the Agency's Office of Field Operations, the
13 national staff, to managers of all of the Agency's
14 District Offices. The Agency says in part, and I
15 quote, "At the time the sample is taken, the IIC
16 will obtain from the establishment the name, point
17 of contact, and phone number for establishments
18 supplying the source materials for the lot of
19 ground beef being sampled." In fact, this is
20 resolved partially by what --
21 MR. TYNAN: Your time is up, but if you
22 need just a second to summarize and conclude.

MR. MUNSELL: Okay. Yes, just this example is one of many common sense solutions which, if implemented, will enable FSIS to provide tracebacks to the source. Thank you for the opportunity.

MR. TYNAN: Mr. Munsell, I appreciate it. Thank you for your comments.

The next name I have on the list is Felicia Nestor. Ms. Nestor.

MS. NESTOR: I'm Felicia Nestor. I'm a senior policy analyst with Food and Water Watch, and I've got to speed through my comments, too.

The first thing I want to say is it's a disappointment that the Obama Administration is telling transparency, and yet in this meeting that we've asked for, for two years, consumers and the public cannot ask any questions about the Agency's current policy or future plans. At the FDA meeting in early December, there was ample time for public questions. It's meaningless to have a listening session and ask for public input when you refuse to say what your actual current policy is.

Currently, the Agency's website, as well as the compliance guidelines, indicate that FSIS will do testing to try to identify the actual source of contamination when its routine testing program finds product at a grinder. FSIS now tests at the grinder after the product goes through the grinder. Most of the time when FSIS tests, the grinder has not used the full lot of the original source material. When FSIS finds the positive, that means that there is other contaminated source material still out in commerce, probably at other grinders.

The only way that FSIS can have the authority to recall that product is to do a sample of unopened product. I've asked a number of FSIS insiders this, and that is the case I know since at least 2002. FSIS personnel in the Agency have had vigorous discussions about testing unopened product which would identify the slaughter source of contamination and the proponents have been shot down almost every time. Twice they tested unopened product, and it led to the 19 million pound ConAgra

recall and then a million plus pound recall by Taylor Packing.

The only way FSIS has the authority to identify the majority of contaminated product out there and recall it from the market is to test unopened product. We've been asking the Agency to take this step. It's worth noting the public should note that large industry representatives do not want anything more than what the Agency is proposing to do, which is to go to the plants, read their records, look at their reviews, do more reports, and not come away with that piece of information that authorizes the Agency to recall the contaminated product to prevent other foodborne illness. The Agency says that prevention is its number one goal. That isn't what the policy says.

Let me see what my other notes here say. We're going to be submitting very substantial comments on this, but -- yeah.

If you look at the history of the Agency's testing policy, *E. coli* testing policy, the basic seam that runs throughout is don't look,

1 don't find. From 1998 through 2003, they basically
2 exempted the largest slaughterhouses from testing.
3 Once the ConAgra recall happened, they couldn't get
4 away with that anymore. So then all the plants
5 were tested.
6 The modification then was they would only
7 test pretested products at the largest plants, and
8 that occurred through 2007 when Rosa DeLauro, you
9 know, asked what the heck sense does that policy
10 make.
11 MR. TYNAN: Okay. Your time was up
12 already, but if you want to do a summary comment.
13 MS. NESTOR: Yeah, just one other point.
14 The current follow-up testing that FSIS does is not
15 of the associated product with a positive. It's of
16 new, completely new, unassociated product that the
17 plant gets a forewarning that it's going to be
18 tested. The current follow-up sample is not and
19 has no power to identify the original source of
20 contamination.
21 MR. TYNAN: Okay. Thank you, Ms. Nestor.
22 Christopher Waldrop. Mr. Waldrop.

MR. WALDROP: Hi. My name is Chris Waldrop. I'm with Consumer Federation of America. Thank you to the Agency for having this meeting, but I've got to tell you, I'm disappointed.

