UNITED STATES DEPARTMENT OF AGRICULTURE

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SHIGA TOXIN-PRODUCING *E. coli*

ADDRESSING THE CHALLENGES,

MOVING FORWARD WITH SOLUTIONS

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Washington, D.C. 20007

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I-N-D-E-X

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

(8:39 a.m.)

DR. GOLDMAN: Can everyone hear me fine? Can you hear in the back, Danny? Okay. Good.

Well, good morning. This is David Goldman. I'm an assistant administrator here in the Food Safety Inspection Service overseeing the Office of Public Health Science. I will be the moderator for today and tomorrow for our meeting here on Shiga Toxin-Producing *E. coli*.

I want to personally welcome all of you and thank you for your attendance. There was quite a bit of interest in this meeting. The room is nearly full, and I expect it will be full later. We have quite a few people also joining us on the phone. I will come back after our welcome and opening remarks and give you a few more details about the outline of today and tomorrow's schedule so that you are oriented to what we are attempting to accomplish and know things like where the bathroom is and all of those sorts of things that a moderator needs to let you know about.

But before I do all of that, I would like to introduce the Agency's administrator, Mr. Almanza, to provide a welcome. Al, most of you know by now, was appointed by Dr. Raymond, Under Secretary, then Secretary Mike Johanns announced back in June of 2007 that Mr. Almanza would be the administrator of FSIS. He is, as you are familiar, a well-experienced leader, as well as a long-serving employee of FSIS, nearly 30 years. He can tell us exactly in just a minute. He has a strong record as an FSIS manager. He has been involved in recruiting and training efforts and employee relations, and he does not hesitate to take strong and swift regulatory action in order to protect public health.

Al served previously as the district manager in Dallas, which, of course, includes 350 federally inspected establishments. He is a Texas native and did join FSIS in 1978. As I mentioned, he held previous positions as a slaughter inspector, labor relations specialist, special assistant to the district manager, and a, finally, deputy district manager before becoming the district manager.

Please welcome Al Almanza, who will provide the official welcome to this meeting.

MR. ALMANZA: Thank you, David. Yeah, as a matter of fact, May 5th will be 30 years and I -- thank you for the introduction. Welcome to everybody in this room. It's springtime in Washington with the cherry blossoms. I hope everybody gets to see those. I used to come to D.C. quite often and never experienced them, but they're quite a sight. I'm not sure that it's as nice as it was a few weeks ago when they were all pink, but nonetheless it's quite a sight.

What we hope to do today is have a healthy discussion on *E. coli* 0157:H7 all rolled up in one big package.

I want to welcome everyone, make sure that it's a very constructive meeting over the next day and a half. This meeting we'll explore options, options that we'll need to take a good, hard look at. And by the title of the meeting, "Shiga Toxin-Producing *E. coli*, Addressing the Challenges, Moving Forward with Solutions," certainly is a mouthful.

However, by title alone, it conveys that we have quite a bit of meaningful and dynamic topics to discuss.

Because of the content, this meeting has surely generated a significant amount of interest, and no doubt you all can tell in this room that it's quite full, and as of yesterday I think we had a little over 200 people signed up for it. So try to keep yourselves as comfortable as you can.

On behalf of the Agency, I want to express my sincere appreciation to the folks who have arranged this meeting in short order and our partners from outside FSIS who agreed to present and discuss vital information that will help us all achieve our ultimate objective, improve food safety and enhance public health protection.

The fact that we have such a well-attended meeting attests to your strong devotions and commitment in making our food supply the safest it can be and to the impact FSIS has had on the lives of almost every citizen, every day, in America.

FSIS is accountable for protecting the

lives and well-being of approximately 300 million U.S. citizens and millions more around the world.

Our Agency's 9,500 employees include approximately 7,800 program personnel who are assigned to approximately 6,200 federal slaughter, food processing, and import establishments every day.

Since our workforce plays an integral part of serving the needs of millions, I'm very pleased to acknowledge that we have representatives from three employee focus groups here today to take note and weigh in on any initiatives discussed in this meeting that will affect their daily livelihood.

Stanley Painter from the National Joint Council traveled up from Alabama to see us.

Luis Zamora from ATSP came down from Philadelphia.

Keith Reynolds from the NAFV traveled from Kansas to be here, and I also noted Dr.Basu as well.

I'd like to thank each of you for your being here and any other folks from your respective organizations. We certainly value your many contributions to this Agency's policy and day-to-day

operations.

This meeting is one of 11 key initiatives that FSIS announced last autumn to protect public health against the risk of *E. coli* 0157:H7, initiatives ranging from testing and the analysis of trims, testing more domestic and imported ground beef components, working with small and very small plants, and working with our many partners.

These initiatives demonstrate FSIS' holistic approach to addressing problems and coming up with timely solutions to deal with them, all with the end goal of improving food safety.

But this can't be done without your support and ideas, and we certainly welcome any new ideas put forth on the table that will help achieve our common mission to protect the public health.

As always, FSIS is committed to transparency, and I look forward to this meeting serving as an important mechanism to enable that.

Thank you again for your attendance.

DR. GOLDMAN: Thanks, Al, for that welcome. Now, it's my honor and pleasure to introduce the

Under Secretary for Food Safety, Dr. Richard Raymond -- as such is responsible for overseeing the policies and programs of the Food Safety and Inspection Service and as well chairs the U.S. Codex Steering Committee, which provides the oversight and guidance to our U.S. delegations to the Codex Alimentarius Commission.

Dr. Raymond has extensive experience in developing and implementing policies and programs designed to improve public health. Prior to coming to USDA years ago, Dr. Raymond served as director of the Nebraska Department of Health and Human Services, Regulation and Licensure Division, where he oversaw regulatory programs involving healthcare, environmental issues, and was also Nebraska's chief medical officer since January -- in that role as chief medical officer, he directed a large number of public health programs, including disease prevention and health promotion. He also developed several anti-bioterrorism initiatives and a statewide healthcare alert system. He also played an integral role in developing health districts in each of

Nebraska's 93 counties.

He previously served as president of the Association of State and Territorial Health Officials and was a member of that association's Preparedness Committee for over three years.

A lifelong resident of Nebraska, he practiced medicine in rural Nebraska for 17 years and then later established and directed a community-based family practice residency program in Omaha. He also served as president of the Nebraska Medical Association, chaired one of then Governor Mike Johann's Blue Ribbon Panels on infant mortality and served on other state committees related to public health.

He attended Hastings College where he earned his bachelor's degree, and he earned his medical degree from University of Nebraska in Omaha. Please join me in welcoming Dr. Raymond.

DR. RAYMOND: Thank you, Dr. Goldman. Sounds like a guy who can't keep a job for very long -- welcome.

Good morning to everyone. Thank you all

for coming here today or getting on the phone with us and participating in this very important two-day meeting. Given the short notice that you all had after we got the webpage -- those of you who know me know that I don't usually -- this meeting --

I'm glad to see so many of our partners from the whole food safety spectrum here with us for today and tomorrow, folks we've been working with for the past two years to improve food safety in the United States by working in an open and transparent fashion to improve communication and collaboration in such important efforts as our highly successful Salmonella initiative, risk-based inspection, attribution, and non-O157 STECs.

Since I've been at the USDA, I've always said we must tear down old walls and silos that prevent us from working together toward achieving our common food safety objectives. This approach towards addressing challenges will continue to be a major priority of mine in my final year here. It's labor-intensive, but it is a labor of love, trying to improve food safety --

This meeting is a perfect example of just such an approach with our challenge of getting Shiga-toxin producing *E. coli* out of the ground beef that most of us in this country love to eat.

Over the long haul, we've made some tremendous progress in controlling *E. coli* 0157:H7. Between 2000 and 2006, as you see on this graph and as you well know, FSIS testing shows the percentage of samples testing positive for *E. coli* 0157:H7 declined by nearly 80 percent. Maybe this is not the best indicator of prevalence of the bug, but it certainly is an indicator of trends, and it's an indicator of increasing industry control of this bug until recently.

The Agency's *E. coli* 0157:H7 initiatives and industry's collective response in 2002 helped drive the rates of these positive samples down, and these rates remained at approximately 0.17 percent for 2004, 2005, and 2006. But in 2007, that rate did increase to 0.23 percent. It did not seem like much, and to put it into perspective, out of 12,000 samples that were taken in 2007, only 27, a rather small

amount, were positive for *E. coli* 0157:H7. That's one way to look at it. Another way to look at it is we had an increase of 30 percent of samples that tested positive.

So as far as sampling goes, we have improved tremendously in the long run. But, unfortunately, we've plateaued for three years, and then we slipped a little bit last year.

But the bottom line is not product testing or how much it shows as positive. It's human illness, and those numbers did rise in 2005 from its low in 2004 where we actually reached the Healthy People 2010 goal, and then it rose again in 2006. The foodborne illness data from 2007 are officially due out this Friday from the Centers of Disease Control and Prevention's morbidity and mortality report. Now, Bob is here today, and I hope he doesn't speak ill of 2007 -- we can only hope that 2007 isn't further bad news with further trending upwards in human illness. But we have to look at these trends in illness and product testing to know that it is time for bold steps to be taken.

Last year we also experienced an increase in the number of recalls related to *E. coli* 0157:H7. Last year we had 21 recalls, with ten that were due to reported illnesses.

And to put this data in perspective, we have to realize, from 2002 to 2006, the number of recalls of ground beef due to *E. coli* 0157:H7 had decreased significantly. This is not through chance or luck, but rather through our collective efforts and our commitment to control this pathogen and lower the risk of foodborne illness to consumers.

The breakout is this. In 2002, we had 21 recalls, two were reported illnesses; 2003, we had 12 recalls with five due to reported illnesses; 2004, it was 6 recalls with three reported illnesses; and in 2005, it was only 5 recalls with 4 of those being due to reported illnesses. In 2006, we went up a little bit. We had 8 recalls, but all were due to product testing positive. There were no illness-related recalls. Last year, 21 recalls. Ten of those were due to reported illnesses and outbreaks.

I don't think anyone became complacent in

the last year or two. What we may have seen is a change in the ecology of the bug or the prevalence of the bug or the concentration of the bug on the hides or in the gut of the herd that we process. We don't know yet what has caused this disconcerting upward trend in recalls, positive samples, and human illnesses, and until we do know that for sure so we can attack the problem, so we can attack the problem at the pre-harvest stage, we must do everything possible to reverse the trends and to protect the public health. That is our collective responsibility, and we must take that responsibility on together.

We did take a number of steps last year to address the increase in positive samples, as Al mentioned, and recalls associated with the pathogen, which you'll hear about today, but these might be considered nibbling around the edges of a problem with policies that are relatively non-controversial.

These were good changes. But now we need bolder, stronger initiatives. The bottom line is, I simply want harmful *E. coli* out of the ground beef

supply in the United States, and you all do, too, or you wouldn't be here today. Or you wouldn't be on the phone today with us if you didn't share the same goal.

Now, how we're going to achieve that objective relies on how much we're willing to work together during this meeting and at the meetings that will surely follow. What you see on the agenda is not the same old thing. We're going to be discussing things that may make some of you uncomfortable. They probably already have made some of you uncomfortable based on what I read in the media. But the media isn't where this problem will be solved. It's at the collective table with everybody's sleeves rolled up and everybody ready to work collaboratively in an open but transparent fashion.

The discomfort that some of you are feeling is something I want people here today to experience. You may hear things that you don't agree with. That's expected, but I want you to engage in constructive dialogue to tear down those walls that can divide us simply because we don't see eye-to-eye

on certain issues. Progress will not occur if we let the walls stand or if we continue to build them up even higher. Progress won't occur if we're just wanting to avoid discomfort by maintaining the same old status quo. The *E. coli* bug is obviously not satisfied with the status quo, and neither should we be.

We know this is not going to be easy, but we all share a common goal, and we need everyone's input here to move forward with viable and practical solutions.

In keeping with the goals and practices of this administration and this Food Safety Inspection Service Agency and the Office of Food Safety to be open and transparent in our deliberations, today we are announcing that we are seeking a dialogue regarding our next steps with *E. coli*. Because of the highly infectious nature of *E. coli*, even when present in small amounts, we not only cannot rely on it being cooked out of ground beef, but we also cannot count on it not cross-contaminating other food products as has been demonstrated to do over and over

and over again.

We need to discuss what your community, whether you're a producer, a processor, a consumer, an academic, or a public health official, we need to discuss what your community is going to do on this problem, not just pointing the finger and claiming what the other community should do. I've been reading the comments on the Web and the blogs, and I see, "Tell them just to cook it, stupid." Or I see the finger pointed at feed lots or at line speeds or at corporate bottom lines. These are old and worn-out phrases. Finger pointing like this will not help us protect the vulnerable populations that need our help. They need our help, and I hope you're up to that task.

Yes, the *E. coli* 0157:H7-related outbreaks made us all unhappy, which is why I want to tackle this problem head-on. I want to take a big bite, not just nibble around the edges anymore. I want to take a big bite out of this problem by moving forward with some measured, practical, proposed, I stress proposed, solutions. We will review the responses

from the 30-day comment period that will follow this meeting, and we'll plan the next steps based on the input we receive here today and in those comments.

I don't have a lot of time left in my position as the Under Secretary, and the challenges with *E. coli* 0157:H7 are not something I want to ignore during that time period. I certainly don't want to leave this problem for the next Under Secretary to deal with, and I don't want to have a prolonged, fruitless deliberation on this subject. We have a problem. People are getting sick. The numbers show that the problem is going in the wrong direction. So let's work quickly and thoughtfully to find a right prescription to solve this problem. And with all that said, I look forward to a productive meeting, and I hope you all will be providers of thoughtful input to help us with our deliberations. Thank you.

DR. GOLDMAN: Thank you very much, Dr. Raymond, for that putting the charge into the meeting here.

Let me just take a few minutes to orient

you to the agenda and remind you that, as with all of our public meetings, this meeting is being recorded. We have a transcriptionist here to record the meeting. We have participants who are both in the room and on the phone so that when you come to the microphone to make a comment, please identify yourself by name as well as your affiliation so that we can get all this into the transcript of this meeting.

Before I go on with that, hopefully people have found the restrooms, which are out the back door of this meeting room. Of course, you can leave by any of these exit doors here, but the restrooms are in the very back.

If you'll look at the agenda just a minute, you'll notice that we have presentations clustered together. And it may first appear that we don't have very many breaks in this agenda. Therefore, if you need to create your own break, please do so.

You'll also notice that we have provided for question and comment periods after each series of presentations. And, again, we want to use those

opportunities to the maximum to encourage your contributions to this meeting. We are here not only to hear from the formal presenters as outlined on the agenda, but to hear from all of you here who can contribute to the solutions we'd like to come to. By my count, there are about three hours worth of time devoted to public comment and question. So it should be sufficient time spread over the day and a half for everyone to make their point.

I will remind folks, as Robert customarily does, that we'd like for you to keep your comments as short as possible. Certainly, there is also the opportunity to provide written comments, as was just stated, but I know there are people who want to make comments about what they hear during the meeting or about the issues that are being raised. So if you do come to the microphone, please try to keep your comments as brief and succinct as possible.

Okay. Are there any questions before we proceed with the agenda?

(No response.)

DR. GOLDMAN: Great. Okay. And one last

thing on the agenda. We've divided this loosely into three broad areas, a broad perspective this morning. You'll hear from a variety of speakers, some of whom you're not accustomed to hearing from in our meetings, to give their perspectives about the challenges that confront all of us in trying to control this pathogen.

Then, we'll focus primarily on FSIS initiatives that are designed to help us, the Agency, who is responsible for regulating the meat supply, to better understand this pathogen, as well as to control it. So you'll hear a variety of speakers talk about that issue.

And, finally, tomorrow we're going to delve into the many hypotheses that have been put forth since last summer, or since last fall, rather, in an attempt to explain what might have occurred last year. So we'll hear from folks who are either in a position to talk about research that has taken place or at least whether or not some of these hypotheses are testable.

And then, finally, we'll hear from a panel

at the end of the meeting tomorrow who will talk from their organization or agency's perspective about what they may be able to do or their members or constituents may be able to do to help rectify this problem. So that's broadly how the agenda is set out.

We do want to begin as we should with human illness. After all, that's our report card. And so we're very pleased to have with us today Dr. Robert Tauxe, who is currently the deputy director of the Division of Foodborne, Bacterial, and Mycotic Diseases at the Centers for Disease Control. Rob has graduated from Yale for both his undergraduate and Master's in public health work and did his medical training at Vanderbilt University and is a specialist in internal medicine.

He's been at CDC for 24 years working on their surveillance investigation and control of bacterial infections of the GI tract. He's been a close colleague for all of us here at FSIS, and we appreciate him being here to tell us from his perspective about the human illnesses in particular

last year related to 0157.

Please welcome Dr. Tauxe.

DR. TAUXE: Thank you very much, Dr. Goldman. And it's an honor and a pleasure to be here. Thank you for the invitation to participate in this important meeting.

I'm going to review some of the basic information that we have and some of the most recent data from the investigations and surveillance that we do about *E. coli* 0157. I'm going to make just a couple of comments about some of the non-0157 *E. coli* as well. Let's see. The next slide, please.

In 1999, we published a summary of our estimates of the burden of a number of foodborne diseases in the aggregate, and among that was the -- our estimate at the time of the annual number of *E. coli* 0157:H7 infections, 73,000 infections in the U.S. each year of which 2,000 would be hospitalized, and 60 might lead to death.

That is important for us all to recognize, that the *E. coli* 0157:H7 represents a very distinct category of *E. coli*, those that produce Shiga toxin,

and that the illnesses that 0157 and some of the other Shiga toxin-producing *E. coli* cause are severe and have consequences, in fact, that may last for years.

E. coli 0157:H7, on ingestion, rather, it appears that even a very small number may lead to serious illness. After three or four days, typically, non-bloody diarrhea develops, abdominal cramps that can be very severe. In another day or two that may progress on to bloody diarrhea, and then the most feared complication is if the toxin attacks the blood vessels in the kidney or the brain leading to hemolytic uremic syndrome that happens on perhaps 8 percent of the cases that are diagnosed. And most cases resolve, but that feared complication is a major part of why we focus so much attention on this organism.

Some years ago, in fact, in 1996, as a collaborative effort between CDC, FSIS, FDA, and an increasing number of sites based in state health departments around the country, we created FoodNet, a sentinel site surveillance system for foodborne

diseases. At that time, reporting requirements varied widely among states, and it was difficult to construct a national picture for a number of foodborne infections. So we created this system, active surveillance, in which staff contact all the clinical laboratories in the area to find out what they're diagnosing, as far as the major foodborne infections, and also survey the population for illness and exposures that might be relevant.

And since then this system provides our best data on the burden of illness and on trends, providing useful information for risk assessment. And we annually report the results of the surveillance, comparing it to previous years, and we, as Dr. Raymond mentioned, we will shortly be preparing -- publishing this year's -- the report for last year, for 2007, and it's under a press embargo until the time it is published. Next slide, please.

FoodNet began with five sites around the country and expanded to include now ten sites, or 15 percent of the U.S. population, a reasonably representative sample. And one of the things that we

do when we report this is account for that expansion in sites because different sites have different, actually, different prevalence of some of these infections. Next slide.

But just looking at the overall incidents, that is, the number of illnesses per 100,000 persons living in those areas per year and comparing *E. coli* to the baseline number, 1996 through 1998, which was 2.4 diagnosed infections per 100,000 people and a healthy people 2010 objective of 1.0, in recent years, the trend, as was just mentioned, has been frustratingly close. Actually, we got below the 2010 objective in 2004, when it reached .9 per 100,000, cause for real pride, I think, among a large number of people who had something to do with taking that number down.

Since then, unfortunately, the numbers have returned above that objective. 2005, it was 1.05, 2006, 1.31, and for 2007, I'm going to have to refer you to our publication coming up shortly this Friday. I will say that that trend that you see of .9, 1.05, 1.31 does not continue linearly, and that, in fact,

what we are seeing now is -- resembles what we've seen in the most recent years, but does not continue to increase, which is, I think, is a good thing. But it's certainly not below our 2010 objective either. Next slide, please.

This graph shows not the raw numbers, but it shows the numbers adjusted for that expansion and the number of sites as a relative rate, setting the first three years as a baseline rate and comparing how the whole system has performed since then, where one would mean -- the line across means that we're really matching what we saw in '96 through '98, and deviations below that are progress. You can see there's the low point in 2004 and the increase -- oh, thank you -- in 2005 -- let's see. Here's the low point in 2004 and then the increase in 2005, 2006. Next slide.

And as of the 2006 data, that represented a 14 percent decline from baseline, which, unfortunately, was not actually physically significant. Next slide.

How do we account for, you know, this

increase in *E. coli* 0157 certainly over the last few years and this -- the recent search in the actual outbreaks and recalls that have been related to ground beef in 2007. And FoodNet collects other data about the system than just the raw number of outbreaks -- raw number of cases. Sorry. And this shows some of them. I'm going to show you some of that other data.

This is a series of surveys of clinical laboratories in the FoodNet system asking them what proportion of them are looking for *E. coli* 0157 routinely whenever a diarrheal stool is submitted. Perhaps numbers would go up or down if clinical laboratories changed their policy over, you know, whether they were going to culture diarrheal stools or not. And, as you can see, roughly, between 60 and 70 percent of the laboratories have been culturing for 0157 routinely on all diarrheal stools. And the most recent survey conducted in 2006-2007, the proportion of labs was 66 percent, which is pretty consistent with what's been going on over time. So I don't see that a change in laboratory practice

explains recent trends. Next slide, please.

Similarly, we conduct surveys of the population in which very cooperative people to whom we are very grateful answer a number of questions over the telephone about what they -- how they -- their health status has been and what exposures they've had in the seven days before the interview. And in that one of the things we -- is, well, how many people are eating ground beef in the seven days before the interview. And as you can see, that proportions hovers right around 70 percent that say yes in that time, and that has not really changed. The most recent survey, 2006-2007, really within statistical limits for all of this. Not changing. That doesn't seem to be anything that's changing much in the population. Next slide, please.

And then we even ask them -- you know, very few people use thermometers, and it's hard to know how well-cooked the ground beef was, but as an index of that, we ask have you consumed pink ground beef or undercooked ground beef in the seven days before the interview that you noticed. And, again, that

proportion is really not changing much, oscillating around 8 percent, or so, perhaps a little higher in the most recent survey than in 2002-2003. But I don't see these as major changes in population behavior. Next slide, please.

I'm going to turn to another surveillance system that we've been constructing across the country in state health departments called PulseNet. And PulseNet, rather than looking at individual sporadic cases and counting them the way FoodNet does, PulseNet is a system that's designed to detect outbreaks. And it's based in state health -- public health laboratories. Let's see, I guess we need to introduce some elements here.

Actually, since 2001, in all 50 states, and in an increasing number of large cities as well, where the *E. coli* 0157 themselves are fingerprinted -- could we tap again, please? In those laboratories, the PFGE, pulsed field gel electrophoresis, fingerprints or DNA patterns are determined for the *E. coli* 0157 isolated from people with the infection. Looking in each state, looking

for are there clusters of one single pattern. There are hundreds of hundreds of patterns that are being identified all the time, but do they -- if they appear to cluster in an unusual way, then that's a signal. Next, please.

Those images are also stored at the PulseNet database -- one more click, please -- at CDC. And in addition to state scanning and looking to identify clusters, we do that on a regular basis every day at CDC and, in fact, have joined with Canada as well. And so that national database has greatly enhanced our ability to detect outbreaks. But that reached full national participation in 2001 and has not recently been changed. Next slide, please.

This shows the overall system. It's not just *E. coli* 0157. It's also *Salmonella* and *Listeria* and some *Shigella* and some other pathogens as well. The total number of patterns that are submitted to PulseNet has been rising, so that in '06 it was something over 50,000, all of those pathogens together, and over 60,000. So this has been an

increase in participation in a number of different pathogens. But I think we have about 30,000 patterns, not all different, but 30,000 submissions total in the *E. coli* 0157 database. And, as I say, we reached full participation in '01. So I don't think PulseNet has changed in any dramatic way in the last few years. Next slide, please.

PulseNet does detect clusters of illness with matching DNA fingerprints. A match suggests a cluster, an unusual cluster suggests that the infections might have a common origin. This facilitates the early identification of outbreaks, and it makes the epidemiologists do a great deal of work. In a system in identifying outbreaks, persons who have the outbreak fingerprint are the ones to concentrate investigation in and interviews on and when a match occurs between an isolate that's in a suspect food and in a patient or in a whole group of patients that can help to confirm that the outbreak has that source.

Now, we have another very hardworking group of people that we've given the name OutbreakNet to.

Our challenge is that PulseNet is identifying clusters of possibly linked infections, and those, as I say, turn into a great deal of effort to investigate and look into them further. Not all of them are outbreaks. Not all of them are fully formed investigations. But an outbreak coordination team at CDC is in regular communication with counterparts in every state. And the goal of this team, OutbreakNet team, is to promote the systematic investigation of cases and coordinated investigation of multi-state outbreaks when they occur. And it has a very strong working relationship with FSIS and with FDA, as well as with the states. And part of what this team does is conduct the systematic and collection and review of all foodborne outbreaks reported by state health departments, of which there are approximately 1,200 a year, considering all the etiologies, including the most common etiology of all, which is etiology not determined.

This shows the number of *E. coli* 0157 outbreaks over time reported to the United States between 1982 and 2006. And this is to give you just

a sense of how the outbreak surveillance has been going on. You can see back in the 1980s, there were very few outbreaks identified or reported. That is before clinical laboratories were doing much culturing for this at all. It was before surveillance began. Only the very largest and most obvious outbreaks would be identified.

A very large outbreak occurred related to ground beef in the western states in early '93. Shortly after that, *E. coli* 0157 became nationally notifiable. You can see the number of outbreaks increases because many states began looking for it and getting these notification reports. PulseNet was turned on here. And you can see, at the same time, much more stimulated reporting from states of a variety of different foodborne outbreaks, a much more participatory system. And since then all reporting of all outbreaks practically doubled in '98, not because necessarily of PulseNet, not because suddenly things got worse, but because surveillance for outbreaks was greatly reported at that time.

And since then, the *E. coli* 0157 outbreaks

have gone along at about 40 and then maybe 30 per year. This is through '06. '07 data are still quite preliminary and not closed out yet, but it looks like the '07 data for the total number of reported *E. coli* 0157 outbreaks is going to be similar to that of '06. We're not seeing a large spike. So it's going to be similar to '06. Next slide, please.

Here is a summary of the sources of those outbreaks that comes from a review we did in 1980 to 2002 showing that there are many different ways, unfortunately, many different pathways by which *E. coli* 0157 can reach us, the consumers. 61 percent of the illnesses in all those outbreaks were accounted for by foodborne transmission, 15 percent by drinking water, some percentage never figured out, 8 percent by person-to-person, chiefly in day care centers, child day care centers, some animal contact, recreational water, and a tiny proportion that were actually acquired in laboratories.

So foodborne was the dominant form of transmission during that time. Thank you. I think that continues to the present. And then of the

foods, at that time, 33 percent of the foodborne -- of the illnesses related to food, 33 percent it was specifically ground beef, 11 percent other beef. An important fraction for us to recall is that about a third were related to produce items, and then there were a scattering of others. So ground beef and other beef accounted for certainly the greatest proportion of the illnesses. Thank you

And this slide shows, again, between 1982 and now through 2006 the percent of the outbreaks reported to us which were attributed to beef. And this is among, I think, those for which there was a food source identified. So you can see early on those early outbreaks -- this may be just one or two outbreaks a year, but beef was the complete story for the first decade.

And as more outbreaks began to be reported and investigated, there were also the recognition of transmission in day care centers, transmission through produce. This would be just foodborne, so this would mean produce and other sources other than beef.

And then an interesting trend -- and as of 2006 -- now, 2006 was a very interesting year for *E. coli* 0157. I'm sure people in this room remember. Large spinach outbreak and several shredded lettuce-associated episodes that produce really announced itself as a major fraction in 2006. And we reached this remarkable point where 25 percent of the outbreaks in 2006 were due to beef. So kind of a lower number there than had been seen in many of the previous years.

And I don't have the final numbers for '07, but I can say that it is not going to be 25 percent. It'll be at least twice that. And so 2007 is going to be a year where to summarize the outbreak data, the preliminary information that we have -- the overall number of outbreaks does not change dramatically from '06, but the proportion due to beef increases and that's what -- that's a change in the system. Next slide, please.

Now, to refer briefly to those outbreaks because I think in a way there are some relations here that we mustn't forget. Baby spinach, in 2006,

large outbreak nationwide, approximately 200 cases, traced back -- that were all cultured and confirmed -- traced back to four farms, one of which sampled environment had the outbreak strand of *E. coli* 0157 near that environment. And the isolate came from beef cattle that were in a pasture not terribly far away from a stream which passed through the beef cattle area and then not too far from the spinach field from the feces of wild pigs, which were roaming the area and a soil sample. So it was very clear that this was the environment in which this occurred. Next slide.

How exactly the spinach became contaminated and whether there was an indirect connection with beef was not -- oops, can we go back, please -- was not so clear. The cattle were a half-mile from the spinach field. They were not adjacent. There was a question about spring flooding of the streams into irrigation wells used for the spinach patch. And there was a question about the wild pigs traversing the spinach fields. And as I said there was the feces from wild pigs carried 0157, which may reflect

the fact that they were drinking the water from the streams. Next slide, please.

A shredded lettuce investigation also carried out in the field by a remarkable group, the California Department of Health, the California Foodborne Emergency Response Team, who has posted the results of their investigations. In this outbreak, 36 cases in two states traced a taco change. Why? The shredded lettuce in the tacos that was the implicated part of the taco came from a California farm. I'm pointing to the actual field where that came from, and you can see that this field, in fact, is curiously and interestingly virtually adjacent to two separate dairies, which are here. These photographs are from the CalFERT report. And there are -- tap it one more time.

There are here right -- sorry. This is the field here, and right next to it is a water-mixing device, and samples from the outbreak strain of 0157 came from both dairies and from three fields, and the pipes made it possible, though certainly not the intention, it made it possible that the tailwater

from the manure lagoons could be connected up with the irrigation systems for the fields. Thanks.

That's a device that brings four different water supplies together in a way that is rather complex to predict what the outcome would be with various valves, and it's right adjacent to the spinach field. Thank you.

Now, to turn quickly, as mentioned, 2007 was a year in which there were a number of outbreaks associated with beef recalls after the year of 2006 being zero, and that was certainly a noteworthy event. Next slide, please.

This is the outbreaks that we have tracked related to those recalls, just showing by month and year that there was an early cluster in March or April when half of them occurred rather early in the year, and then a later cluster at the time when *E. coli* infections in general are more common later in the summer.

Looking at nine outbreaks which were associated with beef recalls, ignoring events in which a single person was ill but had an isolate that

matched something from beef, there were five multi-state and four single state episodes. The location of the exposure was the home for seven outbreaks, a restaurant for one, a concession stand for one. The average number of persons ill was ten ranging from 2 to 45. That number is not smaller nor larger than the average number for outbreaks here recently for 0157. And the age ranged, of course, across the entire population.

So these outbreaks are not dramatically different in any particular way to me. They're not all very small outbreaks that were picked up only because of PulseNet, for example. They were that average size of ten. And that's what we can say about that. Next slide, please.

One particular outbreak I wanted to mention, a complicated one, in September of 2007, PulseNet in several states identified a cluster of a particular pattern of *E. coli* 0157 infections, and in this one, *E. coli* 0157 was identified in frozen ground beef patties from patients' freezers and from retail samples.

Where this one got particularly complicated is that in sampling the meat, I think more than one pattern was identified. And all of the sudden we're not talking about just pattern X and this very pretty picture where a pattern is an outbreak, a pattern is a cluster. For this, more than one pattern was present, in fact.

And then we go back to PulseNet and say, well, gee, well, this other pattern, are we seeing that in humans, and we contact those people who have been ill and we find out if they had ground beef and if they've eaten the relevant ground beef. Then it becomes interesting and ping-ponging back and forth between what was in the meat and what was in the people.

Six different PFGE patterns were emerged in that investigation. And a total of 43 cases in ten states with one of those patterns. Now, pattern X was still the predominant one, but there were these others. 88 percent reported they consumed ground beef. 92 percent of those said that brand X, frozen ground beef patties was what they were eating.

And then I mentioned PulseNet crosslinks with Canada, and Canada began to identify cases as well. The beef, it turned out, was from a producer in Canada, and the result was a large-scale recall. Next slide, please.

The Canadian investigation found only four cases that they had in PulseNet with pattern X. They didn't get those frozen beef patties, but they identified the same pattern X in beef from producer. And that beef included ground beef, other cuts from producer A, and they also led to a recall of production although it was a slightly different product, but it was from the same producer. Thank you. Next slide.

I want to say just a few words about the non-0157. The non-0157 have not been routinely sought in clinical laboratories, and this is ones where the diagnostic practices are changing recently, and more and more are being detected because of surveillance. Oops, can we restore the slide, please? And the trend, at least in FoodNet, is one of increasing numbers of non-0157 STEC that are being

identified and reported, and that's because of changes in laboratory practice. And it's not possible to say that there is any real trend in the actual disease related to non-0157 STEC. It is possible to say that more laboratories are looking and they're identifying more cases.

Of those cases, they are often serotyped -- I'll continue without the images, which I hope can be restored here shortly. Though the human isolates are sent to CDC where we serotype them and of the ones that have been sent in for some years, it's -- from FoodNet, it's clear that there are six particular serotypes that account for the bulk. 83 percent of the non-1057 STEC infections are accounted for by six particular serotypes.

And when we look at these illnesses and we look at the serotypes that are involved, we see illness that is similar to, though in general milder, than *E. coli* 0157, not as likely to produce bloody diarrhea, not as likely to lead to hemolytic uremic syndrome, although some of them clearly do. And those six serotypes account for, as I said, 83

percent of what's been detected in FoodNet and 95 percent of the outbreaks of the non-0157 STEC. Ten of those outbreaks were foodborne. And those particular serotypes are also -- or serogroups -- sorry -- are identified by numbers, and the numbers are essentially just in order of when they were identified or appeared. And they are 026, 045, 0103, 0111, 0121, and 0145. And this becomes sort of a numerical alphabet soup. But those six serotypes, in addition to 0157 are of a particular concern to us.

So I will conclude by saying the recent trends in surveillance are that the earlier decline, which was so encouraging unfortunately reversed in 2005 and 2006; that I don't see that that's accounted for, and I don't see that that's accounted for by changes in laboratory practices or consumption patterns; that outbreaks overall have continued at roughly the same level in the most recent years; and that beef and produce are the main sources.

But they vary by year. And while 2006 was a year of more produce problems, 2007 was a year that was tilted towards more beef problems. There were

certainly more recalls associated -- beef recalls associated with outbreaks in 2007.

And then our outbreak investigations really have only reinforced for us that there are complex pre-harvest ecologies that link the reservoirs and beef and the transmission through produce. Can we go to the slide just before this, please? Well, when you're ready.

And that I think the most recent '07 multi-national outbreak illustrates that we can have outbreaks with multiple patterns, which is interesting and also illustrates that we have a North American market and that an outbreak can manifest on both sides of the border, sometimes not always in the same meat product.

And, with that, I thank you.

DR. GOLDMAN: Thank you, Dr. Tauxe. We're going to pause for a few seconds until we can get the next set of slides up. And as I mentioned, we will hold questions until the end of this session, which we'll -- the comment period/question period will be at 11.

Okay. Now I'm going to spend just a few minutes talking about the outbreaks that occurred in 2007 and our Agency's involvement in those outbreaks, and, specifically, our collaborations with our state and federal public health partners in investigating those outbreaks.

And I'm going to specifically focus on 11 outbreaks that resulted in some public health action, for the most part recalls, but there was one public health alert. And I will do this in an aggregate, descriptive way. I won't spent any time at all on any of the individual outbreaks because, you know, you can find some information about them indirectly through our recall database, and there will be other opportunities for longer explanation about this. But this is an attempt just to briefly summarize what we've found.

So I want to do three things. I think it's important for this audience, even though many of you know this, to talk a little bit about how we get involved in outbreak investigations or foodborne illness investigations, and, as I said, I do want to

present some summary data on the 2007 investigations related to 0157:H7. And then there are not a great number of conclusions that are drawn from this descriptive analysis, but it does raise a few questions which I'll end up with, as well as some issues for further exploration.

So our Foodborne Disease Investigations Branch is part of what has recently been renamed the Applied Epidemiology Division, which was formerly the Human Health Sciences Division. This is the branch and the staff within FSIS that is responsible for coordinating illness investigations. They are the staff who hear first, typically hear first, from their public health partners about illness investigations that may be associated with products that FSIS regulates.

Currently, they are stationed in two different regional offices and have responsibilities for an active liaison with public health partners in the various states and territories. They also serve, once an investigation is underway, as a liaison between those local public health partners or state

public health partners and our field force, our inspection personnel. Next.

So just a little bit more about what we call our public health and epidemiology liaisons that I've just described a little bit. They do assist with trace-back, both providing assistance to our partners, many of whom especially recently have come to us with some trace-back information already in hand, but also internally within the Agency, they assist with trace-back and seek assistance from other programs within the Agency to conduct trace-back of foods that are assumed or at least initially thought to be associated with illness, trying to trace them back, obviously, to the slaughter processing establishment that has produced them.

Mentioned earlier the liaison with public health partners. During an active investigation, they are critically involved in the role of assisting state public health departments with sampling products. So giving them direction about samples that would be of interest to us for further characterization. Some of this is done in the state

ag or public health labs. Others of this work is done at the USDA's food regulatory labs.

And, finally, they assist, again, during the investigations in providing epidemiologic assessments as the investigation unfolds and provide their expertise when, for example, a state health department presents us with a case control study and the results of that study. And they help us to interpret that. Next.

So I want to spend a little bit of time on this slide here. This is a depiction of some of the data that you've already -- that Dr. Raymond referred to and as well as Dr. Tauxe. It's going to be a little bit different because we count differently, and I'll mention that in just a second.

But there are three bars for each of these. The tallest bar there is labeled OPHS. That's the Office of Public Health Science, *E. coli* Investigation. So each year we get contacted often early on in an investigation by a state health department or ag department or the CDC directly and they say we've got a cluster that's just been

identified. We believe FSIS-regulated products are among those that may be implicated. So you can tell why that's the tallest bar there.

And then the second, the purple that is the second tallest bar for most of the years, is the total number of recalls related to 0157:H7.

And then, finally, there are, as a subset of those recalls related to this particular pathogen, there are those that have been initiated by illness investigations or outbreaks that have been investigated by our public health partners.

Let me make a few more points about this slide. And I'll also come to this in just a minute. But I will tell you in a little bit about why -- I'll elaborate on why we have so many investigations that we are initially involved in and why we don't continue, why they don't result in some public health regulatory action. Okay. Next slide.

So in 2007 -- I really want to focus on that particular year. That division and the Foodborne Disease Investigations Branch in particular was involved in 36 illness-cluster investigations

related to 0157:H7 and associated or thought to be associated with beef products. Again, that resulted in ten voluntary recalls and one public health alert. All of these clusters that are presented to us are linked at least among themselves, initially, to -- that is, the cases are linked by PFGE patterns. And then, of course, in those cases in which we have that information, they may also be linked to food products.

Last year in particular, there were six combinations, that is, the two-enzyme PFGE characterization, that were brand new to the PulseNet database -- and I'll say a little bit more about that in a second -- four that were characterized as rare, and one that was common.

As I mentioned, this was a year in which we actually did a public health alert as opposed to recall. And in that particular case, the reason there was not a recall done is that we made the determination that the product that was potentially contaminated was all fresh product and was out of the marketplace and not in distribution at the time that

we made that determination.

Let me just elaborate a little bit about the 25 investigations that did not result in a regulatory action. There are common reasons that vary from year to year, sometimes in combination, that result in our inability to take an action.

Last year in particular, there were two cases in which, ultimately, there was no FSIS product identified. Again, commonly we hear early on that there's a cluster or an outbreak, there are several possibilities among the exposures that are thought to have resulted in illness, and in two cases last year, there was a different exposure that was just ultimately determined to have caused the illness. There is commonly a lack of complete epidemiologic information, and by that I mean the food histories, which would help us definitively link what we only have by way of PFGE matches, a product to an illness.

In five cases last year, there was insufficient product information to complete a thorough and complete trace-back. What that means just generally is that when we attempt a trace-back,

we need to have identifying information on the product packaging, of course. We also need, when we are conducting the trace-back, to be able to trace through records and document reviews throughout the distribution chain and going backwards, of course, from a distribution center back through and including retail. And in five cases, again, we did not have sufficient or complete information to take an action even though we may have had information which suggested there was one establishment or perhaps several that were among those that might have produced the contaminated product.

And then in five cases as well last year, there was product that was actually collected later in the investigation and was found to be negative for 0157:H7. So I just wanted to give you flavor for the investigations that did not lead to an action.

I do want to say a little bit about new PFGE patterns. When new PFGE patterns are recognized in PulseNet and there is a matching pattern between a product and an illness, that gets our attention because in the absence of any other information,

that's a very compelling link. Now, of course, we still depend on the food histories to make that link tight. And we have to have information from the epidemiologic investigations, the food histories, and as well other epidemiologic analyses to help make the case. But, certainly, a new pattern suggests a stronger likelihood that that product has been the exposure that has caused the illness.

I do also want to point out that last -- the one case in which there was a common pattern. So think about what I just said from the other end of the spectrum. We have a common pattern circulating in the environment, among the cattle, perhaps even in the human population. In that particular case, we had very definitive information from our state public health partner, which was provided to us and allowed us to make a link even despite the fact that there was a common pattern. So in that particular case, the PFGE pattern was not as helpful. However, there was other epi information that helped make the case. Next slide.

So this is just aggregate information about

all of the 11 investigations I just mentioned, and I just want to review this just briefly. Among the 170 case patients that were found in the 11 investigations, 112 were culture-confirmed and epidemiologically. The illnesses ranged among those 11 outbreaks or clusters from 1 to 47. I do want to note here Dr. Tauxe mentioned that -- I think he reported nine outbreaks related to beef products.

We take an action on a single case if we have sufficient information to make the link between the exposure and the illness, so that's why you see in our range there a one, the mean number of illnesses slightly higher than the information portrayed by Dr. Tauxe a minute ago. There were 56 percent -- 56 were hospitalized, about a third, and the number of cases that resulted in HUS was 7 percent. And you recall, he said the average is usually about 8 percent. And we had no deaths that were reported.

Okay. I want to focus now on how we learned about these investigations by way of demonstrating that our liaison efforts do work. In 8

of the 11, we were contacted directly by state health departments. As is typical, we hear about outbreak investigations in other ways. One in particular I didn't mention earlier, we do have a full-time Agency-liaison who is stationed at CDC. So in one of these cases, she let us know directly about an illness investigation that was just beginning.

An average of 4.7 states per investigation. It is now routine that these investigations especially with 0157 and especially with PulseNet are multi-state investigations. Interestingly, we found that the FoodNet states that you heard described a little bit ago by Dr. Tauxe were heavily involved in the investigations from last year. They were either participants or in many cases led the investigations.

The last bullet there talks about the time from first notification of FSIS -- that's what I should say -- to regulatory action. So among the 11 investigations that resulted in a public health action, it took an average of 9.9 calendar days. And, of course, you see the range there as well.

The involvement of FoodNet I'll come back

to in a minute, but, certainly, FoodNet sites have benefited over the years from additional resources. They have been recognized as some among the strongest health departments across the country when it comes to foodborne investigation.

One last point that's not on the slide here is that we calculated the average from earliest onset of a case in a state or among the states to when our Agency was notified as being an average of 40 days. And we can talk more about that, or you might have some questions about that. The range there was 8 to 65 days. So that is the time from the first onset of a case in that cluster to notification of our Agency was an average of 40 days. Okay. Next.

I show this to make a few points here. This was one of the investigations we were involved with last year, and I won't go into great detail. But the red coloring there depicts the distribution of product. And several people have already made the point, and you well know this, that beef products, as well as most food products, are widely distributed in this country today. In this particular case, the

entire western states received product that ultimately was found to be contaminated and resulted in a recall. Click one more time, Keith.