The fact that the Agency is in listen mode and not interactive mode I don't think is quite the openness that we expect from the Agency and were hoping from the Agency, and I think it's very telling particularly in this particular issue. You're at least transparent in saying that you're not going to take questions or comments, I'll give you that, but it's certainly not open.

I think the Agency has been doing a nice dance today in this performance today and sort of circling around the big issue, and the key issue on this. Judy Riggins' presentation about the new EIAO activities that will be done with presumptive positive, there's a lot of nice questions being asked. Like Nancy said, it's good information to gather, but the Agency doesn't take that next step forward of listening to the presentation, of what are you going to do with this information? You

know, if certain questions raise certain conclusions or provide the Agency with certain information, what is it going to do? How will it act on that information? And is it going to be one piece of information or is it going to take several different questions to bring in some information before the Agency actually acts? None of that was presented in this outline today.

It also seemed at the very end of it, it's just going to be a report. You're going to put all this information together in a report and file it somewhere. There was no indication, there was nothing about identifying any product that was at the grinder. Once that presumptive positive is found, there's nothing about testing that product, testing unopened product, to try to really determine where the source of the contamination is from, and I think that's the thing that the Agency's been dancing around here and not focusing in on. There was nothing about that in Judy's presentation. So I think that's information that the Agency should be looking at as they're

1 considering this policy. Thanks.
2 MR. TYNAN: Thank you, Mr. Waldrop.
3 The next person I have on our list is
4 Mr. Joseph Blair. Joe, you've decided against it.
5 That will be the first time you've not had a
6 comment. Okay.
7 And, John, I think your name showed up
8 again. You don't have a twin here.
9 MR. MUNSELL: No.
10 MR. TYNAN: Okay. I have Ms. Pat Buck.
11 MS. BUCK: Hello. My name is Patricia
12 Buck, and I am the Executive Director for the
13 Center for Foodborne Illness Research and
14 Prevention, and I have a few quick comments I hope.
15 First of all, I was very, very pleased with the
16 announcements that Dan made earlier about FSIS'
17 intention to seek out labeling of mechanically
18 tenderized meat products. I'm very happy about
19 that.
20 Also likewise very happy about FSIS'
21 intention to improve baseline studies, particularly
22 pleased that there's going to be an effort to

implement a baseline that will look at beef carcasses after hide removal, and as well as post-chill, after interventions, but prior to fabrication. I think the information gained from these baselines will be very informative to the Agency.

Of course, CFI fully intends to do its part and submit written comments, and some of them will be short, but some of them will be quite lengthy based on what has happened today.

Also, I just wanted to comment that I think Dr. Engeljohn at some point was talking in his discussion about the Healthy People, about the verification testing program, and it has been our position all along that the verification testing program cannot be used to show any indication of prevalence of food pathogens in the food supply. Barbara is not here, but would she be here, she would have said something. I'm sure about that.

I do have one recommendation, and that's the only recommendation I have and then a conclusion.

1 CFI recommends that FSIS increase testing
2 of their food products, in particular, the
3 complicated food products, in order to seek out the
4 implications of those products. We believe that by
5 doing this, the Agency will be better able to
6 identify the impact of multiple suppliers which in
7 turn should help them better identify the sources
8 of the contaminated food, and I think that is very,
9 very important. You need to increase your testing.
10 You may, but I'm not a statistician, you may have
11 to increase the amount of sample size you're
12 taking.
13 Finally, I am somewhat confused and
14 perplexed by the meeting, I'll be honest. This
15 meeting has been long, long awaited, and all
16 present would have benefited from a format that
17 encouraged a more open exchange of information,
18 including a question and answer period. Thank you.
19 MR. TYNAN: Thank you, Ms. Buck. Now,
20 the last person I have on the list for comments is
21 I believe it's Beverly Edwards.
22 MS. EDWARDS: BJ.

1 MR. TYNAN: BJ, please.

2 MS. EDWARDS: Good afternoon. I'm

3 Beverly "BJ" Edwards representing Deloitte and

4 Touche. I just had some questions of present and

5 future consideration.