Okay. The stars there represent the state health departments that notified us during their investigation. And, in essence, five state health departments notified us at more or less one time that they had cases or it came to our attention at one time. And this resulted, the information that we received from these states, resulted nine days later in a recall. Now, click one more time.

Then there was another state that let us know several days after this first set of states that they had some cases that ultimately were determined to be part of this same outbreak. And that resulted in an expansion of a recall. In fact, there was another expansion that wasn't prompted by, specifically by new information from a particular state.

But I say this to make a couple points. One is that this overlay of illness and a distribution of product can be very important to us

during investigations. Certainly, it can be supportive, as it was in this case, but you may be asking yourselves, well, what about Washington, Oregon, Montana, and the other states who didn't report cases. And that is a very good question.

The other point I wanted to make with the stars was that it is a fact of life that we don't get all the information that we'd like to get to take a single action. As much as we would like that to be different, we have different relationships with some states. They have different capacities to do food histories, to do investigations, to upload their PFGE patterns. There are many steps along the way that are required by individual states in order to determine that cases are linked, and we just don't get it all at one time.

Okay. Just a couple more slides here. This is the characteristics of the products that were involved in those 11 events, 29 million pounds. You can see the range of the number of pounds that were involved. The one point that I want to make here is that this big orange slice of a pie is frozen

products, and looking back at least three years, we have had recalls associated with both fresh and frozen products. I don't think we can draw any particular conclusions from this year that suggest it's any different than before.

For example, in 2006, when there were eight recalls and a relatively small number of pounds of product were recalled. There was none that was identified as frozen, but in the years prior to that, 2005 and 2004, 99 percent in 2005 were characterized as frozen and 83 percent in 2004 were characterized as frozen.

And, finally -- next slide -- by way of the data, this just shows you the establishment size and its relationship to the implicated products that resulted in public health actions. Again, there are not many conclusions to draw from this slide, but I just wanted to show you this data. And this, of course, would vary from year to year as well. Next slide.

The conclusions here, FSIS obviously saw an increase in investigations related to 0157:H7 and

also recalls. You know, I mentioned, or it was mentioned that there were 21 recalls. Of course, 11 resulted in a public health action because they were spurred by illness. The other ten, of course, were recognized primarily through microbiological testing. Recalls of frozen ground beef products was noteworthy, but, again, I said it was not particularly different from years past. PFGE continues to be the kind of the foundation of our ability kind of across the public health spectrum to detect outbreaks and to engage in those investigations. And FoodNet sites, as I mentioned, contributed perhaps disproportionately to the investigations.

So there are a few points that might be raised by this brief descriptive analysis. The point about FoodNet sites being involved at least suggests the possibility that because they are resourced somewhat better than other state health departments that if other state health departments had similar resources, among other things, including training, there could be more recognition or more timely

recognition and investigation of outbreaks.

I mentioned already the timing issue between illness diagnosis notification and regulatory action. We are always trying to seek ways to shorten that time. We continue to conduct those outreach activities. I mentioned earlier we participate in a group called the Council to Improve Foodborne Outbreak Response, or CIFOR, which is engaged in developing best practices and guidelines for public health departments so that we can recognize outbreaks sooner and come to some definitive action that will protect public health.

In addition, we are -- both FSIS and FDA are sponsoring meetings. Ours will be May 15th and 16 on enhancing collaborations and communications during outbreak investigations. The FDA will have -- it'll be a part of their meeting this summer. So both of the food regulatory agencies are, I think, in kind of constant states of trying to improve our relationships with our state public health partners through meetings and collaborations. Next slide.

This is the last slide. We wonder whether

there is something particular about frozen ground beef, but we have somewhat informally decided that perhaps it was only matter that frozen ground beef is more frequently recognized as a cause simply because it's available for testing and therefore can be associated with illnesses.

We do wonder, though, or have wondered from time to time about the survivability of pathogens in the middle of frozen patties and especially since frozen patties come in different shapes and dimensions. And we have asked ARS, our partners at the Agriculture Research Service, to help us by doing a small study which might get at this information.

The last point there is just to suggest that with fresh products -- as I mentioned, they're not often available for testing. However, trace-back that I mentioned a while ago is a very important feature of our investigations, and we depend on grinding logs and record keeping throughout the production chain to help us in those cases when fresh products are not available for testing. And we are hopeful that we can continue to see that improve in

the retail sector so that when our investigators go into those facilities, we can find information, which will help us determine where the implicated products originated and then to take whatever appropriate action there may be.

So I thank you for your attention. And we will move on to the next presenter.

Okay. I guess I made us late. Next up, we will hear a presentation by two FSIS members who will talk to us about the follow-up the Agency has taken since last October's meeting on non-0157 STECs. And we will have -- as I said, it will be a co-presentation. We'll have Dr. Elisabeth Hagen, who is our executive associate for public health and who herself is an infectious disease specialist, will talk about some of the methodologic issues that the Agency has worked through or continues to work through since that meeting.

And then Dr. Daniel Engeljohn, who is our deputy assistant administrator for policy, will talk about the thinking the Agency has in developing, possibly developing a regulatory program for these

other STECs.

So, first will be Dr. Hagen.

DR. HAGEN: Thanks, David. Good morning. It's really good to see all of you here. Our time is brief, and Dr. Engeljohn and I are going to share it. So we're going to give really just kind of an overview treatment to this subject and kind of bring us all up to speed, and, as David said, bring everyone up-to-date about what we've done since we last met on this subject.

So what we'd like to do is tell you just kind of what the Agency's current thinking is, what our current considerations are on the subject of non-0157 Shiga toxin-producing *E. coli*. I'm going to begin with a review of really just the most salient information that emphasizes -- moving forward with plans for possibly developing a regulatory sampling program and then share with you just a bit about our approach from a methodological standpoint, how do we think we're actually going to detect these organisms in a regulatory laboratory setting. Dr. Engeljohn is then going to discuss some of the challenges

associated with policy development in this particular area.

So I thought I'd start with where we left off. As many of you know, FSIS initiated a public discussion on this issue last fall. On October 17th, 2007, we hosted a public meeting, which was co-sponsored with our partners at FDA and CDC. And that meeting was very well-attended. In fact, many of you in the room and on the phone joined us for that very important first step.

We had a full agenda and we had speakers both from the United States and from Europe discussing really a whole range of subjects, including the human health burden, prevalence in food animals and in certain food categories, some of the challenges to detection and surveillance and the efficacy of certain processing interventions. We had a lot of good comments and questions that day and in the follow-up period as well, and I'd like to just briefly walk you through kind of just the key pieces of information.

So the clinical spectrum of illness and the

illness burden estimates are really important data to consider. As David mentioned earlier, that's always where we start. There are many non-0157 serogroups and many of those are not pathogenic. As we heard earlier from Dr. Tauxe, those that are pathogenic tend to cause, in general, syndromes that are milder, but they certainly are capable of causing the entire range of illness that we see with 0157:H7. That includes diarrhea, bloody diarrhea, hemolytic uremic syndrome, and even death.

There are over 200 serogroups of non-0157 STEC. And, really, six of them are the most important because they cause at least three-quarters of the illnesses associated with this group of organisms. Those serogroups are, just to repeat them, 026, 0111, 0103, 0121, 045, and 0145.

Reported incidents of these infections with these organisms is definitely increasing. But what's unclear, as Dr. Tauxe alluded to, is whether that incidence is really, incidence of infection, is really increasing or whether what we're seeing is better reporting, more spread utilization of

detection capabilities and enhanced surveillance programs. Next slide, please.

So in FoodNet, there were 575 non-0157 isolates submitted during the period of 2000 to 2006. And just for purposes of contrast, compare and contrast, there were 35 in 2002, and there were 209 isolates submitted in 2006. And we will know in just a couple of days how many were reported in 2007.

What we seem to be seeing is that if you look for these illnesses, you will find them. And there have been a number of special studies and enhanced surveillance projects in different states in which reports have shown that the prevalence of non-0157 in diarrheal stool samples and the incidence of infection actually outnumbers or is at least equal to that of 0157:H7. And I've listed Virginia and Idaho up here. Those were two of the studies that our group reviewed in some detail. But I should also have mentioned Nebraska, Minnesota, and Connecticut have done these types of special enhanced surveillance programs as well.

And outside of the United States, in

Australia and some of the western European countries, non-0157 infections clearly predominate as the cause of STEC-related illnesses.

So determining the true incidence of non-0157 human illness has been difficult for a number of reasons, and I haven't really even listed all of them here. But just go through them briefly.

First, there's a very limited awareness of STEC other than 0157:H7 in the clinical community. As David mentioned, I joined FSIS from the medical community as an infectious disease physician, and I can tell you that the awareness really isn't there. And in many systems, where laboratories don't automatically look for STECs of any kind, it really depends on the physician thinking about the possibility first in order to order the test. And if that doesn't happen, then a lot of these stools are just never looked at for 0157 or any of the STECs.

Second, there is a non-uniform surveillance for these organisms among public health departments. non-0157 STEC became nationally reportable in 2000, but the ability of states to consistently obtain that

reporting data really varies from state to state. In some clinical labs, for instance, only a Shiga toxin screen is done on samples, and those samples are then discarded, while in others, the broths will then be sent on to their state labs and onto CDC for further characterization. So we're really not getting consistent information from state to state.

And, finally, just the laboratory detection challenges themselves make getting ahead on the true incidents difficult. There are a number of these, and we heard a lot about these in our meeting in October, but the most basic of which is that the non-0157 STECs do not distinguish themselves from other *E. coli* on growth media. And that's in contrast to *E. coli* 0157:H7, which is readily distinguishable because of its inability to ferment sorbitol and its unique appearance on selected growth media. Next slide.

So another source of information that we heard about and that we've been following in terms of human illness burden is the outbreak data. There have been outbreaks reported worldwide, actually

quite a few of them, and they've been associated with non-food vehicles and food vehicles, including meat products. Particularly, sausages are one category of meat product that we've heard reports of internationally. There have been 23 outbreaks reported in the United States since 1990. Just under half of those outbreaks were attributed to foods, and then half of those were attributed to specific foods, and it's important to note that none of them in the United States have been attributed to meat products. Next slide.

So moving on from the illness burden, we heard a lot about the prevalence in food animals and food products, and FS scientists have actually been reviewing a much more drastic set of data than what I'm presenting here. But the data on prevalence in cattle, which is a primary reservoir, is important. Estimates in dairy cattle range from 0 to 19 percent, and in beef cattle from 19 to 56 percent in feces and hides, respectively.

The prevalence in specific food categories is really largely unknown. There have been a number

of individual studies. We did get some data specifically about beef carcasses and meat products at our meeting in October. We learned that the prevalence on pre-evisceration carcasses was over 50 percent in two separate studies from recent years. And in a recent study of retail ground beef by Dr. Samadpour's group, there was a prevalence of 2.3 percent reported in retail value.

And just as we see in the human illness setting, there are certainly the same challenges to laboratory detection of these organisms in animals and in food products. And, consequently, there really are very few validated methodologies for isolating and identifying these organisms in food matrices.

So I've briefly reviewed the highlights of the large amount of information on non-0157 STECs that FSIS has been considering since our public meeting last fall. We feel that the data, and also the feedback that we have received, are compelling and that we really need to begin trying to think about how do we get a handle on the extent to which

these organisms may be present in our products and whether we need to be looking at a regulatory sampling program for them. Next slide.

So what are our plans? FSIS will soon begin testing ground beef and ground beef components for the presence of the selected non-0157 STECs, the six serogroups that we've discussed this morning. Now, the primary objective, initially, is going to be to determine the magnitude of the issue. Once we get a handle on that, we can determine whether a regulatory program is warranted and how we would go about implementing such a program.

Our microbiology division has been working and will continue to work closely with agricultural research service scientists to develop and transfer the technology as part of a complete methodology suitable for a high throughput regulatory testing environment.

Now, a key feature of our methodology is going to be that we'll be focusing on those top six serogroups, greatest public health concern, rather than attempting to detect all STECs in all of our

products, because many of them are not going to be pathogenic, and we feel that this approach is really most consistent with our primary public health mission.

So as I've said, the methodology is really still under development and validation phases, so some of the details are evolving, and I can really just share an outline with you at this point. But our general approach will be that we're going to be doing a two-step PCR screening on enrichment cultures, first looking at a combination of virulence factors that we see in -- that are associated with pathogenic STECs and then those that are positive by that initial screen will go on to receive a second PCR screen looking at the six specific serogroups.

Eventually, we will then be moving on to further isolate and characterize the organisms so that they are culturally confirmed, which we think would be necessary for any regulatory-type testing program.

So we recognize that the cultural confirmation part of the methodology development is

going to take the longest, but we do plan to implement the PCR-based testing while that development continues. We'll soon begin applying this two-step PCR screening protocol on all confirmed regulatory positives, positives for 0157. And in the next phase, we're going to be looking at those samples, regulatory samples that were negative for 0157. And it's important to know that during this period, which we are considering a study period, these results are going to be considered study results and not regulatory results.

So beyond the issues of developing methodology for the laboratory, there are certainly challenges associated with gathering and applying data on these organisms which are not currently defined as adulterants in a regulatory setting. And my colleague, Dr. Daniel Engeljohn, is going to join us on the podium now to discuss some of those challenges. Thank you.

DR. ENGELJOHN: Good morning. I represent the risk management part of the Agency, in terms of how we go about addressing risk with the products

that we regulate. And so from my perspective, I'll give you an overview about how we're going to go about addressing the issue of the non-0157 STECs.

I'm going to touch on in the next slide really five points which get at ensuring that we have the laboratory methodology issues resolved, that we're assessing the magnitude of the problem, that we're determining the circumstances in which non-0157 STECs could be considered an adulterant. We would then be informing our stakeholders about the FSIS determination that if, in fact, we determine them to be adulterants, how we would go forward with that. And then, finally, identifying an implementation plan for this particular policy.

And I would just say that having been with the Agency back when we initially identified 0157:H7 as an adulterant, we do find that it's critical that we have the infrastructure in place before we actually implement a program, which is not exactly what happened when we started the program with 0157:H7 in '94.

So with the laboratory methodology issue,

we'll be looking at the validation, and as Dr. Hagen identified, we're making sure that we have a validated method that can discern the non-0157 STECs that we have selected, in this case the six that was mentioned, from those other 0157 STECs. And it's also important to note that because we're a regulatory agency and we deal both with not-ready-to-eat and ready-to-eat products, we also have to consider how we're going to go about addressing the ready-to-eat products as well and whether or not that methodology would be different.

In terms of assessing the magnitude, this really gets at helping us identify the sense of urgency that we need to move forward if, in fact, we're finding that there's a significant amount of these organisms in the products that we regulate and, frankly, that are getting through the system by just focusing on 0157:H7. So what our intention would be to do would be to craft a federal register document that would notify the public about when we intend to start analyzing samples.

In this case, it is our intention at this

time to use our regulatory testing program as the population of samples that we will be working from. And having said that, then, the Agency's intention would be to first start with those samples that are confirmed positive for 0157:H7 and then focus on identifying in those samples whether or not there are the six selected non-0157 present in those samples.

In this particular case, the Agency's expectation would be that the industry would hold that production -- product. As you know, we do not require that production locks when we collect regulatory samples for *E. coli* 0157:H7. It's our recommendation that establishments do so, and it's also the reason why we have product recalls, which occur when we find a positive in a sample from product that's released into commerce.

The Agency has made known to the regulated industry as well that we are pursuing a rule-making that would make it mandatory that product would be held when we pull regulatory samples, but that would not be a process in place at the time that we begin this study program.

With those samples that screen negative for 0157:H7, then the Agency will be saving those samples and we'll also be conducting an analysis on them and looking for the selected non-0157:H7s, but not as the priority. Again, these are the regulatory samples that the Agency pulls, and we will be focusing on looking for the 0157:H7 first, and then after that, we would be focusing on a process by which we would be looking for the non-0157 STECs in those that do not confirm positive.

In this case, we would -- we're not making the recommendation that the industry hold this product although this may be a prudent response by the establishment themselves. It is our intention to report back to the establishment, as quickly as we have any results, the findings that we have.

Our intention, then, would be to assess this data over a limited period of time. Again, the issue here for the Agency is to have infrastructure in place to be able to implement a regulatory program should we move in that direction. And it's important for us to know what the magnitude of the problem is.

And so from this we will identify what the likelihood of presence of the selected non-0157 STECs are in the samples that we collect and then make some determination about how quickly we could or should move forward.

Then we would identify the circumstances for what would constitute adulteration. In this case, the conditions for which the selected non-0157 STECs are present are presumed to be the same conditions for which 0157:H7 is present, meaning during the slaughter dressing practice is probably the most likely place where contamination occurs. And then throughout the rest of the process, it's distributed in the products that are handled thereafter.

Based on the evidence that we developed on this testing as well as any other evidence that might be presented to the Agency, we would consider that and make some determination as to whether or not from a public health protection perspective we should broaden the aspect and go forward with a broader interpretation whereby we would and could include the

non-0157 STECs in our determination of what, in fact, would be adulterated. This, too, would then lead us to have to define which products or processes would be applicable to any determination and at what points the Agency likely would begin a testing program in order to verify whether or not this particular hazard is being controlled.

Then we would, again, issue a federal registered document that would inform our stakeholders about the information that we have gathered about the decisions that we have come to conclusion on whether or not we're going to declare the non-0157 STECs as adulterants and the conditions under which we would make that determination.

And then, finally, we would set forward an implementation plan. It's important that all stakeholders know when we're going to begin this program so that, in fact, all the conditions can be set such that control can be actually applied by the industry. And this is also important from a domestic and from an international perspective, because we would not treat international product coming into the

country any differently than that from which is produced domestically.

So if we then decide that we would go forward with an adulteration policy, we would need to identify a date that we would begin this. We would have training outreach education in place for our own employees, as well as for stakeholders involved and, importantly, identify very clearly when and how we are going to go forward, and then the Agency would move upon that. Thank you.

DR. GOLDMAN: Thank you very much to Drs. Hagan and Engeljohn. We are now going to invite two, the two last speakers for this session up to the podium, and we'll have all the speakers available for questions, but we just don't have room up here for all of them at one time.

But, next, we'd like to invite Dr. Mansour Samadpour to join us. Dr. Samadpour is a microbiologist and a molecular epidemiologist who previously was on faculty at the University of Washington School of Public Health, which is my alma mater. And he recently in the past few years

established a company called the Institute for Environmental Health. And he has in that capacity been involved in quite a number of outbreaks and recall events as well as with a considerable amount of testing on beef products for the presence of 0157 and perhaps even for some of the non-0157 STECs as well. So please welcome Dr. Samadpour to give us his presentation.

DR. SAMADPOUR: Thank you. Next. We had a really bad year -- *E. coli* 0157. Everyone in the room knows how we struggled last year. We are hoping that that was an anomaly. We have yet to see the new results to indicate if we are going to have another 2007. I think going through the experience has kind of like forced some of us to rethink what we have been doing, come up with some new solutions, and a different way of looking at eliminating this bacteria from the food chain. The non-0157 has been underemphasized -- and that's one of the purpose of this meeting, and the issue or presence of *E. coli* 0157 on sub-primals and primals. I will be addressing all the issues but the last one during the

presentation. Next.

I want to briefly describe how we reacted to this increase in the numbers of the *E. coli* 0157. After that, we're going to briefly talk about the non-0157 issues. And during the course of last several years working in this industry and working at FSIS, I have identified some points that I think we need to discuss and get clearances from the Agency and maybe even some re-thinking on the Agency positions. Next.

Again, 2007, we had tremendous increase in numbers of *E. coli* 0157. There are many, many theories as to why this happened. I don't believe that there are consensus on the issue.

Public get exposed to the organism through ground beef. If this level of -- sustain itself, we probably need more interventions and firewalls between slaughter operations and grinders.

The way we tried to address this issue was we had been using statistical process control on the basis of pathogen data. The way we screen these samples for presence of *E. coli* 0157 is slightly

different than other groups. We use seven different targets, and these are various virulence factors associated with *E. coli* 0157 and non-0157 STECs. We also simultaneously look at *Salmonella*.

Now, having all these signals and looking at the trim has allowed us to design or implement statistical process control charts and use it as an early warning system that the process is giving us the control. We have to put pressure on the plan to go back to assert control.

The next thing was that we wanted to make sure that nothing escapes us as much as possible, statistically possible, and the way we approached that was we came up with a pilot program in which we switched one of our major clients to a single combo testing lot. We argued by reducing the lot size and increasing the sample size, we will be increasing the likelihood of identifying the pathogen if it is there. And we also increase the confidence in the negative results. Next.

During several of the establishments and plants, one thing that, you know, I always do, I

worry about plants that are not popping positives. So in one situation about two years ago, I had a plant that didn't have positives, just refused to have positives, regardless of how hard we are working, or looking. And after looking at all processes, then the next thing was, well, you know, if they give us this bag of sample coming to the lab, if *E. coli* 0157 is there, we'll detect it. If it's not there, we can't. So let's start auditing.

So we designed a process in which we for about 10 percent of all the samples that come to the lab, we count -- we do a piece count to see whether an equal at 60 is indeed an equal at 60 or we are getting 20 pieces.

And later on, when faced with another situation, we further refine that, and we also in our audits, we see whether how -- what percentage of these internal pieces versus external pieces. It's not sufficient to collect surface samples. If you get a sterile muscle and take a surface sample from that, now we have to send this piece of sterile tissue to the lab, and we are not going to find

anything in it. Next.

This is not the way we audited. We actually transferred them aseptically from one bag to another one, but this is what, you know, usually comes to a lab, a number pieces of meat. Next.

In this situation, the blue dots represent the piece count. On the left, you have lines representing how many. And when we started doing the piece count for this particular plant, although the program was an equal 60, they were hovering somewhere around 30. Once we had sufficient data, few days worth of data, we communicated that with the plant and the corporate, and instantly it jumped to an equal at 60. So those are the blue dots.

Now we look at the pinkish or the reddish dots, those are internal versus external pieces. So we were struggling with this plant at the time, still, you know, pushing them to collect more external pieces. Next.

This is another establishment that was doing it correct from the beginning. We -- equal 60 and they were all external pieces. Next.

Another situation, you see that internal versus external is scattered. Another kind of drastic example of -- they were collecting 20 to 30 pieces, so 60 was actually 20 to 30. And then after it was communicated with the company, it just corrected itself. Next.

In March, January, February, March, that's when they pushed to an equal 60, the statistical process control contract moved up in response to now, you know, sending us more samples, because that's how we are sensing whether they are in control of the process. The weather got hotter during June, July, you know? You see that preaudited they go out of control. Red dots are number for 0157 positives that they were having. So it all comes together that the more you collect, you do proper sampling, and, you know, monitoring, you have tons of data that you can use to improve the process. Next.

So after sampling issues, the next thing was how can we find 0157 if it is there? How can we increase the likelihood? Now, one thing that no one wants to discuss openly is that we all use IC-MSF

statistics to justify or say that a five-person contamination or -- rate an equal of 60 will deliver 95 percent, we have 95 percent confidence.

There are no bases for those statistics in beef or in leafy greens. We cannot apply those statistics. We just have to intuitively look and design sampling plans for the time being. We may be using the statistics for the convenience of communication and we have to -- empirical data and then go back and do modeling.

In this particular situation, what we decided to do was to go from an equal at 60 from five combos to an equal at 60, meaning 60 samples taken from a single combo. Next.

This is emphasized as definition of robust sampling for trim. Takes 60 samples, 375 gram, 12 thin slices from each combo, try to take surface samples. Next.

This is the type of samples that it generates. But every combo, remember, we are taking only 12 samples. So 75 grams out of 2,000 pounds is the representation we are getting for a single combo.

Next.

The main point was that if we are going to go to an equal at 60 single combo testing, one of the major impediments would have been sampling. This device was developed by the government of Australia for sampling. That was brought in and was validated, and this is what we use for single combo testing. Next. Next.

Small plugs are taken, and they're deposited in sampling bag. Next.

This is the way samples look if you take a minimum of 60 samples from each combo. These are independent samples. Next.

Now, this is the real proof of whether system is working or not. This particular client was using an equal of 60, extension samples, five combos, and we are comparing 2006 data to 2007. At this point, in 2007, we switched them to single combo. So compared to 2006, you see, yeah, we're increasing number of positives. Month-by-month is increasing. If you look at November, we didn't have any positives in 2006. In 2007, they're having about 200

positives.

So the data clearly shows that by having to -- by going to this system, we are finding a lot more positives than before. And now we're amending the data for the months, early months, in 2007, when we did not -- were not using a single combo testing. And in January, we are comparing 2006, 7, and 8, February and March. So even in those months, we are finding more.

So, to us, this is really good proof that this system is working and that's one way of reducing the risk to the public, by doing more intensive sampling. Next.

Now, one of the issues, again -- you know, public gets exposed to 0157 through ground beef. One of the things that has really puzzled me is this directive or this notice by FSIS, the way they define ground beef sampling. It just defies logic. We just cannot have a situation where we don't have equivalency of -- you know, we can't tell people go ahead, for trim, you are limited -- you know, your lot cannot be more than five combos, 10,000 pounds,

and then for ground beef, where most of -- you know, this is where the exposure is. They're telling them, go ahead, define your lot. It can be entirely -- production, and, at the end, test 65 grams. That really needs to be considered. Next.

Those are the rest of the elements of that notice. Now, if an establishment is doing, as an example, 150,000 pounds, one day of production, one lot, clean up to clean up, and they decide to do one sampling. Well -- next. And you compare that to the same thing that someone who is testing trim is doing, for trim, it is going to be if you are doing five combo testing, 15 analytical units. If they are doing single combo, 75 analytical units. They'll be taking 60 samples for each analytical unit. So this is 900 to 4,500 pieces for the same amount of meat. They will be testing 5,625 grams of this product -- it is trim testing for *E. coli* 0157 -- versus 65 grams.

So, again, these are some of the issues that you have to consider and also consider the tremendous delusion factor that we have in ground

beef. Ground beef testing is not the best way to find *E. coli* 0157. Trim testing beats ground beef every single time, no matter what sets of data we look at. Next.

We have been talking -- have been giving lectures to leafy green -- up to 2007 the success that we've had in the beef industry. The beef industry had tremendous success in controlling *E. coli* 0157. And this is the data that previously was shown. This is FSIS ground beef testing data. And, as you see, in 2002 versus 2003 there was a drop, and that drop was maintained. That drop is attributed to the fact that in 2003, the trim that was destined to become ground beef was tested. So this drop is because this is secondary testing. This is not primary testing of ground beef.

This also shows that in the testing programs that we have, statistically, we know that, but this is, you know, this documents the fact that there is a certain percentage of positives that run under the radar. They cannot be detected. It's not usually because of the method that we use. It's

because of the sampling. We need better sampling. Next.

We've got to talk about the statistical process control. I briefly mentioned that because we use several signals for every test. And we look at a sample after enrichment. We think this is a very effective way of monitoring the process. Next. Next slide.

Now, the difference between using generic *E. coli* and the pathogen data for statistical process control is that when you look at sets of data for generic *E. coli*, they are most zeros. You cannot go toward your process if 98 percent of your samples are zero. In this situation, because we go through enrichment, we increase them tremendously in numbers, and then we use PCR to detect the signals, and we are using the virulence factors. We are using STECs, EHECs, *E. coli*, and *Salmonella* signals to control the process. Next.

We have been doing it for carcass, for tree, for ground beef, and for environmental samples. And we view carcass indexing as an early-warning

system. So by the middle of the chill process, we have the data that there was issue and loss of control, partial loss of control during the process. That can allow us to implement more control measures as carcasses enter fabrication. Next.

These are the type of -- go back one. Go forward. These are the type of data that -- daily basis. Every day we chart. This is comparison of establishment's performance. There are several within the same group. And we also do trending on monthly basis. Next.

Now, every day we count the number of signals that we see, total number of signals in the establishment samples, and we have this formula translated to a point. And this is very high. This is where we want it to be, in this area. At that point, they have control over the -- they have full control over the process. Above red, we are going to call positives. But this is a situation where working with the plant, they being aware of the fact that they were -- they did not have process -- control of their process, they were pushing it down

considerably. So it is possible once you have these types of indexes to react to them and push the process down. Next.

We keep track of the two shifts. We have shift A and shift B, and if you look at the process control, this is shift A and that's shift B, same day of production. In this case, the plant has to take a different action. They know that they were having a problem in one of their shifts. And in this situation, it's going to be lack of supervision.

Then we have situations where both shifts trend up together. At that point, we know that there may be a mechanical problem, one of the interventions, maybe hot water pasteurization is not working, sprays are not working properly. So there are some indexes that we use to draw different conclusions. Next.

This is when we first implemented this system in 2004, and this was one of our earliest charts. We talked to the establishment. We told them this is what you are going to get. This is what it means. If it trends up, we are going to be in

trouble. We don't have control. For five days, we were sending them e-mails that the process is not in control. They popped 17 positives. And after that, then they started paying a lot of attention to this. Next.

This is another example of two shifts not performing the same in the same plant and two shifts going up together. Again, supervision issues and mechanical issues. Next.

Another example of divergence between the two shifts. Next.

Now, we always talk about the contamination being surface-borne. We keep track of different types of trim that we receive and we analyze. This is data for low, lean content trim. So those are fatty kind of -- 50 percent, 65 percent trim. And here are the lean. And most of the signals come from the 50 percent, 65 percent-type excess fat trim. So this is a good example of how it's, you know, surface contamination. Next.

This is carcass indexes and how they correlate to trim indexes. Carcass was trending up.

Trim was going up. They had a positive here. Another situation they had a positive. Next.

This is the good news. Once we use this in a plant, these were -- this is two years' worth of data and how their signals have come down, how they have controlled the process. So if you are working with them, giving them this data on a daily basis and they pay attention to you, it's possible to control the process. Next.

Keeping track of different types of trim that we receive and assigning a risk-based index to them, most of our risk comes from excess-fat trim. This is about 20 percent lean, 80 percent fat. After that, you go 50 percent, 60 percent. So the more fat you have, the more likely you are going to have 0157. We do have some plants that don't have some of the -- they are not behaving properly and we have -- peak in one of these items. Next.

The issue of non-0157 STECs. And if you remember, if you notice I put EHECs and STECs. People don't seem to agree on terminology. So the first thing I want the Agency to do, please, before

you do anything, define this organism for us. What do you consider to be a pathogenic STEC? What are the virulence factors that *E. coli* should have to be considered to be a pathogenic STEC. If we don't do that, we are going to be in heaps of trouble.

Shiga toxin-producing *E. coli* can be found in beef supply, in any kind of food, any kind of fresh food, up to 20 percent, okay? So we just don't want to have false alarms, or we don't want to start regulating something that we can't measure. We definitely need a good regulatory definition, precise molecular level so we know what is a pathogenic STEC.

The other problem is we don't have an official method. So you are right. You -- develop one, and this is very good to have an FSIS method that everyone can use. There are no commercially available test kits, rapid screening test kits -- we need them for this industry. Next.

These are some of the serotypes that are intimin-negative. Most of them cannot cause any of this, cannot even cause simple diarrhea. Next.

These are the serotypes that are just as

bad as *E. coli* 0157. They can kill you. And the problem is that they don't look any different than any ordinary *E. coli*, and that has been our challenge in trying to find out. Next.

These are the ones that could cause diarrhea. They will not cause hemolytic uremic syndrome. So if we want to consider something an adulterant, it really has to be, you know, in the 0157 *Listeria*-type category, the ones that would cause -- could potentially kill someone. Again, it all goes in how we define this at a molecular level so, you know, we know what we are looking for. And this exemplifies some of the challenges that we have with this group of pathogens. Next.

These are my own personal conclusions. In the absence of an official method, I agree with you guys. You know, we don't have a method at this point you are going to be developing. At this point I don't believe that we can consider these things an adulterant. We just don't have the infrastructure to do that.

I think that FSIS has taken the right

approach in planning to conduct a baseline study dealing with the developing the methodologies and validating it. Once we have a gold standard, then I believe there will be a lot of commercial kits that can become available -- and one thing for everyone, as, you know, most of you know, is that the same things that control *E. coli* 0157 are going to be controlling the non-0157 STECs. So if you're controlling the process, you can keep them out of beef successfully in -- next.

Okay. This is a laundry list of some of the issues that I wanted to bring out. First one, four working days, guys. Why do we always have recalls and outbreak-related issues 4 p.m. on Fridays?

(Laughter.)

DR. SAMADPOUR: Please, start the moment you know there is something going on. You know, the slide show that are, like, on average -- David, you had, what, nine days from the time you guys are informed, okay? Add another 20 days that it took the public health system to get to you, okay?

The system is too slow. We are not really protecting the health of the public. By the time we are recalling, most of the stuff is gone. You're just counting the number of, you know, people who have become ill. The sooner you involve the industry, the sooner you talk, the sooner you communicate, and even the right -- you know, ask the right questions, you are going to be way ahead, and we are going to be way ahead.

In one recall conference call, I was -- then I ask for epidemiological data so I can go in and -- it and identify, you know, what we are talking about. What should we recall. Was just blatantly told, that has nothing to do with epidemiology. We need precise data. We need to know where we have the patients, when they got sick, all the information, establishment -- that information to be able to define the extent of contamination, to just have a single recall, not go through rolling recalls. Okay.

Some of the things that we ask the industry to do just don't make sense. Every single time we have a positive 0157, the establishment is asked to

reassess. We have epidemiologists here. If someone forced you for every single sporadic case in a community to identify a source, can you do that? It's impossible. Give me three positives, five positives, ten positives in establishment, I can tell you probably where they came from. Give me one positive, there is no need to reassess the -- these are unforeseen events. These things just happen. So but the point is, when we ask them to do something that doesn't make sense, they're not going to take the whole thing seriously anymore. Okay.

I have been often asked on behalf of the industry to provide statistical justification. If I'm saying, okay, got to do this -- show us the statistics. Now, I want to emphasize to do the same thing. How would we justify when we ask people do modification by quarterly samples? Where is the statistics behind that? What is it going to do? Especially forcing it on very small establishments that don't have the means even to do something like that.

The last point is you guys also need to

start talking to each other. The equivalency program that we have for other countries is not -- equivalence. It's very simple. If we are asking a establishment in this country to define lot of trim as no more than 10,000 pounds, can we go to another country and say your entire day of production can be one lot and then get containers that have five days of production with one certificate of analysis. And if you have a positive or if it results in an outbreak, we are going to have recalls that would make the top recall look like a joke. So we really need to kind of like -- to adhere to same principles and applied uniformity. Next.

This has been a pet peeve for a lot of people. Some of the worst cross-contamination situations that I have seen happens by FSIS inspectors or in-plant personnel. We need to provide uniformed training. There is no excuse for having a knife into every organ, one after another on a gut table and not sanitizing it; no excuse for going from the live side to fab without changing.

These are some of the issues that have

been, you know, people have been talking about it, but let's bring them up. Actually, you know, we are going to have -- we have a level of cross-contamination that can be due to that.

We consider your hazard matrices. We have a situation that, you know, say, okay, if it has the highest volume, that's where I'm going to concentrate on that. Some of the low volume items, some of the variety meat are more -- than anything I've seen. I mean, they're smoking hot with regards to 0157. So we consider that. See -- look at the process and see where we can -- where we have products most likely to be contaminated as -- rather than the volume.

Don't punish plants that are looking for -- and are finding it. Worry about the ones that don't have any. Simple. If we look, if we look hard, we are going to find it. Our intent is to find it and control the product, not send the contaminated product to the market. That's what we want to do. Don't take punitive actions for those plants. If someone doesn't have any positives, start paying attention.

Provide guidance when guidance is due. I still don't have a regulatory definition for *E. coli* 0157. It can be defined in so many ways, it's not even funny. But we really badly need a molecular definition: *E. coli* 0157, the adulterant, should have these virulence factors. If it's a non-pathogenic *E. coli* 0157:H7, how am I supposed to eject the load? If it's a pathogenic 0157-H-, am I supposed to release the load to the market?

Again, clearance -- two more points. I'll be off.

(Laughter.)

DR. SAMADPOUR: You have some guidance but I have --

UNIDENTIFIED SPEAKER: I think you said enough.

(Laughter.)

DR. SAMADPOUR: An attorney with a heart.

(Laughter.)

DR. SAMADPOUR: I know what to do when I have one positive. I know what to do when I have two, three, four, five positives. When I have 20

percent positive, 15 percent positive, you know, I usually spend a whole day to -- there's a gray area, 8 percent, 9 percent, 10 percent, 12 percent. You need to define that. You need to define that for small establishments, medium-size establishments, and large establishments. Have in mind that small establishment may have four samples a day. So having one positive is 25 percent. That's why you separate them. Next.

For God's sake, do something about this one. The so-called third-party audit has become more of a joke. I have not seen any recall situations, any plant that has been in trouble that doesn't have several of these things with 96+ scores, okay? We need uniformity. If a company is not a certification body, they have no business doing auditing. So let's tighten that. It has become a deterrent. We have plants that are getting audited on a weekly basis. It actually deters from, you know, the attention of trying to -- process. Next.

We have put all the emphasis on the producers, on slaughter operations, to a point that

they're using every intervention possible in the market and they are using several that have no effectiveness and they're just using it for the psyche.

Grinders. They are the recipient of slaughter operations process failures. They have no control over their processes. They receive loads if it's a negative certificate of analysis, and then they have an outbreak. We need to do something. We need to help the grinding operations. Next. Next. Go ahead.

The process control that we have, all the interventions, they have a capacity. If we have cattle entering the process highly contaminated, it can exceed the capacity. That's why we have process failure. It's time to pay more attention to pre-harvest.

And last, not the least, we ask the processors to do all the interventions, all the testing, all the controls, and no one wants to pay for it. This is becoming a big issue, has been a big issue. The industry is hurting. Very few people are

actually in the black, and we keep asking them to do more. Retailers have failed to assign a premium to beef safety and actually pay for that. In the absence of retailers doing this, we may need some level of government legislation that would give the processors tax credit or incentive for food safety efforts.

DR. GOLDMAN: Thank you very much Dr. Samadpour.

Our last speaker for the morning session is Mr. Bill Marler, who is, as many of you know, an accomplished personal injury and products liability attorney. He began litigating foodborne illness cases back in 1993, when he represented one of the most severely injured survivors of the Jack-in-the-Box outbreak in the northwest. He travels several days per month speaking to food industry groups, fare associations, public health groups about foodborne illness litigation and the issues surrounding it, and he writes frequently on foodborne illness and has, I think, a blog on his website devoted to that.

He is a graduate of the Seattle University

School of Law and has recently become the law school's lawyer-in-residence. He received undergraduate degrees from Washington State University and was recently awarded Seattle/King County Bar Association's outstanding lawyer award for 2008. He was chosen by the attorneys in the State of Washington as a "super lawyer" and received an AV rating from Martindale-Hubble and is listed in the Bar Register of Preeminent Attorneys. And we are very pleased to have him join us today to talk to us about his experience in dealing with *E. coli* 0157:H7.

MR. MARLER: Does anybody want to stand up? You can stand up while I talk. Go ahead. Stretch. Can I have the next slide just while we're --

I don't know if anybody can read this. But I get a lot of e-mails, and some of them aren't that flattering, and I thought I'd read one that I got. I'm having a hard time reading this one myself. It was from a FDA food code instructor. And the comment was: "So where did they get that virus, lawyer? Of course, you will tell them it was a restaurant when, in fact, most infections of foodborne illness are

from the customers' own filthy homes. Yeah, that unfortunate fact doesn't suit the law profession, but I assure you, people like myself in hospitality and certification are doing our best to put people like you out of business; first and foremost for the customer's safety; secondly, because once it would be nice to take food out of a lawyer's mouth. Sort of ironic. You shut down restaurants. I shut down lawyers (laugh out loud). Have a bad, bad day, you parasite."

(Laughter.)

MR. MARLER: So, first of all, I want to thank FSIS for inviting me to address this esteemed group today. I'm impressed that the FSIS, CDC and industry are addressing many of the food safety challenges we are all facing today.

Your agenda is ambitious, including how to explore the challenges of addressing 0157:H7, including illness and recall trends, to discuss FSIS plans to being short-term testing of non-0157 Shiga toxin-producing *E. coli*, and probably one of the more controversial issues is to discuss evidence that may

support the determination that raw ground beef products such as primal cuts and box beef contaminated with *E. coli* 0157 are adulterated. This is ambitious, but it's very important.

I've been at this for a long time, some to this group's dismay. But in January of 2007, I wrote an op-ed commenting on something J. Patrick Boyle, the president and chief executive of the American Meat Institute had written to the New York Times, regarding an article that had been written called, "100 Years Later, the Food Industry is Still the Jungle."

Mr. Boyle wrote, "Since 1999, the incidents of 0157:H7 in ground beef samples tested by USDA had declined by 80 percent to a fraction of a percent, a level once thought impossible."

I agree with Mr. Boyle. *E. coli* illnesses, especially those tied to red meat consumption, were down, way down. A report in 2005 released by the CDC, in collaboration with the FDA and USDA showed important declines in foodborne illness due to common bacterial infections. From 1996 to 2004, the

incidence of 0157 decreased 42 percent.

Interestingly, we saw the same results in our law firm. From 1993, the Jack-in-the-Box outbreak, to 2002, ConAgra, 95 percent of the cases in our office were *E. coli* cases tied to red meat consumption. After 2002, we saw an enormous drop in clients and, most importantly, ill people nationwide. That's important. Recalls fell to nothing.

I agreed with Mr. Boyle despite the fact that since 1993 most of my clients had been sickened by tainted meat. In fact, between 1993 and 2002, I took over $250 million from the meat industry in verdicts and settlements, on behalf of my clients, mostly children, with kidney failure caused by consuming *E. coli* contaminated hamburger.

In February of 2007, just a few months after suing the spinach industry on behalf of people sick and then killed by eating *E. coli*-contaminated lettuce, I was surprisingly invited to Salinas, California to attend a spinach luncheon. I told the leafy green industry to follow the beef industry's example. However, within a few months, my words

began to haunt me, as reports of meat recalls, outbreaks, and illnesses started hitting the news. First, it was some sick little leaguers from Sonoma. Then some folks in a bar in Pennsylvania.

By June of 2007, it began to look and feel a lot like late springs and summers from 1993 to 2002, when hamburger recalls and *E. coli* illnesses were a large part of every summer, much like vacations and baseball season. Kids were getting sick, and my phone was ringing. An area of my practice that I thought was gone had pulsed back to life.

No sooner could I get my lawsuit ready against AFG in California then the now bankrupt Topps recalled 21 million pounds of meat, and a food giant, Cargill, another 2 million pounds. I was suddenly back in the beef business.

Speaking of Topps for a second, in late August and early September of last year, a teenager, who is now my client, became ill after consuming frozen boxed preformed patties. Within days, she suffered HUS. Florida health officials would

eventually link her illness by PFGE to leftover Topps product in the family's freezer. But the recall was not called for weeks later after several other people consumed and became ill with that tainted hamburger. Why? Because FSIS and the industry had an understanding that a recall was not necessary because the only -- there was only one illness and the leftover hamburger came from an open packet.

Interestingly, that was the same set of facts that occurred with Topps in 2005 when a product nearly killed an upstate New York 10-year old. I am pleased that the open box of meat understanding is no longer the rule. One wonders if a recall in 2005 would have alerted Topps to issues in its plant foreign suppliers. One wonders if a recall earlier in September of '07 would have saved both the company and several ill people.

But, of course, I fear the downturn from 2002 and 2006 was not -- was too good to be true. Over the last several months, *E. coli* has certainly returned, and there is only one person in this room who benefits from that. The last half of 2007 showed

a substantial increase in the volume of recalls and illnesses in any year since 2002.

We've seen those statistics, but I'm just -- by way of comparison, 156,000 pounds of meat recalled in eight recalls; 2007, over 30 million pounds of meat was recalled in 21 recalls. Well over 100 people sickened, some developing acute kidney failure. Most have contacted me. There are several *E. coli*-related deaths that may eventually link to hamburgers. Lawsuits have been commenced on behalf of victims of HUS against Interstate Meats, Nebraska Beef, United Food Group, Topps, Cargill, Fresno Meat, and Rochester Meats.