6 I wanted to ask, are these stringent

7 guidelines regarding product traceability also

8 applicable to foods and meats we receive from

9 foreign countries? If not, will guidelines, both

10 present and future, also address processes already

11 in place for traceability regarding new processing

12 plants supplying meats to U.S. that are shipped to

13 us from foreign countries?

14 What about meats and products with more

15 than one type of meat, such as beef hot dogs or

16 chicken franks where part of the meat might be from

17 the U.S. and part of the meat is from another

18 country? This is more of a traceability issue

19 question regarding grinders, as we discussed

20 earlier, used at both foreign and U.S. processing

21 plants. When I say meats, I mean, of course,

22 ground beef, trim, mechanically tenderized meats,

as well as other types that cause this type of *E. coli* contaminant, also whether we call them guidelines in such cases, should contamination occur. Thank you. That's it.

MR. TYNAN: Okay. Thank you, Ms. Edwards.

That concludes our comment period. I'm going to introduce our Administrator, Mr. Al Almanza, for some final comments and adjourning the meeting.

MR. ALMANZA: Well, first of all, I want to thank everybody for taking time out of your busy schedule to come. We've heard a lot of interesting comments, and certainly we appreciate the opportunity to continue our discussions on ways that we can improve how FSIS conducts product tracing.

A couple of things of note, that in the future we can discuss how the forum will be kind of laid out before we have these public meetings. Certainly we have the meetings every month with both consumers and the industry, and we're open to

these kinds of comments that you give us. In fact, some of the public meetings that we've had in the past, you know that we've acted on them, we've issued notices, directives, and tried to be as transparent as we can -- not as we can. We actually provide information to folks. In fact, a couple of weeks ago I got a phone call wanting some additional information to be prepared for this meeting, and we provide it. I mean that's the mode that we're in, and so this Administration clearly wants us to be transparent, and they clearly want us to provide information to prepare you all for these meetings because that is the goal, for you all to tell us what you're thinking and for us to be better prepared. Can we do better? We can always do better. But we appreciate your comments and your interest in food safety. That's what this is about.

The meeting demonstrates our ongoing commitment to safe food, but it also shows that there's much more work to do.

The Secretary has personally stated to me

the importance of finding every possible path to strengthen food safety. Product tracing is one way that we can also improve our system. That's why I feel that this meeting today was so important, and again I want to thank you all for taking time out of your busy schedule to be here. Thank you.

MS. NESTOR: Al, we have 45 minutes. Can we have an impromptu question and answer period? We've got plenty of time for it, and in the interest of transparency, I mean we have people in the Agency that know -- they know their business obviously. So maybe we could ask a couple questions.

MR. MANDE: (Off microphone.)

MS. NESTOR: Which wasn't what I asked, right? You gave me part of what I asked for, but we didn't -- what we need here is for the Agency to get up and state publicly, not in a private meeting with consumers where reporters are not allowed in, we need for the Agency to get up here and state publicly what the current policy is.

MR. MANDE: (Off microphone.)

MS. NESTOR: How can the public provide comment on what your policy should be if you can't clarify what your policy is right now? How do you expect the public who's going to read this transcript to provide meaningful comment to you if you can't -- you won't even answer the most basic questions? What are they going to comment on?

COURT REPORTER: Excuse me, sir. If you want this to be part of your transcript, you're going to have to go to the microphones and talk because I cannot hear you if you're going to talk in the middle of the auditorium. Both of you.

MR. MANDE: We'll try. You know, we don't have -- I don't know if Judy's still here, but Phil and Dan are here. So we'll try to answer what questions we can. Again, as Al said, and I'll emphasize, I think we're opening to structuring these meetings anyway folks feel would be the best way to structure them. The thinking here as Al described was that we were looking for a forum where we can present people our thinking, let others present their thoughts so people can hear

that, but we do have really extensive and are willing to do more in terms of meeting with folks in a room, to sit down and discuss these things. Felicia, if you would like to have press at your meeting with us, you're welcome to invite them as well.