There as many theories as to why the uptake in *E. coli* exists as there are authorities, researchers, meat packers, and at least one trial lawyer. Over the past couple of months, I've talked to them and theories abound. And I think Mansour did a great job of not only stealing a little bit of my time by sort of laying out what the theories are, so I won't go over those except to say that I think there is still -- I still believe that there is a lot

of work to be done to try to figure out why we saw this uptake in '07. I think that's important to sort of get our hands on, and I commend the FSIS for doing exactly that.

One other issue facing not only the meat industry, but all of us, is the extent to which non-0157 *E. coli* may be present in food products FSIS-regulated or not. It is clear that non-0157 Shiga toxin-producing *E. coli*s have emerged as a public health issue. Some non-0157s possess the same range of virulence factors as 0157 and are capable of causing serious illness or death. Numerous serotypes, including all that have been mentioned today, have been identified as a foodborne illness risk diseases. I've seen their nasty work, not only in the Dole spinach outbreak, but also in an outbreak involving a Wendy's in Utah.

Since 1990, 13 outbreaks of 0157 *E. coli* have been reported in the U.S., Fortunately, so far, none from me. While 0157 is a principal isolate here in the United States, isolates of non-0157 Shiga toxin predominate in other countries, including

several of our beef trading partners like Australia, Brazil, and Canada.

I will leave all of this to the scientists and the public health officials to sort out. However, perhaps one needs to look no further than the Federal Meat Inspection Act and look at the term adulterated for an answer. That act reads, "A product is adulterated if it bears or contains a poisonous or deleterious substance which may render it injurious to the health."

If non-0157 *E. coli* fits the bill, then, to me, that answers the question. However, not to raise a whole bunch of other issues, well, what do you do with *Salmonella*, *Listeria*, *Campylobacter*, and *Shigella*, especially those with particular virulence and antibiotic resistance.

One thing to remember. Whether a product is considered to be an adulterant under the FMI or not, if a food product contains a bacteria or a virus that sickens or kills, civil liability can and often will attach. My vote is to simply get pathogens out of your product.

This leads me to the final and likely most controversial issue facing this room today. Should primal cuts and boxed beef contaminated with 0157 or, for that matter, any pathogen, be considered adulterated? This is both a complicated and a simple issue, one that we have seen -- had some experience in this room first-hand with the now infamous Kriefall versus Sizzler -- case.

In part, that case was fought over the desire of the meat industry to hide from liability on behalf of the victims of the contaminated product. But more to the point, an appellate court decided that an intact cut of meat is, in fact, adulterated if it is contaminated with 0157:H7 and the seller knew it was to be further processed, and in that instance needle tenderized in the restaurant.

A little more history. That non-intact/intact distinction was first introduced in 1999 FSIS policy statement that the meat industry had long pushed as a way of deeming 0157 an adulterant only in ground beef and other non-intact meat not further processed in a federally-inspected facility.

This was only a policy statement but has since been treated as if it was the rule.

This was further elaborated on in an FSIS -- in an October 2002 policy statement issued in response to the ConAgra outbreak and recall. Notably, what was never clarified was whether this rule was really meant to apply to meat that was intact when it left the plant or, instead, meat that only reached the consumer as intact. As such, the meaning of further processing was never explicitly said to apply to processing that happened in retail.

Meanwhile, the meat industry has consistently operated under the assumption that 0157 can only -- can be on anything that is intact when it leaves the meat plant. Indeed, in the last several years, meat processors have started using disclaimer statements to introduce meat that is possibly contaminated with 0157 into commerce.

There should be either zero tolerance or not, but as it currently exists, the non-intact meat rule is the exception that swallowed the rule. It is a loophole you could drive a caravan of trucks

through. This issue needs to be resolved. Purchasers, retailers, and consumers need to know the score. We should not allow a tragedy as the one that killed Carolyn Hawkinson and sickened members of a church and patrons of a restaurant in upstate Minnesota to occur again.

Perhaps the facts of this case show the problems of this intact/non-intact meat issue. It began in the summer of 2006 in the small town of Longville, Minnesota. A local grocery store, Tabaca's (ph.) received in late June of 2006 another shipment of chuck roll, this time 1,900 pounds, from its supplier middle man, a company named Interstate. The chuck rolls, as usual, were ground into hamburger. The church bought 40 pounds of the hamburger.

The chuck rolls originated from Nebraska Beef, produced in mid-June. About the same time those chuck rolls were produced, Nebraska Beef -- FSIS found an 0157 positive sample in trim, a positive that would eventually link by PFGE Nebraska Beef to the ill-fated church picnic. That trim was

either destroyed or sent to further processing.

The chuck rolls were shipped, but this time the invoice was labeled, "Non-ground beef items are not intended for ground beef." From the invoices we've seen from this litigation, this was the very first time this warning had been placed on any invoice at any time where chuck rolls were sold. Hmm. To borrow a well-used phrase in this town, it's going to be interesting to know -- for them to know when they knew it and why they knew it. Nebraska's Beef to all of it -- response to all of this? They've sued the church. FSIS response to this? We withheld the name of Nebraska Beef from the Minnesota Department of Health. We got the information, obviously, through the litigation.

In conclusion, not too long ago, I wondered if the beef industry had actually wisened up and was about to put me out of business of representing people they made sick. After a decade of nearly continuous outbreaks of deadly 0157:H7, from Jack-in-the-Box to ConAgra, the beef industry suddenly did clean up its act. That would have been good news for

all Americans, especially young children who are most vulnerable to foodborne illness. It would also have been good news for the beef industry. And, believe it or not, it would have been good news to a lawyer who would prefer never having to see another three-year old child hooked up to a kidney dialysis machine.

DR. GOLDMAN: Thank you very much, Mr. Marler for that interesting discussion. At this point, we are a few minutes behind. I want to invite the morning's presenters up. We now are at the point where we have allotted 30 minutes for your questions. Remember we do have people on the phone, so we'll include them as well. So we'd like for Mr. Marler to stay up here.

MR. MARLER: Oh.

DR. GOLDMAN: If you will, and Drs. Tauxe, Hagen, and Engeljohn to join us here. And as a reminder, please come to the two microphones we have in the room or else, when you're on the phone, identify yourselves by name and as well by your affiliation. And for these comments and questions,

if, of course, you have a particular question for one of our presenters, please, direct it to that person. But we'll be sure to include time for discussion by other of the panelists as well.

Okay. Let's start with in the room. Felicia. Go ahead.

MS. NESTOR: Hi, Felicia Nestor from Food and Water Watch. I'll save all my appreciative comments for the comment period because I know this is short here.

Dr. Goldman, I was happy that you talked about the trace-back in terms of epidemiological cases, but I really wish that the Agency had had a whole section or at least a presentation on trace-back when there is no illness. According to my calculations, there are about 933 times the amount of product that was recalled after people got sick as there was after there was an FSIS testing. That's almost 1,000 times more product after people got sick.

Now, I think it's terrific we're using epidemiology to recall, but I think that the Agency

should be more proactive in response to its positives. Looking at the Agency's trace-back samples, the trace-back samples are all -- the number of plants that have been traced back, according to FSIS' data, has always been less than the number of positives. So that means in a number of cases, you're not taking trace-back samples when there's a positive.

And, Dr. Goldman, in your presentation, you talked about, what was it, 10 of the 11 plants were small I think?

DR. GOLDMAN: Yes.

MS. NESTOR: And I was just wondering, you didn't mention how many of those were those that slaughtered, those that slaughtered and processed other grind -- other products, and those that only processed. Looking at the recall data, it looks to me that it's generally about 50 percent of the plants that only process that are subject to a recall, which means in 50 percent of the cases, you're not getting back to the slaughter plant.

Dr. Samadpour -- and I hope I'm pronouncing

that correctly -- you put up the slide with the number of FSIS tests and showed the dramatic drop between 2002 to 2003 through 2006, and I'm just wondering whether you controlled for the fact that prior to 2003, the Agency was processing all of the samples that it took, whereas in 2003, it was only processing samples that had been pretested or that many of the -- yeah. It would not process a sample that had been pretested by the industry and had flunked the test. So, basically, in 2003, the Agency started only testing the A students to find out how the educational system was working?

DR. SAMADPOUR: That was the point of that slide that I made, that everything that was tested in 2003 on has been -- had been tested once. The trim had been tested, so this is taken --

MS. NESTOR: Yeah, I mean, given that, I would -- it's unfortunate that we found any positives since it was only on the second --

DR. SAMADPOUR: It's not -- it's not unfortunate.

MS. NESTOR: -- on the second --

DR. SAMADPOUR: It's statistics. You cannot collect a sample that fully represents a lot.

MS. NESTOR: Well, that -- yeah.

DR. SAMADPOUR: That's the issue that I raised.

MS. NESTOR: Okay.

DR. GOLDMAN: Thank you. Excuse me. We're going to have to do one question per questioner --

MS. NESTOR: Uh-huh.

DR. GOLDMAN: -- at least. And then you can recycle from the back.

MS. NESTOR: Okay. Let me ask one more question, okay? Have you ever, have you ever correlated the N-60 per combo with purge sampling and compared that to purge sampling with N-60 for five combos? And that's my last question. Thank you.

DR. SAMADPOUR: I have not done that, but purge sampling is not practical. It has been mentioned several times. Some people believe that purge is more contaminated than the trim. But it's not practical. By the time we have purge is when -- dump the product in the grinder. Many of the types

of things that we use don't purge or don't purge in the short time that we have that we are taking our samples. So purge sampling is absolutely not practical.

DR. GOLDMAN: Dr. Raymond?

DR. RAYMOND: I just want to clarify that. That is not a statement from the USDA that purge sampling is not practical. It will come up for discussion this afternoon and it's something that we are looking at and considering, number one. Number two, for the record, Felicia, when you say 50 percent of the recalls were processing-only plants so therefore we didn't get back to the slaughter facility. Actually, twice that I know of and there may be more, but I know twice we did get back, did do the trace-back successfully, and that, then, results in another recall. So there was at least one -- two recalls -- and then there was the -- of beef up in Canada.

DR. GOLDMAN: Okay. Thank you. I'm going to alternate between the two microphones, and then we're going to add someone.

MR. KOOHMARAIE: I can speak loudly. I'm addressing --

DR. GOLDMAN: Oh, go ahead, and identify yourself and your affiliation, please.

MR. KOOHMARAIE: Mohammad Koohmaraie, USDA/ARS. Question for Dan. You are setting the test for --

DR. GOLDMAN: Come up to a microphone, yeah.

MR. KOOHMARAIE: All right.

DR. GOLDMAN: You can still alternate.

MR. KOOHMARAIE: Mohammad Koohmaraie, USDA/ARS. Question for Dan. As you are beginning to do a baseline for non-0157, you said correctly that if you find it to be a 0157:H7 positive, you will look for non-0157. And the second part is what bothered me. You said if the sample was negative, you will hold it, and then you will test it for non-0157? It's undoubtedly sooner or later you will find a positive, and what will you do in that case?

DR. ENGELJOHN: This is Engeljohn. To respond to that, the -- as I had on the slide, the

Agency's intention at this time is to gather the information that we're getting into negative samples. And at this time, it isn't our intention to recall that product or to pull it out of the marketplace although now is the time in which we're taking input on this issue and considering where we're going with this particular issue. But at this time, we're considering taking those samples and then analyzing them at a later period simply because we are analyzing our regulatory programs in the FSIS testing, and so it's a matter of how we prioritize that test.

MR. KOOHMARAIE: But sooner or later you're going to find a sample that's in the commerce that's positive for non-0157. Thanks.

MS. WARREN: Wendy Warren, Food Safety Net Services. My question is for Dr. Samadpour.

This is regarding the early detection or early warning system and directing it towards process control, which I completely agree with. The closer that we can get to the process and the faster we can get the feedback into the process loop, the better.

In fact, that's the major justification for microbiological testing is to have good feedback and drive process control and, ideally, process improvement.

However, the major key to having that early warning system is very much surrounding the performance criteria of the test methods that you're using to include the enrichment and detection process. Most importantly in my mind is what is the limit of detection? And I wondered if you might provide your opinion to the industry with regard to what that limit of detection should be?

DR. SAMADPOUR: Limit of detection, as stated in IC -- position should be somewhere around 1 CFU per 25 gram. If you want to further take this -- expand on that, you know, we had the previous FSIS method, which stated 1 in 25 gram. It was posted, or the document had the title and it was presented as 1 in 65 grams. The current method that emphasized the new enrichment that emphasized -- states that the limit of detection is .23 CFU gram in a 25-gram sample that equates to 5.785 CFU per 25 grams. There

is one company that took the 65 -- 1 CFU in 65 and put that on their specification, and that is another producer who is asking for 1 CFU in 375 grams. In short, the whole thing is a mess. But the regulatory guideline that we have right now, they emphasize -- stands at 5.75 CFU in 25 grams now.

MS. WARREN: And is that what you believe it should be at?

DR. SAMADPOUR: For a microbiologist, you can't really say it's 1 CFU, because if you -- 1 CFU, 70 percent, 80 percent, or maybe 60 percent of your samples do not receive anything. So, you know, all we can say, it is somewhere in 1 to 5 or 1 to 5 CFU in 25-gram sample has been established to be what people have been asking for, or regulators have been asking for. Whether we have to make it more sensitive, is it possible? Yes. Whether it's needed, I am not sure, because, I mean, I don't think that you're ever going to have only 1 live cell in -- on a piece of meat. You have to look at the source. The source is fecal material. These things are loaded. It's not there -- if it is there, usually,

it's large numbers.

So what we have right now I think is sufficient. Most of the measures that are available actually are more sensitive than the regulatory.

MS. WARREN: Thank you.

DR. GOLDMAN: Thank you. Let me check with our operator, see if we have any questions on the phone.

OPERATOR: -- no questions on the phone line.

DR. GOLDMAN: Okay. Thank you. So we'll go back.

MR. MAIER: Thank you. My name is Wolf Maier from the European Commission. I was very interested to hear once again how strongly results are affected by the methods you use and by the sampling methods you use. So I wonder -- I mean, we are all interested in -- best practices. And so I'm asking you whether you have any abilities right now to discuss these -- and sampling methods and analytical methods also in CODEX or in multi-lateral setting so that we can have, I don't know, possibly a

harmonized approach at least that people are aware of best practices and so we can adjust and learn from this data. I think this is very interesting.

DR. RAYMOND: Wolf, yes, we do intend to do this, and the fact is, I just was in Canada yesterday and the day before for the quadrilateral meeting with Australia, New Zealand, and Canada, and beef was one of -- top of the issues. And during that conversation, the quads, the four leaders, the four principals that were there, said our next step needs to get with the EU in D.C. and have a discussion there which will filter in a CODEX -- to get your commission on board with us.

MR. MAIER: Thank you.

DR. GOLDMAN: I would just add -- this is David Goldman. On the domestic front, we, the Agency, have asked our National Advisory Committee on Microbiological Criteria for Foods to help us with an approach to new methodologies to include sampling and testing methodologies. So that's an active sub-committee of -- underway right now.

MR. SMITH: Tom Smith. I'm a small-size

processor, and by looks of all the ties in here, the processors aren't too well represented today. Is this cutting in and out? At any rate, my compatriots here to the right and I represent HFX, and we don't know what it's like to have a sickened by *E. coli*, but we went through a recall last summer that was part of what's going on here, and so we know what hell was like.

I guess my comment is, Dr. Samadpour, I got some enjoyment out of your words because you cannot come in -- FSIS cannot come into a plant and rip the place apart by a positive testing. It provides disincentive for us to cooperate at all even though we know it's probably the right thing to do.

The other issue is, there is a pinch-point here, and we're in the middle of it. We get invoices from major packers that say, "This -- beef is not for trim." Well, on the other hand, we're receiving information, according to best practices, that you need to test more.

Two issues. If you're running a big meat packing plant, do you want to sell us beef knowing

that we're testing more than people down the street? That's a ridiculous dichotomy there. The other thing is, is the -- where am I at here? I do have a question here.

My number one -- the number one point is that we're willing to do what we need to do to help this situation, but putting us in a situation where we cannot win does nobody any good. And we're a small processor by numbers-wise, but there's a lot of us. And, you know, getting invoices that say we can't grind this product, I don't know where that leaves us. And, also, to tear apart our -- by one positive is a complete disincentive. So, you know, that really is a comment more than a question. I'll leave it at that.

DR. GOLDMAN: Thank you.

MS. BUCK: Did you want to check the phone lines again, see if anyone is --

DR. GOLDMAN: We'll go to you and then we'll check.

MS. BUCK: Okay.

DR. GOLDMAN: Thank you.

MS. BUCK: My name is Patricia Buck, and I'm with the Center for Foodborne Illness, Research, and Prevention. And Barbara Kowalcyk, if she were here, would have a lot of questions to ask about the discussion that was raised about the methods and the statistical information that has been already presented. And, hopefully, she'll get on the phone.

What I'm interested in as a consumer representative is I look out there into the sea of what we need to do, and I see we need trace-back, I see we need a better way of coming up with identifying what products or what processes cause contamination, but I also see a big gap in our public health systems and the way the states report to just the very basic information to CDC. And I was wondering if Dr. Tauxe could comment on what are the types of things that are needed to improve not only the capabilities of FoodNet and OutbreakNet and PulseNet, but also in getting a reporting system that will really allow the people to have greater access to your leadership at CDC?

DR. TAUXE: Thank you for the question. I

think our public health surveillance system in this -- multi-party process that involves counties and county health departments and states and state health departments, and it involves the national-level agencies, CDC and persons within the regulatory agencies as well.

And PulseNet was a tremendous -- in systematizing and standardizing collection of information about themselves and subtyping. I think it has driven an approach that's been really transformative. We're only part way there with coming -- with having similar levels of precise information-gathering and standardization on the epidemiological side. And that's a long-term process that involves a lot of different agencies and counties and states agreeing to collect more uniform information and to collect more information, which is something that they are not resourced to do.

I think that increasing the inter-comparability of the information collected from different counties or different states is the direction that public health surveillance is headed

in, and it's something we're very much only part way there.

MS. BUCK: Well, thank you very much. But I think, specifically, what I was interested in, right now, the way the situation is, the CDC has no authority if they suspect a outbreak to actually do the investigation unless the state requires it. Is there any way that we can get the CDC to act more swiftly either through FSIS regulation, FDA regulation, or somebody, so that when these things emerge you have the authority to help with the investigations.

DR. TAUXE: I think you're talking about the evaluation of clusters and PulseNet identifies clusters --

MS. BUCK: Um-hum. Yes.

DR. TAUXE: And the evaluation of them, again, begins right with the local or the state health department, wherever that cluster might be first identified. The first step is rapid communication with them. You're correct that authority for surveillance, notifiable disease

surveillance rests with the states, not with CDC, and CDC is a voluntary participant in surveillance activities. And that's the structure of surveillance --

MS. BUCK: Okay.

DR. TAUXE: It's voluntary, not mandatory.

MS. BUCK: All right. Okay. Thank you. Thank you very much.

DR. GOLDMAN: Thank you, Ms. Buck. Let me check with the operator again. Do we have any callers who have questions?

OPERATOR: We do have a question on the phone line. The question is from Barbara Kowalcyk. You may ask your question. And, please, state your organization.

MS. KOWALCYK: Hi, my name is Barbara Kowalcyk, and I'm with CFI. I just had a couple quick comments and one question. I'm going to save my question --

First of all, I'd like to commend the Agency --

DR. GOLDMAN: Barbara, Barbara. Excuse me.

MS. KOWALCYK: -- because I think it's a very good meeting, and I think it brings up some very important issues. My main question is, as we know that in the past there have been legal issues that have arisen when the Agency has tried to act -- take action against plants that failed to meet the *Salmonella* performance standards.

In declaring a 0157 an adulterant across the board, will the Agency have the legal authority to do that so that it can -- so that it will not face the challenges it did in both the Supreme Beef and Nebraska Beef cases.

DR. RAYMOND: Barbara, Dr. Raymond. First of all, I'm glad to hear you listened to your mother. She said you would call.

(Laughter.)

DR. RAYMOND: And we have researched it and do believe the legal authority, yes.

MS. KOWALCYK: Okay. Well, what exactly leads you to believe that you have the legal authority? I mean, I know that -- not that I don't believe you. It's just that it seems that in the

Salmonella case, the Agency probably thought that it had the legal authority to enforce the performance standards, but then the judicial system disagreed. And I'm just very concerned that if we go down this path, which I think is a very good on, that we don't get caught up in that type of situation again.

And, by the way, it's very, very difficult -- I don't know about others on the phone, but it's very difficult for me to hear anybody on the panel respond.

DR. RAYMOND: Okay. We'll try taking care of that last issue. The first question you raised, what makes me think we have a legal opinion is it's the attorneys that work for us that tell me we have the legal authority. And, you know, the attorneys -- or if someone else may have a differing opinion, and, as you know, with the *Salmonella* case, it's usually the courts that decides who's right and who's wrong, so all I can go with is the legal advice that I have today.

MS. KOWALCYK: Thank you.

DR. GOLDMAN: Okay.

OPERATOR: Again, if you have a question on the phone line, you can press star one.

DR. GOLDMAN: Do we have any more questions from the call-in participants?

(No response.)

DR. GOLDMAN: Okay.

MS. ROSENBAUM: Good morning. Can you hear me? I'm Donna Rosenbaum. I'm here from STOP, Safe Tables Our Priority, and my question is directed to any people on the panel who can answer regarding non-0157s, especially to Dr. Engeljohn and Dr. Hagen.

We tremendously appreciate the progress that's being made, starting with the October '07 on non-0157s and the framework that you've started to lay out for dealing with this as we move into the future. Although it doesn't quite have a time frame on it, it certainly has some steps that you've outlined. I have a comment and then a question on this.

The comment is that your seminar that started this process in October of '07 was good and put together a lot of important issues on non-0157s.

However, I've just come to realize in people that have approached our organization that approximately three weeks after that seminar was held, there was potentially an outbreak of 0111. And we have been in touch with a family that lost a 14-year old daughter due to 0111. And, unfortunately, all of this is coming too late to impact their situation.

But my point here is that sometimes you need to go ahead and take those bold steps to declare things as being suspect and wanting to -- them as adulterants is important to move the system in the direction of even investigating it in the first place, as we saw with 0157 15 years ago. This family didn't have proper attention to investigation because, potentially, perhaps, it's not yet an adulterant. So this happened and it didn't get investigated very well. We're trying to have a system a little bit. But I would like to not see that happen again.