So today's session was designed to just lay out things and get some initial comments. We have a meeting later this week with industry, one next with consumers, where these issues can be discussed at length, but since we do have a little bit more time today in people's schedule, if there are questions that we can try to answer, we'd be happy to try to do so. So I know Dan's here, Phil's here, Al and I are here. David's still here, and so to the extent that we can help do that, we will, and if not, we will take your questions and answer them when we meet with you in the next two weeks, and again, use the microphones please.

MS. NESTOR: In your December 1st meeting, some members of the Safe Food Coalition

1 met with the Agency. What occurred? I'm going to
2 ask you if you heard correctly?
3 MR. MANDE: Excuse me. Can I --
4 someone's waiving their hand. I'm just trying
5 to --
6 COURT REPORTER: They're going to have to
7 identify who they are for the record because I
8 don't know who these people are.
9 MR. MANDE: That's fine.
10 MS. NESTOR: I'm Felicia Nestor, senior
11 policy analyst for Food and Water Watch. What we
12 heard is that if FSIS takes a routine test at a
13 grinder, FSIS will not test unopened product at the
14 grinder in order to identify which of several
15 suppliers contributed the original contamination,
16 or if there's a single supplier, that's necessary
17 for FSIS to go back and mandate that the original
18 supplier recall the full lot.
19 So those are my two questions. Am I
20 correct that unless the Agency has that conclusive
21 test of unopened product, or illnesses are
22 associated -- so I don't want to talk about illness

1 cases. I want to talk about routine positive cases
2 only. In a routine positive case, without that
3 test of unopened product, does FSIS have the
4 authority to recall the full original contaminated
5 lot from the slaughterhouse?
6 MR. MANDE: Well, I'll try my best, and
7 then I'll invite others to add in as they can. The
8 purpose of today's meeting is to look about routine
9 testing wherever we, of course, find a positive for
10 O157 because an adulterant, we would have the
11 product recalled. The issue is that if you have a
12 routine positive, what additional steps could the
13 Agency take in tracing back that positive to make
14 sure that we make every effort and work with all
15 those involved to assure that positive product does
16 not end up in commerce.
17 And so what we've done today is lay out
18 for you our thinking and the additional steps we're
19 considering taking to make sure that we get all of
20 that product, and what we're looking to hear from
21 you are steps that you think we should add to this
22 or not include already, and so that's what we're

trying to do.

So what I hear you're saying is that one of the things we want to make sure we do is if we find a positive in the final test, that if we can find any unopened product related to the production of that ground product, we should test that as well. Sounds reasonable. Of course, today we already test at a grinder. We would test periodically for verification purposes the final product, and in a slaughter plant we would, that produces the trim, we do testing there as well. But if there's additional testing that could be done in the course of these investigations, that's something we'll consider in coming up with this new policy.

MS. NESTOR: So can we assume, can the public assume that you do not do that testing now? That's what I'm trying to get on the record. That's what we were told in the meeting with FSIS. And I presented that in the December 9th meeting, and no one corrected me, but I want it clear for the public that you do not currently do that

testing because how can the public advise you to do something differently if they don't know what you do now? So if we could just get that clarified, that you do not routinely do that testing now.

MR. MANDE: Like I said, in the final ground product, we do verification testing and expect companies to test that product as well. We also expect that they would have a certificate certifying that the trim that they got was tested as well. So the incoming trend is test it and the final product is tested. That is the current policy.

You're saying that if you find a situation where the ground product in the end is tested, you know, what additional steps can we go back and do? Testing. That's what we're trying to figure out today, but Dan can add in terms of what we do today.

DR. ENGELJOHN: Thank you, Jerry. Yes, to be direct in your answer, to answer your question, the Agency does not presently under routine testing program test unopened packages of

incoming source material at a further processor. We test the finished product.

There are a number of reasons for that, but the Agency has been looking into how we can modify our program or whether we need to modify our program, and I would just point out there are a couple of issues as to why we don't. I'll just say them, and that will give you some information that you can use to comment because we are further developing this policy. But the issue is we don't do that today. We do expect the establishments that are producing ground beef products that bring in source materials to have in place programs to verify that their incoming material is meeting food safety expectations.