So my question, therefore, is in the interim period we have now that you set out all these protocols and things that are going to happen with

non-0157s, what happens today and tomorrow if you start to get some phone calls, if anyone starts to get phone calls where there is a product that you regulate that is attached to a situation of clusters is a non-0157? What's going to happen?

DR. ENGELJOHN: This is Engeljohn. I'll start it, and then Elisabeth may join in as well. But I would say the Agency does have the authority to act on a case-by-case basis, and we do and have in the past. And it really does amount to what are the circumstances and can we define the product, can we identify which product needs to be removed from the marketplace, or, in fact, if we don't have that kind of information, do we issue a public health alert to get general information out to the public for handling. So I would say that the Agency does have the past practice and will continue to operate on a case-by-case basis with the epi information driving that.

In the meantime, on the issue of our targeted non-0157 approach, it really does matter that we have validate methods, and so that is the

approach that we're taking, is getting the validated methods, first of all, to find out if any of the six targeted ones are there and then, most importantly, which of the six, so that we would have that characteristic associated with each of those. And so from a regulatory perspective, the methodology matters, and that's what we will focus on. But, again, if we can tie product to a situation where there's illness, the Agency will act on that.

MS. ROSENBAUM: Can I clear up on that? You would act on that meaning that if perhaps one of the six that you're looking at were involved in a situation where you had a cluster of illnesses that tied to a product that you regulate, you would go ahead and initiate recall --

MS. HAGAN: We would act. I mean, that would be -- we would have to have definitive evidence that the illnesses were linked to the product, the particular lots of product that are identifiable through the system, and that would be -- dietary substance.

And I will tell you that shortly after I

started at the Agency, we did have a case of infection of 0103 in New York State, and we were very aggressive in investigating that and -- to taking action and, unfortunately, never had enough identifying information available with the product to allow us to trace it the whole way through the system.

MS. ROSENBAUM: Thank you. Like I said, sometimes the declaring it an adulterant moves -- we feel would move the system towards identifying even more -- first place because it puts it on the radar screen and it makes it something that somebody is actually looking for versus something they're perhaps not. Thank you.

DR. GOLDMAN: Okay. Thank you.

MS. WALLS: Yes, my name is Isabel Walls, and I'm with USDA's Foreign Agricultural Service. I just like to say I'm really glad that you're looking at the non-0157:H7 and that the six strains that you've chosen to start with is probably a very good way to go.

My question is for Rob Tauxe and possibly

Elisabeth Hagan. Elisabeth stated that she came from the clinical side of the house and that many clinical labs are not testing for 0157:H7 and maybe they don't even have the capability to do that perhaps. My concern is will we now start asking the clinical labs to test for non-0157? And what will be the impact of that, and what can CDC, FSIS, or any of us do to make sure that this -- you know, right now, the evidence suggests that most of the illnesses are from 0157:H7 and we may not be catching all of them. What can we do to improve things in the lab and make sure that the introduction in looking for non-0157 doesn't backfire in any way and certainly improves things?

DR. TAUXE: Well, that -- thank you, Elisabeth [sic]. This is Dr. Tauxe.

I should say that's been an area of great concern to us and great interest. The introduction of a Shiga toxin testing assay into the clinical laboratory system makes it possible to identify an infection that's likely to be Shiga toxin-related quicker, which is a benefit to the patient. And our concern has been if that toxin is the end of things,

if detecting the toxin is the end, then we would no longer know whether it was 0157 or something else and we would lose our PulseNet capacity.

So the critical step is to combine that new assay, which is increasingly used in some clinical laboratories and which might detect 0157 as well as the non-0157s in the screening fashion, to combine that with the effort to go ahead and isolate either *E. coli* 0157 or other non-0157 strains from that same specimen or that same sample.

We issued the first set of guidelines in consultation with a group from state health department laboratories and with the clinical lab diagnostics industry last fall and published those guidelines in the MMWR for how to approach this. And we just, in fact, last week had another meeting with that same group to update and revise those guidelines to really try to push forward the notion of expanding testing.

Now, what this turns out to mean is that a lot of detection happens at the clinical lab, and then the broth that was positive needs to get

referred to the state public health lab for further isolation and further characterization, which transfers some of the work from the clinical lab setting to the public health lab seating. And this is important, and it's well-recognized that this is a critical activity. Supporting it and making sure that our public health lab system has the resources to handle this is part of our -- part of the challenge.

DR. GOLDMAN: Let me just check once more on the phone if we have any questions. Questions from the phone?

OPERATOR: We do have several questions on the phone line. The first one is from Amy Smith. You may ask your question. Please state your organization.

MS. SMITH: This is Amy Smith with Dupont Qualicon. Dr. Engeljohn, this is for you. I hope I didn't miss it. We were cut off on the phone for a little bit. Is there a target time frame or a target number of -- for the -- non-0157 as possible adulterants?

MS. HAGAN: This is Elisabeth Hagan. I'll

actually go ahead and field that question. The question was do we have target time frames for our assessment of the non-0157 STEC issue. And, you know, we've been hesitant to give exact time frames because, as Dr. Samadpour so aptly pointed out, and as we've learned, there really aren't any methodologies out there right now that are easily transferable to our particular regulatory setting. These methodologies are being developed and validated in partnership with Agriculture Research Service and will then take some additional time to work out through our own laboratories. Once we know that they work, you know, how do we put them to work in our particular setting.

So what we really hope to have done is to have that initial PCR screen that I mentioned, which we'll be screening for STX and EAE, the gene for intimin, and have that up and running really within the next couple of months. And then, with any luck, have a secondary set of PCRs that look for these particular six serogroups, have them up within a few months after that. But we really can't commit to it

at this point because, you know, everything is still being worked out and we really appreciate the collaboration with our ARS partners who are trying to expedite this process as much as possible.

So that's, you know, where we really hope to start. It's going to be quite some time after that, and I can't give you a firm time frame, about how long we'll have our cultural confirmation methodology up and running.

DR. GOLDMAN: Okay. We'll take another question from the phone.

OPERATOR: Next question on the phone line -- Ilene Arnold, you may ask your question. Please state your organization -- your line is open. Please check your mute feature.

MS. ARNOLD: I'm sorry. That was not a question. I was just trying to report the problem.

OPERATOR: -- is showing no further questions.

DR. GOLDMAN: Okay. We'll come back into the room. Okay. We're going to take a few more questions before we get to the long-awaited break --

lunch period.

MR. STEVENS: Good morning. My name is Shawn Stevens from -- department at Gass, Weber, Mullins -- representing also meat -- food companies nationwide -- defense of foodborne illness -- so I guess I'd be Bill's counterpart.

Since we're going to be talking today and tomorrow about future treatment of 0157:H7 whole intact cuts, I thought it was important to stand up and address or at least respond to or maybe build on some of the points that Mr. Marler made.

First of all, my understanding, and I am very glad that this is the case, is that there really haven't been many illnesses ever associated with 0157:H7 in whole intact cuts, and that's a good thing.

With respect to some of the more publicized events, as Bill had talked about the Kriefall case in Wisconsin, I think it's also important to note, in that particular case, nobody had fallen ill from eating whole intact cuts containing 0157:H7. As a matter of fact, each of the people involved in that

outbreak had gotten sick from eating watermelon, and that watermelon had been recycled from day to day to day by the restaurant, something -- would have been a correspondence issue by the FSIS.

It still remains in question to this day whether that particular outbreak that was talked about earlier was really triggered from 0157 in a beef product or something else altogether.

With respect to the second example that Bill talked about, this case up in Minnesota, it does create some questions with respect to the current USDA policy as to what does further processing mean. If a whole intact cut containing 0157:H7 is intended for further processing, I think both the legal community and the industry needs some additional guidance. We have treated that as meaning that that particular product would need or require or be intended to be further processed at another USDA-regulated facility. Bill would make the argument that any further processing intended at the retail level would qualify. So additional guidance would be helpful in that regard as well. Thank you.

DR. GOLDMAN: Thank you.

MR. CUSTER: Carl Custer, non-affiliated, though I did once work for the microbiology labs of FSQS out at Beltsville.

Dr. Raymond, FSIS jurisdiction essentially starts at the anti-mortem pen, whereas the Animal/ Plant Health Inspection Service has wide and draconian jurisdiction over flocks, herds, and farms. What's the prospect of having Animal Plant Health Inspection service to begin addressing human pathogens on those farms and flocks?

DR. RAYMOND: We have no jurisdiction at FSIS on any animal on the farm.

MR. CUSTER: But the question is what's the prospect of having Animal/Plant Health Inspection Service begin to address human pathogens?

DR. RAYMOND: The Animal/Plant Health Inspection Service is not even in the room today, sir, so I would ask you to please address that question to that agency.

MR. CUSTER: Okay. By the way, Jill's been waiting here patiently.

DR. GOLDMAN: Okay. We have two more questions.

MS. HOLLINGSWORTH: Okay. Actually, mine is two questions, but they're two questions, no comment. Elisabeth, you said that since 1990, there were 23 outbreaks in the United States of non-0157 STECs and none of them were associated with meat. With that, it makes me think perhaps what we need to be looking at is working with CDC and other federal agencies on an overall public health strategy for these other pathogens. Do you know what some of these other products were if they were not meat?

DR. HAGEN: I don't have that list in front of me, but some that come to mind, I think there was ice -- I don't know if you remember --

UNIDENTIFIED MALE SPEAKER: Ice, lettuce --

DR. HAGEN: There was definitely some greens.

UNIDENTIFIED MALE SPEAKER: Milk, milk.

DR. HAGEN: There's a milk, yeah. I don't remember all the commodities, but that -- I have that data available for you. But, yeah, of course we

think we need to always be working with our federal partners for an overall strategy.

MS. HOLLINGSWORTH: All right, because I think it may go way beyond meat in this case. And my second quick question, in light of some of the other comments that were made and Mr. Marler's comments about products going to retail -- and, I'm sorry. I didn't identify myself. Jill Hollingsworth with the Food Marketing Institute.

With products that we see more and more going to retail that do, in fact, have information on them specifically saying this product should not be trimmed, this product is not for grinding, which sends kind of a questionable message when you receive a product into retail. Is FSIS aware that beef is being sent to retail with that kind of disclaimer on it, and what is your position on it?

DR. ENGELJOHN: This is Engeljohn. And I would say we, the Agency, have, in the past, issued instructions on what we view to be appropriate labeling-related instructional statements and disclaimer statements, which we viewed as being used

by the industry as trying to get out addressing the contaminate on the product. And so we have very restrictive requirements as to what can be labeled and how they have to be handled within a federal system.

For products that have labeling that says not for grinding -- I think you said not for grinding -- whatever --

MS. HOLLINGSWORTH: Not for trim, not for grinding.

DR. ENGELJOHN: Not for trim or grinding. I'm not immediately coming to mind, you know, where that was how product was labeled. I certainly know we don't have a guidance on that issue, and I would find that probably not to be acceptable to the Agency, but we'll certainly follow through on that one.

MS. HOLLINGSWORTH: Thank you.

DR. GOLDMAN: Thank you. And our last question in the room for this morning.

MR. PAINTER: Yes, my name is Stan Painter. I'm the chairman of the National Joint Council on

Food Inspection Locals. They represent the food inspectors in the field. An issue was brought up earlier today in one of the presentations about inspectors working on the line and not washing their knives and equipment. And, certainly, we support that.

But in the late 1980s, line speeds and slaughter operations were going approximately 185 carcasses per hour. Now they're allowed to go 390 per hour. You barely have time to look up. Of course, carpal tunnel and other things come into play with that. So, you know, it seems as though the speeds have increased and yet the Agency continues to want or to think that the cleanliness is going to be increased as well.

I've heard the Topps situation mentioned as well. I haven't heard anyone say anything about the slaughter facility that produced the product that went to Topps. It seems though Topps is taking the fall for what happened at the slaughter plant. The HACCP program apparently at the slaughter operations, whichever operation that may be, I have not gotten

the information yet as to which plant or plants the *E. coli* actually came from because it seems at this point no one knows. And the HACCP program at that location or locations did not work and the Agency needs to recognize that the HACCP location or locations did not work.

In the area that we're talking about, the northeast, the Agency is currently holding a 20 percent plus vacancy rate for inspectors. So if there's going to be more testing, who is going to be doing that testing? Who is going to be doing the verifying? We go out west to the Westland Hallmark situation. We're looking at a 10 plus percent vacancy rate there.

It was mentioned earlier about training, the training of the inspectors. We certainly support that. We're certainly trainable and well capable of doing the job, but once you train us, give us the ability to do the job. Give us the ability to use what you've trained us. We go to the FSRE training that's currently being given, and then we're told when something comes up -- my supervisor says so-and-

so that's contrary to the training. Then we're told then do what your supervisor says.

So in all of that, I need someone to address this situation with the training, someone to address the HACCP failures in the plants that produced the product for Topps, and the vacancy rate, as well as the line speeds.

MR. RAYMOND: If I might, for the record, one of the suppliers, at least, to Topps was called Rancher's Beef. That is a slaughter facility that's no longer producing. They're out of business. We do trace back every opportunity we can, and when we do trace back, we take further actions. As I mentioned in response to Felicia, there was another incident domestically where a slaughter facility was traced back to and then a no recall was put in place there.

As it was mentioned by someone earlier -- I believe Mr. Marler -- there was more -- and Dr. Tauxe, too -- there was more than one PFGE coming out of the Topps outbreak. We were not successful in tracing back to all the slaughter facilities. It was a large producer that bought the trim from a lot of

places. So that's in response to that.

In response to the comment that Hallmark may have happened because there's a 10 percent vacancy rate, that plant had no vacancies during the two years of that recall. That plant had five full-time positions that were filled. The vacancy rate overall did not affect that particular plant. And just so everybody in the room knows, our vacancy rate currently for our inspection service is somewhere between 7 and 8 percent overall nationally. We do have pockets where it's difficult to fill. A year ago, we were at about 13 percent. We have made good progress in decreasing our vacancy rates.

MR. PAINTER: You didn't address the fast line speeds, and I was saying that in correlation with what was mentioned about washing the knives or washing the tools and things of that nature, and the HACCP programs.

DR. RAYMOND: We will have an offline discussion about that cross-sanitation possibility that was described. I'm not familiar with what we require of our inspectors on that point, Stanley.

MR. PAINTER: I would ask you, Dr. Raymond, if you would, to check the statistics again on the vacancy rates, and I notice that you mention that the vacancy rate in the west, the less than 10 percent, and I'm going to take you at your word at this point, but you didn't address the 20 something percent vacancy rate in the northeast with the Topps recall.

DR. RAYMOND: All I can say is we have a very aggressive hiring program. We are trying to fill spots where they're difficult to fill. We have 184 more inspectors in the plants today than we did one year ago at this time overall nationally. There are pockets where we still have unacceptably high vacancy rates.

MR. PAINTER: The last issue that wasn't addressed, when we receive training and it's contrary to what our supervisors tell us to do and we're told then you do what your supervisor says, what do we do then?

DR. RAYMOND: Stanley, today we want to try to keep our conversations what we can do to reduce the *E. coli*s and policies we do want to talk about,

and, really, if you want to have discussions about the workforce, I do believe there are people who are much more knowledgeable than I that can discuss that with you.

MR. PAINTER: I understand that, Dr. Raymond, but it all goes hand in hand.

DR. RAYMOND: I'm not saying it doesn't. But --

MR. PAINTER: Okay. Thank you.

DR. RAYMOND: Yeah.

DR. GOLDMAN: Okay. Thank you.

MR. MARLER: David?

DR. GOLDMAN: Yes?

MR. MARLER: Just one -- I couldn't help but comment on Shawn's issue on the Sizzler outbreak, and I guess I get the end -- in the end the winner of that case gets to sort of have the last say, and since I won that case, I get the last say.

(Laughter.)

MR. MARLER: But I do think it has -- it's important that he raised that issue because there is some -- there is a legal discussion about whether or

not this intact tri-tip was the cause of the outbreak. But one of the things I think it really does underscore is something that Dr. Raymond said earlier is the risk of intact cuts of meat, and that's why you're seeing these odd little, you know, small print warning labels being put on them, that intact cuts of meat have the potential for cross-contamination of other products in a retail setting, whether by trim or grinding or if they happen to be on the same table that then you have the watermelon on.

So I think the fact that we're looking at that aspect of the trim, we're looking at intact cuts of meat, boxed meat, is a real important issue, and I think we can't, you know, stress enough how important the risk of cross-contamination is especially with 0157 having such a high virulence and, you know, a low infectious dose.

DR. GOLDMAN: Thank you.

MR. SMITH: Just very quickly. This'll take 15 seconds. Just another comment.

DR. GOLDMAN: Identify yourself, please.

MR. SMITH: And it specifically relates to--

DR. GOLDMAN: Mr. Smith, just identify yourself again.

MR. SMITH: I'm sorry, Tom Smith, processor. It refers to or it relates to the timing of test results, and so on. I find it interesting that on the sampling sheet when our inspector comes in to take a sample of ground beef that the establishment number where that particular primal came from or that particular box of meat that we're grinding, there is no place on that paper for the establishment number for where it came from. And I would think that if traceability is an issue and timing is an issue, wouldn't -- I mean, that, to me, seems like the most important piece of information that should be on that sheet. And as of two months ago, it was not.

DR. RAYMOND: Let me respond to that one, too, David. Mr. Smith, that is an area that our common friend that we both know very well is his, you know, his common march, and we are taking a look at it. We've done some surveys with some of the

associations and discussed with them. We don't have a position to change yet at this point in time, but it's another area of concern of mine to trace back, anything we can do to improve it and still be practical. Thank you for your comment on it, though.

DR. ENGELJOHN: This is Engeljohn. I need to follow up on Dr. Raymond's comment. We did change our policies this last year in that we did begin identifying with any positive sample that the FSIS gets, in terms of identifying who the supplier was to that production lot. And then that gets put into our positive supplier database for which the Agency has a process by which we either do 16-sample follow-ups in those operations, or if they've been listed twice in the last 120 days, they also are given an increased testing by FSIS; as well as any time there is a positive in an FSIS test program, there is always the trace-back into the suppliers to look at the O2 procedures and the HACCP plan for the supply and operations. So we do have some procedures in place. There are things that we could do to look at that to see if we can improve upon it, and we certainly are.

DR. GOLDMAN: Okay. Thank you. With that, I want you to pull out your agenda if you don't have it in front of you already. I'm going to excuse everyone for lunch now. You can eat your break with your lunch. Obviously, we ran over. So we will resume here at 1:00 with the presentation from Mr. Alvares. Thank you.

(Whereupon, a lunch break was taken.)

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

(1:04 p.m.)

DR. GOLDMAN: -- 0157:H7. You're going to hear from a number of Agency speakers on a variety of issues, as outlined in your agenda. And we're going to hear again from Dr. Engeljohn, actually, on two different topics in this particular session, so I won't reintroduce him.

But we're going to begin this session of three presentations with a presentation by Christopher Alvares, who is an analyst with our data analysis and integration group, which is the relatively newly formed group that right now sits in the Office of Food Defense and Emergency Response. In that capacity, he provides data analysis expertise in support of a variety of projects and programs.

And before he came to FSIS, he worked for Gene Logic, where he was a manager of data analysis services. He also previously worked in operations as the manager of Microarray QC, which is a company

name, and developed quality control metrics that are still being used today. Prior to Gene Logic, he worked for a company called Encore Med, a diagnostic testing lab, and he, along with others in that company, in 1998, were awarded a National Inventor of the Year Award for their work on sequencing of a breast cancer gene.

His bachelor's degree is in biology from Johns Hopkins, and he has a Master's in biotechnology from Johns Hopkins as well. And I'd like for you to welcome Mr. Alvarez who is going to talk to us about the beginnings of the analysis of the responses we got to the checklist, fondly known as 6507.

MR. ALVARES: Good afternoon. My name is Chris Alvares, and I'm, as mentioned, a data analyst with the Data Analysis and Integration Group. One of the projects I've been working on is this *E. coli* checklist and the reassessment that are part of Notice 6507. And I'm going to talk a bit today about the analysis that we've done to date. It's still a work in progress, so we have some findings that I have prepared today, but, certainly, additional work

needs to be done. Next slide.

So just to give you an outline, I'll talk a bit about the background and methodology behind the Notice and the associated checklist and reassessment. I'll talk a little bit about some of the results, including response rates to these -- both of these -- the checklist and reassessment, as well as some details around those and then talk -- and finish up a little bit with next steps and where we're going to as far as completing this analysis and preparing a final report. Next slide.

So the checklist and the reassessment were two projects that came out of FSIS Notice 6507, and that notice was issued in response to several events. I think we touched on these events a little bit already. Adverse trends in the positive rates of *E. coli* in FSIS clarification testing, an unusual number of positive tests for *E. coli* in a relatively short time span. In calendar year '07, there was 28 establishments that had positive tests. And positive samples and recalls associated with *E. coli* related to certain source materials used in ground beef.

Now, the Notice was focused on certain beef operations and seven that we focused on are listed here, slaughter, trim fabrication, enhanced product, mechanical tenderization, grinding, re-grind, and patty form. Now, all of these areas are parts of the checklist. We haven't gone through and analyzed all the operations yet. In fact, most of the data I'll show today is focused currently on grinding, but I want to point out that there's quite a bit more to do, as you can see. Next slide.

In terms of methodology, the reassessment and the checklist were sent to USDA inspection personnel. It was their job to fill out the questionnaire and send that back for data analysis. We are, like I said, in the process of analyzing responses to those questionnaires, and we'll see some of that data today.

The outcome of this is that we'll prepare a final report of all the questions from the checklist and our goal is to -- we're planning on taking that by July of this year, and we hope that the results from that will be used to aid in informing Agency

policies future initiatives to prevent *E. coli*-related illness.

Now, in terms of data collection, I mentioned that the FSIS inspection personnel filled out the assessment and the checklist, and the way that that was done was differently for the -- somewhat different. For attachment 3, which is the reassessment that I'm talking about, inspectors were instructed to meet with the industry's management, discussing the need to reassess HACCP, sanitation SOPs, and other prerequisite plants.