The finding of a positive in the finished ground product, and, in particular, if it's a sole source operation, would lead one to conclude that the other material from that production lot, from that supplier likely would be adulterated. The Agency has further looked into that, and I think the policies that we put forward today directly get

at that issue for sole source operations. It directly would implicate that situation.

Where there are, in fact, multiple suppliers, the issue becomes more complicated. Our own data, and we know that the industry's data would show that the likelihood of finding a positive in that unopened trim is very, very low, even though it may be the source that contaminated that production lot. And so we don't hinge all of our responses on finding that positive.

Can we take an action to declare product to be adulterated if, in fact, we don't find a positive? Yes, the Agency can, and it does that based on the total information that we look at with regards to the food production process. We take all that information into account, and if we can conclude that there's evidence that there were insanitary conditions, we would take action on that product, and we have. So it's not a situation where we have to have a positive to move forward.

But in terms of managing the Agency's resources, it has been the decision that we would

not additionally take a sample incoming source materials. We have been looking at how can we provide the appropriate incentive for the users of that product to have in place programs where they're doing ongoing testing of their suppliers. If they had programs in place, such that that was a routine operation for them, would the Agency consider taking a sample? That likely would influence us differently, and that is, in fact, a policy we've been developing.

So I do want to say that it's not our current policy, but we certainly have it on the agenda to develop further. We think the steps that we announced today have the most immediate and most important impact on getting back to the suppliers to assess whether or not those food safety systems were working.

On the issue of multiple suppliers, there are a number of issues we need to deal with there, and we can improve that, and we are looking into that.

MS. NESTOR: Thank you so much for being

willing to answer that question. I'm serious. Thank you very much.

MR. MANDE: Next question.

MS. DONLEY: Nancy Donley from STOP, Safe Tables Our Priority. I just want to kind of say that the frustration that you're really hearing in this room is the fact that we know that what's been going on all these years is we're talking about life and death matters, and it's something that what we really, really, really want to do here is, and I think we're all in agreement, is we want to move the public health agenda forward. What we do know is that, you know, the reported incidences of foodborne illness, that's just the tip of the iceberg. There are so many more illnesses that are unidentified and unattributable to things, that go unrecognized, the isolated cases as a for instance.

Right now what we have, and this is my understanding, is currently that the only time that the Agency does a traceback is in the event if it's linked to illnesses, and if I'm wrong here, I would really appreciate, you know, being corrected, and

1 will take it back further. I think what the Agency
2 has here is an opportunity that when they do detect
3 a positive at a grinding facility, to trace it back
4 because once again even though there's been no
5 illnesses associated, that those source materials
6 have probably been shipped to additional grinders
7 and that who the heck knows if that has a positive
8 there and it's going out. So we just really,
9 really, really, look here is to say, and you can
10 also by taking these steps, tracing them back, is
11 help identify problems where they occur.
12 And then lastly again, and I had
13 mentioned this earlier, it should not be looked at
14 as simply high events being the controlling force
15 of how policy and how you are doing your tracebacks
16 and forwards.
17 MR. MANDE: I appreciate it, Nancy, and
18 again, and we've talked about this many times over
19 the years. I mean no one should have to go through
20 what you went through, and we're here today because
21 we are addressing this very issue. So we agree
22 that our products should be traced back, and we're

1 announcing today some steps in our thinking of
2 getting that, and we're working with you to design
3 that system. So thank you.
4 MR. ENGELJOHN: I do want to, just
5 because you asked for a clarification, it is not
6 true in your understanding that we don't do
7 traceback in a routine situation where there's not
8 an illness. We do traceback to the source supplier
9 with every positive.
10 The issue is the degree to which we do
11 the traceback and investigate samples are
12 different, but we today traceback in every
13 situation where there's a positive. Downstream, we
14 go back as far as we can into the situation. So I
15 just want to make clear that we do do that. It is
16 a difference in how we do it with an investigation
17 related to illness. What we announced today is a
18 substantive change to more thoroughly investigate
19 traceback to the slaughter supplier more so than
20 what we do today. So it's a supplement to what we
21 do today, and it's a substantive change to what we
22 do today, but we still do traceback to the source

1 supplier.