There's also a short set of questions that were to be filled out, and that had to do with the responses to those reassessments and resulting status of those plans and programs.

Attachment 5 was a separate project of sorts, and that was the checklist itself that I'll talk in more detail about. The checklist had up to 118 questions, and I say up to because it depended on the types of operations and the number of operations that each establishment was running. So if they were operating just a grinding operation, then there was

only a subset of those checklist questions that were relevant to that.

The inspectors filled out these checklists. They were instructed to share the checklists with the establishment management. This gave management the opportunity to review the checklist, to comment on anything that they wanted to comment on, and also give them the opportunity to make any changes if that could be substantiated. And, lastly, the frontline supervisors were expected to review the checklist and review it in particular for completeness before it was sent back.

So all of that gets into how the checklist and the reassessment were filled out, how the data was sent back, some of the interaction of the checklist with the industry and supervisors. Next slide.

So I'll talk a little bit about some of the results so far. Next.

The first has to do with the response rates to the reassessment and to the checklist. Now, these response rates were for -- obviously, the checklist

and the reassessment were only for beef operations that were in business at the time and subject to the inspection, and by that I mean running the operations that I mentioned earlier.

With regard to attachment 3, the reassessment. We received back 2,002 unique questionnaires, and that represents approximately 85 percent of the plants. For the checklist, which is attachment 5, we received 2,322 responses back, and that was greater than 90 percent of the establishments.

Now, I won't go into the details of all the questions. They are, as you can see here, attachments to the Notice, and they're available online if people wanted to look at more details about the questions. Next.

So the first part that was completed was the HACCP plan reassessment, and that was attachment 3. In terms of results for that plant -- next slide -- out of the 2,002 responses that we got back, 96 percent of the establishments reassessed HACCP plans due to the adverse *E. coli* trends. The

attachment indicated that 33 percent changed these HACCP plans as a result of the reassessment, 15 percent made changes to their sanitation SOPs, 35 percent made changes to other prerequisite programs as a result. Overall, 52 percent of establishments made one or more changes to these various plans or programs that I've just mentioned. Next slide.

Now, the checklist was a more in-depth set of questions, and this is where we're really in the middle of the process, and I'll talk a little bit about the sort of broad categories of the checklist and get into some specific questions. Next slide.

So the checklist, as I mentioned, involved 118 questions, and they covered a variety of different operation types. That also was mentioned earlier. For example, grinding, which I'll talk about in a little bit more detail, was one of the operation types.

So in terms of operations, we had sets of questions that were specific to each of the seven different operation types. The questions were focused around various types of inputs and outputs

and the types of controls that were in place for these types of operations. In terms of inputs, questions focused on things such as the source materials, the components that were being used by the operations. We asked questions about the supplier controls and the prerequisite or the requirements that were in place for suppliers. We also asked some questions about source materials, in terms of whether they were using source materials, how much, and the frequency of use.

There were also a good deal of questions about interventions and testing programs. Where were establishments applying these types of controls, how often were they doing that and what steps, and really trying to identify what the practices were.

Now, this checklist is really, I guess, in one way a snapshot of the operations at a specific time. I'll talk a little bit about how the time component of this might affect some of the interpretation of the results. Next slide.

So we've started to look, as I mentioned, at some of the questions. We've started initially

with the grinding establishments. And we looked at a couple different things. One is that we looked at establishments, the overall set of establishments that responded to the checklist and compared those to establishments that had recalls and positives. And I'll present some data on that.

We also reviewed some question responses related to ground beef components that were used in operations and along those lines looked at some of the purchase specifications that were in place around those components. And, again, the analysis of all questions on the checklist is still to be completed and that is expected to be done by summer or around July of this year. So look for that when it comes. Next slide.

So one of the things that we plan on looking at is HACCP size. And I don't have a lot of -- we haven't prepared an analysis breakdown by size yet, but I did want to put up some information about the types of establishments that were participating in this checklist and reassessment.

About 3 percent of the establishments were

what we consider large establishments according to SBA class or what we also call HACCP size. 39 percent were small establishments, and 58 percent were very small establishments. Next slide.

I mentioned that we looked at the effect -- or some differences in responses between establishments that had positives and recalls as compared to the overall set of establishments. This slide here has responses to four questions about purchase specifications and the implementation of validated interventions.

The first bar for each of the questions is the response rates for the overall set of establishments. In this case, we're talking about 1,373 grinding operations that responded to this set of questions. In terms of operations that did not have purchase specifications, there were about 20 percent of grinding operations that did not. About 40 percent of grinding operations did not have supplier documentation other than purchase specifications, and about 90 percent of these grinding operations did not have validated

interventions on either the ground components or the ground products.

In comparison, we looked at the establishments that had positives and recalls, and those are the next two bars on each of these groups of data here. You can see overall that the rate of grinding operations that had positives and recalls and did not have these kinds of purchase specifications or validated interventions is generally lower than what we see with the overall set of establishments. Now, I want to point out that we only found statistical significance with the third question, no validated interventions on ground components, but I think that you do something of a trend in the other three, which are in some ways related.

Now, why would this be? It's a little bit -- it was initially a little bit counter-intuitive to us to see that establishments that had positives and recalls are actually less likely to not have these types of things in place, and so we don't have an absolute answer to this question. We do have

some theories. One theory that we are looking into and plan to investigate further is the possibility that these establishments that had positives and recalls may have implemented new changes between the time of that event and the time that the checklist was done. And, you know, they may have implanted these changes because of the occurrence of these positives and recalls, the subsequent food safety assessment that was done, and just the steps that were taken to improve the process.

Now, as I said, that's currently a theory. We have to go back and identify some data that would help us to validate that theory. We do plan on going and looking at the food safety assessments for those operations to determine what changes were in place, or I should say, what practices were in place at the time and also to identify what changes were made as a result of those assessments. And that will help us understand better whether what we're seeing here was really due to any changes or whether this was, in fact, a condition that was in place back at that time.

So, like I said, this is an initial finding. We need to investigate this a little further to put some better understanding around the differences we've seen here. Next slide.

Now, in terms of ground beef components. We looked at establishments, grinding establishments here and looked at the types of components that are being used in these establishments. Next slide.

In the checklist, there were 11 types of raw beef components that grinding operations could have indicated that they used or that were used in these types of operations and are listed here. The response rates on the checklist are listed as percentages and number of responders out of 1,373 grinding operations.

The first component type is called boneless trimmings. This is, I guess, the category that is typically considered the -- or is considered sort of the typical source material for grinding operations. It's also the component type that is used for FSIS testing for *E. coli*. The other categories there do not follow the same testing requirements that

boneless trimmings do, and I've sort of taken those and grouped them into three general categories based on discussions about these types of materials.

The three sort of gold colored solid bars there are what we called trim from fabricated primal cuts, trim from mechanically tenderized or enhanced products primal cuts, and primal cuts themselves not intended -- or not trimmed. You can see overall that anywhere from 12 to 63 percent of establishments are using these types of primal cuts or trim from primal cuts in their grinding operations.

The next category, which are these darker green set of bars are a set that we -- that I sort of termed other slaughter components. And these include the head meat, cheek meat, and wizened meat and are generally I think considered somewhat riskier source materials for grinding operations. Overall, about 4 percent of grinding operations are using these types of components, and so those are grouped here as another class.

The last class that we've defined is other raw beef components, and that includes AMR, which is

advanced meat recovery materials, and low-temperature derived materials. So other than the boneless trimmings, where about 62 percent of establishments are using that, the next highest group appears to be the components that come from primal cuts or the trim from primal cuts.

The last two categories, the other slaughter components, the raw beef components, generally constitute about 5 percent or less of the establishments using those components. Next slide.

When you take these categories and you kind of condense them down to just the class levels that we were talking about, you can see that in terms of establishments, about 1,000 establishments or nearly 75 percent are using primal cuts or advanced trim in their operations. About 62 percent are using boneless trimmings, and when you combine the other slaughter components and the other raw beef components, about 7 percent of operations are using these source materials.

Now, I think it's important to point out something about this graph. This is really just

looking at the number of establishments that are using these types of components. This isn't making any statement about the volumes that are being used. We're not trying to say that more volume of primal cuts is being used in boneless trimmings. This is simply a measure of how many establishments are using that.

Now, we didn't take -- as I mentioned, we did measure volumes -- or part of the checklist captured information about volume. Unfortunately, that wasn't broken down by the types of component material. So we don't have -- we're not able to analyze the volumes as it relates to these prototypes. Next slide.

We also looked at purchase specification requirements for the grinding operations and looked at it by component type as well. So in terms of this question, the checklist options were that no purchase specifications were in place or they could have had one of five types of purchase specification requirements, two of those being intervention requirements, and three of those being testing

requirements.

When you look at the overall number of establishments or grinding establishments, grinding operations, I should say, that do not have purchase specifications in place, it's about 24 percent. When you break that down according to the classes that I've defined, anywhere from about 20 to close to 30 percent of the first three classes, the boneless, the primal cuts, and the other slaughter components do not have purchase specifications. And only around 5 percent of the other raw beef component operations do not have purchase specifications.

When you look at the -- with a focus on the other raw beef components, which I'll remind you include the AMR and the low-temperature dry products, and you look at what types of purchase specifications they do require, they tend to be -- they tend to require more often the slaughter interventions, the trim testing, and the other component testing. So that's one observation we made from this particular question.

Another thing that we noticed was that the

third category, other slaughter components, this was the category that we felt was -- contained somewhat riskier source materials for grinding operations and that included the head meat, the cheek meat, and the wizened meat. And it was interesting to us that those -- that class of operations, their rate of purchase specification requirements was fairly consistent with the other types of categories, including the boneless trimmings and the primal cuts. So for that category, there wasn't an increase in purchase specification products associated with the operations that were using that kind of source material. Next slide.

So, in summary, we see that so far what we've seen that grinding establishments with *E. coli* positives, 0157:H7 positives and/or recalls in calendar year '07 appear to be requiring purchase specifications of suppliers at a higher rate than other establishments. And as I mentioned, one possible theory on that is that new procedures and requirements have been put in place as a result of those positive and those recalls. That's something

that, as I mentioned, still needs to be investigated further to determine.

The use of trim fabrication from various sources of primal and subprimal cuts is employed by anywhere from 12 to 64 percent of operations depending on the type of component. And strictly in terms of number of operations, more operations are using the primal and subprimal cut components than boneless trimmings or the other categories. And, again, I'll say that's simply number of operations, not any measure of volume that's being used.

We see that 24 percent of beef grinding operations do not have purchase specifications, and that was fairly consistent for three of the four classes that we defined. It was lower, as I mentioned, for the other raw beef components, the AMR and the low-temperature rendered materials.

We saw that operations using somewhat riskier materials, the head, cheek, and wizened meats do not appear to have a higher rate of purchase specification requirements than other operations. On the other hand, we saw that operations using AMR and

low-temperature rendered materials do have a higher rate, and we saw some indication that those specifications -- focused in particular areas like the slaughter interventions, and others. So, in terms of next steps. Next slide, please?

As I said, this is just a couple of the questions that are in the checklist, and we've just started to look at these. We have a lot more work that is still left to be done. We do plan on looking at -- or we will be looking at the other types of operations and the other questions that are associated with those, and we still have a lot more questions related to grinding operations to look at as well.

All of this will go into a final report. That's planned for July of this year, and that will include some analysis. And as I've talked about a little bit already, responses to these types of question by their HACCP size or the SBA class. We need to provide further analysis on the component types, including head, cheek, and wizened meats, and other categories, and we need to do that for the

other types of operations as well.

And we need to perform further analysis and investigation on the types of establishments with positives and recalls. And that analysis will include the response to the checklist data, and we are looking at the ability to use the FSA or food safety information to shed additional light on what we're seeing with the checklist.

As I mentioned, we'll evaluate practices at the time of the recall to help us understand those checklist questions in greater detail. We hope that based on the analysis we'll be able to make some conclusions about the need for follow-up checklists either to fill in missing information or to assess change over time, these types of operations, and the practices that are in place, and to determine if revised questionnaires should be administered to all the establishments or, you know, maybe a broader scope or maybe a more focused scope of establishments.

And, lastly, we hope that the results from the checklist and the final report will be -- could

be used to help -- the Agency policies and future initiatives to prevent *E. coli*-related events in the future. Thank you for your time.

DR. GOLDMAN: Thank you, Mr. Alvares. I'm sure there will be some questions. But what we're going to do is we're going to have Dr. Engeljohn give two different presentation back-to-back, and then we'll have a good long break for your questions and comments.

So Dan is going to talk about primal cuts and also about some more thoughts about the Agency's views on sampling. Dan?

DR. ENGELJOHN: Thank you. On the next slide, I want to give you just a brief background about the history-related 0157 decision-making at FSIS and where we've been, and then I hope to present you some information as to where we, the Agency, think we might need to go in the short term.

In 1994, the Agency identified that 0157:H7 would be considered an adulterant in ground beef. And the reason the Agency selected ground beef were -- that that was the product at the time that

people were getting sick from. We had reason to believe that consumers were not going to fully cook ground beef and that they considered thoroughly cooked beef to be less than well done. And, as well, we also knew that it was a particularly virulent organism.

We started with ground beef because it was the product closest to the consumer as well. And so the Agency announced that we would begin testing ground beef product at both the federal establishments and at retail. And, at the time, we had a sampling program design that took a fair number of samples split pretty much evenly between the two operations, I believe.

Over time, the Agency recognized that just focusing on ground beef was not spurring industry to take types of controls that we believed were necessary to get control over this organism throughout the entire food safety system whether it be at the slaughter operation, the fabrication, grinding operation, or further processing where enhanced products might be made. And, in fact, by

1999, we had had at least one outbreak that was associated with mechanically tenderized product.

And, so, at that time, the Agency announced that we would be moving away from just focused on finished product ground beef as the identity being a product that would be adulterated, but we would move to identifying that the intended use made a difference as to what products would or would not be considered to be adulterated. And intended use was applicable at all points during the production process.

And so in 1999, in January 1999, the Agency issued a federal registered document with clarification policy that identified that the public health risk presented by beef product contaminated with *E. coli* 0157 was not limited to raw ground beef products. And we set forward three very specific examples of products that we believed needed to be attended to, two of which would be considered to be adulterated if, in fact, they were contaminated, but not -- handled to remove the contaminates such as through cooking or through some other process to

destroy 0157, and then products that we would consider outright not to be adulterated if they were contaminated.

The first product category distinction was made for those non-intact products, meaning those products that had the surface jeopardized such that contamination could have been trans-located into the interior of the product or through combination or grinding such that the interior surface was no different than the exterior surface of the product. This would include product such as the mechanically tenderized roasted steaks as well as ground beef. It did not include cube steaks, thinly sliced beef that might be pan sears, whole muscle steaks, or roast in that distinction.

The next distinction was made for those intact products for use as non-intact products. We considered those products to be adulterated if they were contaminated. And this would, of course, included manufact meat trim. Manufact meat trim generally is not jeopardized such that the interior of the product is contaminated. It's just the cut

surfaces, generally, that are believed to be contaminated.

But we also identified that not all product is identified as manufact meat trim. And this is where the primal cut/subprimal cuts at the time were actually identified as they would be considered to be adulterated if, in fact, they were contaminated with *E. coli* if their intended use was as a non-intact product. And so we made distinct that there would be these non-designated primal or subprimal cuts, cuts that would be tenderized or from which bench trim might, in fact, be derived. Again, those products from the Agency's perspective, since 1999, have been considered to be adulterated if they were to be contaminated with *E. coli*.

And then the third category of product is also a primal cut or a boxed beef type product. But these would be intact products that would be distributed. And we use the words very specifically: for consumption as intact product, meaning that these would be the rib eye steaks, the rib eye roasts, the New York strip steaks, other primal cuts that in

their form as delivered to the retail operation or to consumers would not be considered to be adulterated if, in fact, they were contaminated.

So I just want to make sure everyone is clear because this morning I thought I heard some differences in terms of the interpretations that the Agency may have put out with regards to 0157:H7. Very specifically, if it's a non-intact product such as ground beef or a tenderized roaster steak, it would be considered to be adulterated if it's contaminated. If it's a primal cut or a boxed beef product that may be used prior to the consumer receiving it in a manner for which trim or -- bench trim or in some fashion that product could become non-intact, it would as well be considered to be adulterated. So I think it's important to understand the distinctions that we've had in place since '99.

And FSIS focused on these distinctions in order to implement a program whereby we could focus our resources on the products that we believed to have the highest impact for 0157 contamination and to ensure that it's removed from the marketplace before

the consumer received it.

This leads, then, to some of the policy considerations that we're at today. And this is from Mr. Alvares' presentation earlier. From our checklist, it was the first time the Agency has had a process in place where we could identify what products were produced by which establishments because we currently do not have a data set that captures that kind of information.

And, from this, we were able to identify -- it is our belief from interpreting the data and just from the information that we know that is, in fact, in place, that there is a number of primal cuts likely being used for the purpose of either further trim, to derive bench trim, or in and of themselves are being used in the manufacture of raw beef products. And so from that perspective, we believe that there are both primal cuts that are, in fact, being treated as if they are no different than boneless trim, but they are, in fact, not being handled by industry, in terms of anti-microbial treatments that might be applied to them, such as

some trim is receiving an additional anti-microbial or decontamination treatments.

And, importantly, from the Agency's perspective, these products that are not traditionally thought of as boneless trim in and of themselves are being bypassed with regards to the testing programs that are being used in part to divert potentially positive products from the raw beef marketplace.

And part of this is driven by what FSIS does. And as a regulatory agency, traditionally, the industry does follow what the Agency does, in terms of verification practices. The Agency did identify in 1999 that we did start with ground beef as our primary focus, but our intention was to expand our program to other products as we developed the methodologies and the capacity to do so.

We have been focused on ground beef since the late 1980s, in terms of our testing program. In March of 2007, the Agency implemented a manufacturing trim program on a nationwide basis because we had the methodology to be able to do so. We used the N-60

testing, which we believe to be an effective testing program at least from a practical perspective to implement from the Agency's use.

And then, as well, this last fall, the Agency expanded its program again to include the other components that are used in raw beef. This would be the head meat, cheek meat, and those products that traditionally are handled a bit differently than the manufact meat trim in part because they're either prepared on the slaughter floor.

The head meat, cheek meat, or wizened meat are removed prior to any interventions and certainly were removed prior to the chilling of the carcass or the head. And then the AMR and low-temperature rendered products are handled in a different process as well whereby they are, in fact, generally processed or could be processed in a facility that didn't actually manufacture the original trim that's being used.

In any case, the Agency focuses on some very specific products, which is reflected in the

checklist results from industry in that, for the most part, the things that the Agency focuses on is the things that the industry is focused on.

I do also want to point out that our manufacturing trim testing program that we began last March was designed such that we would limit the opportunity for co-mingling a product and having confusion as to where the potential contamination came from. And so we designed the program so that we'd pull the manufacturing trim samples in the facility that manufactures the trim. And this would be the slaughter fabrication facility.

And so for that reason, bench trim, which is generally derived at a further processing step perhaps at the grinder or at the hotel restaurant or institutional facility where they're making steaks and roasts is not the place where the manufacturing trim is pulled by the Agency. And so we don't pull that as a component presently in any of our testing programs.

And then there has been a great deal of confusion as to whether or not the Agency includes a

two-piece chuck in its sampling programs. And I would say that as far back as in March of 2007, the Agency identified that we are well-aware that there are primal cuts that are used to manufacture ground beef.

Many of you are familiar with ground chuck, ground sirloin, ground round. Those would be primal cuts that are made into ground beef. And those are obvious ones for which are intended for using ground beef. But not all chucks are designated for ground beef operations. But a two-piece chuck in and of itself is for the purposeful intention of being used in ground beef. And we do incorporate it into our testing programs.

We have some basic policy assumptions in that the Agency is working from. Dr. Samadpour mentioned this morning that there were some instrumental changes that occurred in the 2002-2003 era. And this really related to the fact that the Agency began accepting the industry's negative results as opposed to just focusing on positive results, in terms of ensuring that there is greater

control of 0157 in the raw beef industry.

And so, really, since 2003, we have been communicating and discussing and looking at means to have practical ways to control 0157 throughout the slaughter, fabrication, and grinding operations. And this really boils down to what I call point source contamination, in that we do accept the fact that for contamination, that it can be segregated into smaller increments in order to define what is production -- lives in the sense that it is virtually impossible to dismantle an entire carcass without there being some potential cross-contamination throughout the entire process.

But you could, in fact, break it down into point source contamination whereby you designate contamination into grouping, such as what industry was doing at the time was taking five combo bins of product, pulling 12 samples from each to get an N-60 sample for which that became a definable unit that got put into the marketplace.

The unfortunate thing about that today as compared to where we perhaps were in the past is that

those units, those five-combo units that are designated as production lot aren't necessarily sold in the marketplace as intact five-combo bin units, meaning that they get split up. And this is one of the issues that causes the Agency concern and has resulted in expanded recalls in that if we find a positive at an end point processor, looking back to find out where like product came from that was associated with that particular production lot that was used does implicate other product. And so there is a concern, a growing concern about how product's distributed in each of the marketplace.

In terms of our program as well, then, we have been focused on manufacturing trim, which we started last March. Just to give you some perspective, the Agency collects roughly just under 12,000 samples of ground beef a year from all of its establishments that we regulate. We collect just under 4,000 samples a year from beef manufacturing trim, and we collect just, well, right at 1,500 samples of the other components. So we have some disparity in terms of the number of samples that we

collect, and we certainly are looking at our sampling programs to see whether or not we need to redesign them and reallocate those samples in a different manner to put different focus where it might have a greater impact. But, presently, that's the design of our program.

And, as I said, we do not presently target primal cuts or boxed beef that at least are not designated for use for raw ground beef in the federal system. And, as well, we do not target bench trim that's created in a further processing operation because the bench trim is derived from a primal cut that came from another operation. But the Agency certainly is looking at that as an issue to determine whether or not we should begin targeting our focus differently with regards to where bench trim is derived.

And, as well, we do not collect samples of tenderized roast or steaks that have the opportunity of having the contaminant further distributed internally into the product. But we have focused on those commodities that we believe presented the

greatest risk.