2 MR. MANDE: And, of course, Nancy, your

3 point when you met with us and others was that, you

4 know, we do it different as Dan said, and we're

5 looking to see how we can align those processes.

6 MR. MUNSELL: John Munsell again. As

7 Judy Riggins mentioned this morning, the new EIAO

8 responsibilities are that once the sample is

9 declared to be a presumptive positive, then the

10 EIAO starts accumulating all that evidence. That's

11 a one to two day improvement over current policy,

12 which once it's confirmed positive, they start to

13 accumulate it.

14 What I'd suggest since the Agency's

15 asking for suggestions, I'd suggest we can improve

16 on that quite a bit more perhaps and speed it up by

17 three or four more days by collecting that

18 information at the time the sample is collected.

19 It's already being done, and FSIS Notice 2905, it

20 says at the time of sample collection, when source

21 material is identified as being from a foreign

22 establishment, inspection program personnel shall

collect, et cetera, all this information. So the Agency's currently doing that for foreign material. Why can't we do it for domestic?

MR. MANDE: Okay. I appreciate that. In particular, as I said, we've opened this other time up now, people had questions about what we presented today. If we could clarify any of that today, we'll be happy to try our best.

MR. WALDROP: Chris Waldrop, Consumer Federation of America. In that regard, I would appreciate some clarification on what the Agency will do following the collection of all this information. They're going to gather all this information at the originating plant. They're going to gather it at the source plant. Then what kind of actions are anticipated for after they collect that information?

MR. MANDE: Well, again, as is the case today with illness and to a degree with any positive finding, we're trying to find a source of the contamination, if we can, to make sure none of it reaches the public. And so however we can best

do that, that's what we're doing. I think the systems we put in place allow us to better do that, but Judy has comments on the details on how to.

MS. RIGGINS: Yeah, let me explain. I explained that the case specialist is going to gather all that information that will go into an AER. What we will do and what we routinely do is we will then determine what the noncompliances are. We will likely, for every one of those plants that we gathered information from, we will have an EIAO go in, gather additional information to round out our evidence regarding the facts that led to possible contamination, where was there an inadequate system breakdown? And once we gather that information -- and we always, always, do this. That's why, you know, Dan's reemphasis of we always follow back. What we gather, for us, will be under our statute, N4 conditions, conditions whereby unsanitary conditions were created whereby product may be rendered injurious to health, we would then take an appropriate action which ordinarily would be a Notice of Intended Enforcement.

1 So those facts that we're gathered are
2 not just for the sake of gathering facts. My
3 presentation this morning was to explain that we're
4 going to do it at an earlier stage, and we're going
5 to gather a lot more information currently than our
6 inspectors are gathering, and we're going to send
7 in people who have a better understanding of food
8 safety systems in general, and that information
9 will then lead to an analysis that would then
10 either support a Notice of Intended Enforcement,
11 but we intend to take it to the appropriate end.
12 Now, if we get to a point where we don't
13 have a Notice of Intended Enforcement, then we will
14 issue non-compliance records for every one of the
15 noncompliances that is identified. I can tell you
16 just from experience that many of these cases
17 result in a Notice of Intended Enforcement because
18 we do gather the facts that ultimately indicate a
19 breakdown in an inadequate HACCP system.
20 MR. WALDROP: Okay. Thanks, Judy.
21 That's helpful.
22 MS. BUCK: Hello. My name is Patricia

1 Buck, and I'm with the Center for Foodborne Illness
2 Research and Prevention, and mine's truly just a
3 question because I don't quite understand all the
4 information. What are those criteria that are
5 talked about so often about high event periods?
6 How are they defined? I mean is there someplace
7 where I can go to find out what the Agency defines
8 as the high event period or that the industry
9 defines as the high event period? Because to me,
10 it seems that part of our difficulty is not only in
11 seeking out traceback when you have routine
12 positives, but also very aggressively seeking out
13 traceback when you have high event periods.
14 MR. MANDE: Sure. I'll begin, and Dan
15 can fill in. But we've learned over time, and I
16 think the people who work in this industry have
17 known and have observed also over time that more to
18 do probably with seasons, but there are other
19 reasons that there are periods where the level of
20 contamination goes up, and the systems that are in
21 place that effectively protect us most of the time,
22 both the ones that industry puts in place and we

use to verify them, the way they're designed, they're less effective if a load of pathogen contamination goes way up. So, you know, you design the system for not just the normal, but so far beyond that, but it appears that because why do you get outbreaks some of the time and not at other times. It seems that at times the systems that are in place may get overwhelmed. That's one of the things we want to know more about. It seems to be seasonally related, but Dan might add to that.

MS. BUCK: Yeah, well, specifically I was interested in why did we pick the number 4?

DR. ENGELJOHN: This is Engeljohn. And how I would answer that, Pat, is that in the original compliance guideline that we issued in August of 2008 and had the public meeting on, where we sought dialogue on the issue of the event days, laid forward some criteria and our rationale, there and at that time, the Agency used its beef trim baseline results, which was a .68 percent positive, and used that as a lower end of a criteria and then added to that what the likely level of

contamination was in beef trim that the establishments were finding, which is not what the Agency tests. We test product after the establishments have done everything they can to apply interventions and then determine that it meets our non-detectable standard and offers it to the Agency for the market inspection.

We laid forward that criteria. It certainly came under criticism from a variety of sources as to the scientific basis behind that. We've taken those comments and come up with a rationale which would be articulated in the compliance guideline that I said we would be providing for public comment.

MS. BUCK: Okay.

DR. ENGELJOHN: So there will be an opportunity to comment on it again. What the Agency really is looking at is when is there evidence that the level of contamination is greater than what we, the Agency, believe it to be reasonable based on our years of experience of the percent positive rate we find in our verification

testing program.

The N60 test is based on having confidence that there's 95 percent likelihood that there is less than 5 percent contamination of product lot. We don't accept that there should be 5 percent contamination.

MS. BUCK: Yes.

DR. ENGELJOHN: But when we find positives, and we find it at a higher frequency than would be normally found, it's an indication that there's more frequent or higher level contamination. So we are establishing statistical boundaries that tell us statistically that the level of contamination and the frequency of it is greater than what is reasonable to assume under good manufacturing practices. That's the basis behind it. Statisticians would have a heyday looking at that and giving us input on a rationale, but we've provided a rationale that we, the Agency, believe is prudent to follow. We know, as was said in one of the commenter's statement, that each establishment, each corporation is setting its own

criteria right now. We're looking to establish some level playing field to say that if an establishment has a rationale, we would take that into consideration based on their production practices, but we at least want to give our employees some guidance to look at, to say, they're producing above this level. Is it reasonable enough? And then have the technical experts and the Agency then get involved and make more reasoned scientific determinations.

So we will provide that to you in the form of a *Federal Register* document that conveys a rationale, ask for comment on it, and that's what we would put out.

MS. BUCK: Thank you. But, Dan, before you leave, have you hired a statistician to serve in the upper administration to help you carry out these purposes?

MR. MANDE: We have many statisticians who are senior positions in the Agency.

MS. BUCK: Thank you.

MR. MANDE: Any other questions?

I'm hearing none. Again, thank you all so much for your participation today, and I look forward to working with you as we go forward.

(Whereupon, at 12:45 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

FSIS PRODUCT TRACING RELATED

TO *E. coli* O157:H7

IMPROVING PRODUCT TRACING OF FOODS

Washington, D.C.

March 10, 2010

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.

_____

VICTOR LINDSAY, Reporter

FREE STATE REPORTING, INC.