I do want to add that we also have increasing evidence that there is a large number of establishments that do tend to rely solely upon the mark of inspection as evidence that the product would not have a hazard reasonably likely to occur. I would say that in the '99 policy and then again in 2002 and 2005, when we issued clarifications on 0157 adulteration status, the Agency did identify that, at the time, we believed that it was not feasible for a slaughter establishment to not have a critical control point to address *E. coli* 0157:H7. We as well said that we believed that those operations that manufacture -- that further fabrication operations and that make boneless trim also need to justify why they would not be identifying 0157 as a hazard reasonably likely to occur.

We did identify, however, that it might be feasible for grinders, those that receive product and all they do is grind the product, may be able to justify having a prerequisite program on the condition that there are controls in place by the

supplier such that the hazard would not be reasonably likely to occur. And, therefore, they could handle that control through a prerequisite program.

But the Agency did caution that in order to utilize that as the rationale for the control in your operation, you had to have evidence of the effectiveness, the ongoing effectiveness of that type of operation. And it is the Agency's view at this point that that likely is not being handled in a uniform, consistent, or perhaps adequate manner as we go forward.

So we look at what are our next steps? Well, we do think there are some short-term things that we as the Agency need to take into account. We have already began the process of looking at some of the assumptions that we've had in place with regard to our 0157 policies. We do know that what the Agency does typically is what the industry does.

Fortunately, with regards to testing, the industry, in the opinion of FSIS, generally is using methodologies that might be more sensitive or more specific such that they, in fact, might be finding

more positives, or at least they're reacting to presumptives from screens that are in fact more comprehensive, such that it's more protective of public health. So that's a fortunate thing with regards to industry practices.

But, in any case, the Agency is stepping back and looking to see whether or not we've applied the appropriate focus at slaughter dressing operations. We do know that we need to take more attention here to find out what's happening there. We have concerns that what's happening on the slaughter dressing operation may not be communicated to the trim fab -- that's testing the product and then diverting it to cooking if they find positives, but not necessarily adequately looking to see what, in fact, might be evidence of a trend for increased positives in their products. And so the Agency does have some very specific intentions of looking at what is happening with regards to sanitation dressing practices and their effectiveness.

We also want to begin looking more specifically at the relationship between what's

happening on the slaughter floor and the testing results that are occurring in the fabrication operation. We do have an inspector in charge in these facilities who does have the opportunity to look at both what's happening at slaughter and at processing, and so we are looking to see what more do we need to be doing in terms of looking at the data in both operations and then questioning the management as to how they are reacting to the findings that they have.

Again, we're not looking to penalize the industry for finding the positives, but the issue is, what are you doing with the positives and how do you know whether or not the number of positives that you're finding is reflective of a process that might be trending out of control.

And then, as well, the Agency does have concerns about in situations where there may be an increased positive rate on particular days or over a particular time as to whether or not the industry itself is looking at what impact does that have on the primal cuts that are going out the door. Again,

we have been focused on manufacturing trim and what's happening there. The Agency has not specifically been looking or asking questions about what is happening with regards to primal cuts in those circumstances, particularly if the industry has reason to believe and we have reason to believe ourselves that that product may be used in non-intact product.

And then the next issue is to figure out a process by which we can discourage the breaking up of the tested groupings of products. We're pleased to hear that there are industry leaders that are considering going from the five-combo bin units down to at least a one-combo bin unit and looking at reducing the size of the units that are contained within a production lot.

And then, finally, what are we looking at from a long-term perspective? Well, the Agency put in place 0157 policies that were focused first on the products that caused people to get sick. We then put in place clarifications to say that we were going to look back upstream to force some controls in place

throughout the various points in the operation where controls could be applied.

But from the Agency's perspective, we need to look at this more holistically to see whether, in fact, we need to just look at the issue of applying a definition differently. And from this perspective, we have used the intended use concept, but we do have concerns about cross-contamination that occurs throughout the process, whether or not there's adequate industry practices in place to actually be able to control product as it goes through the system, or as the consumer has delivered this product.

And what this really boils down to is whether or not the Agency should redefine adulteration to, in fact, encompass the organism itself as to the product. And so, in this case, considerations that we certainly are looking at is whether or not we should simply define 0157 being an adulterant in raw beef, whereby that would force there to be controls, interventions, and practices put in place upstream as far as possible to prevent

0157 from coming into the operations or from being on products that are further distributed and handled in the system.

To get some perspective about looking at how this could work, it's the opposite approach that the Agency had taken against *Listeria monocytogenes,* where we classified *Listeria monocytogenes* in and of itself as an adulterant. It doesn't matter which type, subtype of *Listeria* it is. It's just if it's *Listeria monocytogenes*, it is, in fact, an adulterant in the product.

And that's sort of what the Agency is looking at with regards to *E. coli* 0157:H7 or, in this sense, non-0157 STECs and the 0157 STECs, as to whether or not as a general rule they just become an adulterant as a means to better control and address 0157:H7.

So those are the issues the Agency is looking at in terms of our approach. We have not made decisions yet of how we will go forward. We do believe that what we have in place now isn't working from the perspective that the focus that we need to

take means that we need to continue to focus on individual products at individual points in the process. We're not sure that that's the most effective way to move forward with a nationwide program with inspectors in the facilities every day, and that, in fact, we may need to just re-look at the way that we define this. And we're looking at it from a broader perspective as opposed to a more narrow perspective. Thank you.

(Applause.)

DR. ENGELJOHN: And I have a few slides on the issue of sampling and other issues really just to put some issues on the table that the Agency is considering, not anything real specific, but just really to get some issues on the table so that as we have our discussions, we can further inform the policy development that we have related to STECs in general.

On the next slide, I identify that the Agency has, in fact, put in place a program whereby we test product at very specific points in the production process, at the handling chain, at various

points in the handling operation, and I would say that, as a consequence of our focus on ground beef and then after that on its intended use, there were production changes that occurred with regards to industry in that there are fewer retail operations that grind product today.

Oftentimes, today, I think the more likely scenario is that product comes in preground from the federal operations directly to the retail operations, in part, that we believe that that was an action that occurred simply because we identified that we would change our focus on where we would take our testing samples.

But, in any case, as we gather evidence as to whether or not there is more grinding that's occurring such as in-house trim, bench trim, or primal cuts at retail that are being ground, the Agency needs to re-look at this issue because, again, we are concerned about the primal cuts getting through the system in the sense that they may not be receiving an additional anti-microbial treatment and they certainly are not likely to be receiving any

additional testing to divert them from the marketplace. And so it becomes an issue for the Agency as to where, in fact, should we be focused.

But I would say, again, going back to our policy that we put in place really after 1999 and then that the Agency itself adopted and pretty much implemented nationwide in 2003 with regards to point source testing and focusing on N-60, the Agency did make clear that our standard would be that product would, in fact, not be determined to be adulterated to the general sense of production practices if, in fact, 0157 is below detectable levels. Our own risk assessment identified that product likely is contaminated as it goes out the door. And the issue is whether or not it's at detectable levels.

And we all know that at the levels that we believe to be occurring in the raw beef operations that there is no testing scheme that we could devise that would be practical or feasible to apply. And, therefore, that N-60 testing is, in fact, a reasonable approach. We have taken into consideration, though, that we probably need to focus

on small production lots as opposed to the larger ones for which it would give us greater confidence that there is less likely to be detectable contamination.

In terms of our next steps with sampling, the Agency, again, we're accepting the industry test practices that they have in place for the most part, although we know that there is extraordinary differences within the industry. Our checklist is one way that we're looking to see what are some of the practices that are in place at the various operations.

We do have some slaughter operations that are testing. We have some trim fabrication operations that are testing. We know there are some primal cuts that are being tested. And we know that there's ground product that's being tested either before it's ground or after it's ground. And there is some testing and interventions being applied to the mechanically tenderized and enhanced products.

But, in any case, the Agency doesn't have a good handle on what are the common industry practices

for the large, small and very small operations, both by HACCP size and by production volume. And so our checklist, we believe, will give us some information as to what some of those practices are.

We will be looking at those practices and developing what we think would be appropriate protocols that could be followed by the industry. I know there were a number of comments this morning raised about the Agency's sampling N-60 quarterly testing, and those kind of things. And I would just identify that there is a need to provide some guidance to industry for practical things that they can do to better demonstrate that their programs are operating effectively. And that's the purpose of the Agency giving compliance guidance.

But, in any case, we do know we need to look at what constitutes a production lot, whether or not we need to make decisions about providing more guidance around that, and what the vulnerabilities are if you make different decisions.

How samples are selected and collected. This makes an extraordinary difference in terms of

the likelihood of finding the contaminant. We will be looking at operations that are, in fact, designing programs to actually find contamination.

And then the decisions that are made about when a production lot may be affected is something that we are concerned about. We do expect that when industry tests that they will find positives. This is a raw product, after all, and it is one for which the interventions in place today, for the most part, are not capable of eliminating the pathogen. They can significantly reduce the likelihood that contamination can be detected, but that's dependent upon whether or not the level is lower or higher than the level that the interventions are capable of addressing.

In any case, we do know that we need to look at those practices and provide additional information to the industry about that. And that information was contained within the checklist. So we would be able to get some information associated with that.

And then we have continuing concerns about

the issue of what we consider finger pointing within the industry in that the HACCP regulations do require that each member of the industry that handles raw beef, in this case, has to take the responsibility for producing safe product. And this would be for the product that comes in the door, while it's in the operation, and then as it leaves.

And so as various segments of the industry have to address whether or not the operations prior to it address the contaminate, it is the expectation of the Agency and through our HACCP regulations that, in fact, those hazards would be addressed by each differing level of handling. And so we need to find some solutions here whereby there isn't this what we are understanding to be some very aggressive steps taken by some suppliers to warn their receivers of product that they cannot or should not test their product or have the likelihood it not being supplied further product.

So it's an issue for which the Agency is looking for solutions for. We're not looking for industry themselves to come up with that solution.

We think we're going to have to step in on that one, but it is a real issue that we know we have to step in and address in the short term.

And then, finally, the Agency is looking at the results that we have in attachment 3, which was the reassessment notice. This did identify what the reasons were for either doing a reassessment or not and then what actually occurred with regards to that reassessment and then, as well, looking at the checklist, number 5, to see what are some of the common production practices amongst the various size and volume operations to see whether or not we can establish production practices for which we can at least provide some guidance as to whether or not we think that they at least meet the Agency's expectations for adequate control for 0157:H7.

We did identify some original best practices in order to get some measure against which we could make some determination as to what's actually occurring within the industry, and we are committed to changing those best practices in particular for the various size operations.

And then the Agency is looking at that checklist. Again, it is the intention to capture more information about production practices so that we know who is doing what. One of the things we did learn from the recalls last year is that there is the problem in that, oftentimes, a production may be, in fact, controlled in a HACCP or a food safety system one way, and then over time it gets gradually changed such that the Agency itself is not collecting information to know when changes are made and when we need to come in and do a more thorough review ourselves.

And so it is our intention to look at the checklist, look to see whether or not we need to provide clarity to some or all of the questions, whether or not we need to refine it, to target it at certain aspects of the operation to get more information, and, clearly, to do it on a recurring basis so that we can find out whether or not there are changes in the production practices.

And then the thing that the Agency continues to rely upon is the percent positive rate

that we find in our various sampling programs. From our perspective, this is our first indication as to whether or not there are changes that might be occurring that we need to attend to.

We did note that there were changes in the percent positive rate in the spring of last year and then followed that through. We weren't able to put in place practices that changed that throughout the rest of the year, but the Agency's intention is to make that more readily available and timely so that industry and other stakeholders are aware of any changes that we see in our production practices within the industry as well as in our own verification program. Thank you.

DR. GOLDMAN: Okay. Great. Thank you very much, Dr. Engeljohn, Mr. Alvares. We now have some time for your questions. You heard -- gave a presentation on our checklist analysis, the beginnings of that, and then you heard a lot of policy considerations for you to react to.

So we want to invite people to come again to the middle of the room. Please, again, state your

name and affiliation for the purposes of our transcript, and we'll go to the phone kind of alternate with those of you in the room. But we'll start here in the room.

MR. DANIELSON: Ready? Do you hear that? Dean Danielson at Tyson. This is Christopher.

MR. ALVARES: Yes?

MR. DANIELSON: On slide 16 -- I don't know if you can pull that back up or not. I have a couple of questions on that.

MR. ALVARES: This was in reference to the component types?

MR. DANIELSON: Pardon me?

MR. ALVARES: The slide in reference to the component types?

MR. DANIELSON: Yeah, components used by grinding operations. There you go. Your y-axis is what? The number of -- what is the y-axis there?

MR. ALVARES: That's the number of respondents beef grinding operations to those -- to that question. So out of a total of 1,373 grinding operations, the number on the axis is the number that

indicated that they use those particular component types.

MR. DANIELSON: Okay. So if you add those all up, that equals -- I don't have an exact number, but over 2,400 total responses, which is above the 1,373 --

MR. ALVARES: Yes.

MR. DANIELSON: -- that were -- total. So, to me, there's some skew in how this data's reported. In fact, those first two bars, almost identical, I really -- can you explain to me what they -- how they're different because, to me, I could see our plants answering yes to both of those on the same material.

MR. ALVARES: Yeah. So this particular question on the checklist allowed the inspector to check all that applied, and so there were operations that used more than one component type. The component types were not exclusive to each operation.

MR. DANIELSON: So as I see that and I see the -- to me there's a bias built onto this slide because the yellow bars are trying to make a point

against sub-primals, but then the first bar, yellow bar and the first gray bar are probably the same information. So I think we're crossing -- in my view, it's crossing over information that may be skewing the picture. That's how I'm looking at that slide.

MR. ALVARES: I'll make a point of that and look into the overlap of those, particular those two, but overall. Off the top of my head, I don't know what the overlap of the first two were.

MR. DANIELSON: Okay. I'd appreciate that.

DR. ENGELJOHN: If I could, though, I'll just opine that in designing those questions, though, the questions were designed such that they ask do you use bones trim. The next question was do you use primal cuts not intended for ground beef other than a two-piece chuck. And so the questions were designed to actually parse out whether or not the inspector identified that this plant used boneless trim, used primal cuts, such as bench trim, as an example, that wasn't from a product that was actually designated for using ground beef. And then the primal cut in

and of itself was that very thing. Was it designated or not? So we did actually write the questions, or we believe we did, to parse out that particular difference.

MR. DANIELSON: And running these surveys are tough, I know. I have my own problems with all ours, but I would -- I know how some of our people answered it, and I know that the meaning is not what maybe what you think it is, at least from our responses.

DR. ENGELJOHN: Yeah, and we do -- and, as I said, we -- actually, we'll look at the questions for which we think we need to either redo for targeting or is there a way that we can improve upon them, but at least we did our best to try to parse them out to break it up to identify are primal cuts or bench trim derived from them or mechanically tenderized products actually being used in production of ground beef at that operation.

MR. DANIELSON: Okay. Second question, again, Chris. You made a statement that head meat, cheek meat, and wizened meat are riskier. My data

does not really support that. Do you have data that does?

DR. ENGELJOHN: I'll answer for Chris on that one. In the sense that from the perspective of the Agency, we're not working from real data that we have to make the determination that is riskier, but what we do know is that this is product that is derived from the slaughter floor in many cases before interventions are applied. In some cases, there may be interventions applied to the head, but it is product that's derived on the slaughter floor before the carcass itself goes through those interventions, and so from that reasons, it's from a riskier operation.

MR. DANIELSON: Okay.

DR. ENGELJOHN: Just as a general statement.

MR. DANIELSON: From that general statement, I see where you're coming from, but from an actual data standpoint, we haven't seen that differential in the pathogen testing that we do on those components.

And then the last thing I'll just -- to purge testing, question this morning, we have studied that over the years, and purge testing -- and we do have studies and data on that, and purge testing is far less sensitive than the N-60 testing in finding 0157:H7.

DR. ENGELJOHN: And we appreciate that from the Agency's perspective. We have looked at the issue and we will continue to do so. In part, we do have concerns that any materials that are used in raw beef could and should be looked at, not just the meat muscle itself. And for those opportunities where there is purge available, I would say the Agency's intention is to pursue this, see if, in fact, it's a reasonable media for which we could collect samples and, if so, make a determination about pulling them in conjunction with the tissue samples that we pull or in and of themselves. But we will be further studying each.

DR. GOLDMAN: Okay.

MS. DONLEY: Nancy Donley from STOP, Safe Tables Our Priority. Dr. Raymond, by my count, this

is the third presentation that Dan has made today, and I think he probably deserves a raise.

(Laughter.)

MS. DONLEY: I'll see what I can do. I just want to make a comment, and that is that I can't -- the last time that I'd been here in Washington D.C. attending these public meetings where I have had really just my spirits lift because of some actions that I see that the Agency is endeavoring to undertake to really protect public health and safety. And the two that I heard from this morning is, one, is looking at non-0157 STECs and also this look at this, this broadening look at 0157 and other STECs as something as not just trying to classify it and put it in a box that it's a problem if it's in this type of product or that type of product and, instead, taking a look at is as being, hey, is it a problem period, is a public health hazard period, and, if so, maybe we should be looking at it that way and not just as where it's -- if a person gets sick from eating it from a ground beef product versus a steak versus a cross-

contamination issue that happens in the kitchen when they're taking their roast or their steak out of their package and it's cross-contaminating in restaurants in a kitchen somewhere also. I really applaud the Agency on this.

That said, this is all going to come at a cost and at a price. It is going to be a cost to industry and the Agency because there is going to be additional testing that needs to be done. We need to give our inspection force the resources that they need to do these things. I feel for my inspector friends. I feel for industry and my industry friends in the sense that I know that this is going to put a burden on you.

The price is in better public health and safety, and that is something that we all have to -- I think that is a very, very, very good price indeed. I think that the consumer community here, one of the things that we can do is that we have to go and work to get the tools and the resources necessary that FSIS, if that is to go to our members of Congress, and get the resources that you, Agency, need. I just

want to applaud you for instead of looking at it from a budget standpoint first and saying can we afford to do this that you are taking the broader step and larger step of saying I first want to see what is it that needs to be done and then we consumer groups will help to get the money to help you do what is right. I want to thank you very much.

DR. GOLDMAN: Thank you, Ms. Donley. Before Ms. Nestor, let me check with our operator and see if we have questions from the phone.

OPERATOR: You have one question from Barbara Kowalcyk. You may ask your question. State your organization.

MS. KOWALCYK: Hi, my name is Barb Kowalcyk, and I'm from CSI, and I have a few comments and just really mainly comments.

First of all, I'm very impressed by what the Agency has been undertaking especially with this questionnaire, and the question I have about it is, is this going to be a limited questionnaire or is this kind of data going to be collected on an ongoing basis? I think it provides some very valuable

information that we consumer groups I think in particular have been pushing FSIS to collect this type of data in its development for the RBI program.

And the second question regarding the questionnaire is, obviously, I don't think that all the establishments responded to the questionnaire, and did FSIS actually look at the self-selection bias? Was there something specific about the plants that did or did not respond to the questioning because that would have been interesting to know more about?

But the main comment that I have is that I want to agree with Dan that I understand that we can't test safety into a product. But I do think, and I've been very vocal on this before. I think we can do a better job at sampling so that we can generalize the results and find -- have better confidence in what we're seeing.

So, basically, I want to encourage FSIS to continue to collect more data and make -- so that they can make educated choices about how and when they should sample. And, finally, FSIS needs to do

more to acknowledge the limitations of their micro testing program and interpret the data appropriately.

DR. ENGELJOHN: Thank you. And I'll just make some comments and then, Chris, if you want to as well, please do.

I will say that it is the Agency's intention generally to be collecting the kind of information that we had on this checklist. As we move forward with our public health information system where we are, in fact, looking at what is occurring in the operations, what interventions are in place, what changes are being made, what is the type of verification that's occurring, that information presently isn't captured in any FSIS database other than a very general plant profile that we have in those plants that are in the performance-based inspection system.

The new system that we actually have designed is designed to capture the very information that we've incorporated into the checklist that was attached to 6507 with modifications because we know we can improve upon the question.

But the intention will be to have an ongoing process whereby any change in the establishment's operation would be captured in this data system and would feed into a process whereby it would perhaps trigger the Agency to make a special focus of doing a food safety assessment or to follow up on any changes that may have some more significant importance. So the intention will be to continuously do this in a process that's automated such that we would have information about each operation.

MR. ALVARES: I think I'll make one comment about the -- there was a question about the sampling bias and the types of responses. The checklist, just to remind everyone, it was filled out by inspection personnel, not by the establishments themselves, and so, you know, from that point of view, I don't know that establishments had much influence on how the checklist was filled out in terms of sending them back.

In terms of the overall response rates, I mentioned that they were over 85 percent. I think that was, you know, in our opinion, pretty good. And

we did show some numbers, and, unfortunately, they didn't make it into the handout, but the breakdown of HACCP size is, from what I've seen, is generally very similar to the overall breakdown of establishments. So I don't think we were over-sampling the very small establishments, but that is certainly a valid concern and something that we'll try to address in the final report.

DR. ENGELJOHN: And I will say that the Agency cast a wide net as to who we sent the surveys to. They went to the actual inspectors at an e-mail address. For those that didn't have an e-mail address, they were mailed out. In any case, if we didn't get a response back or it was incomplete, there was some very personal follow up in terms of getting those filled out. So the Agency made every effort to get as many of the surveys completed as we believe there was operations in effect at the time that the survey was to be complete.

DR. GOLDMAN: Thank you. Okay. Ms. Nestor?

OPERATOR: Showing no further questions on

the phone line. Again, if you have a question, press star one.

DR. GOLDMAN: Thank you.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Did I understand you to say, either Dan or Chris, that you're going to re-analyze the data to determine how many plants reassessed prior to your notice that they -- you were going to be doing this checklist? I mean, are you going to be able to tell us how many plants had reassessed prior to your announcement that this whole initiative was started?

MR. ALVARES: No, I don't think that that was the intention of -- if it's in reference to what I was saying about food safety assessments. One of the reasons why the notice went out and the checklist and the reassessment were done was in response to the increased positives. And one of the things that we've been dealing with is the fact that the checklist, although it's a snapshot in time, it's not a snapshot of the recall and positive establishments at the time that the recalls and the positives occurred.

And so in terms of interpreting the checklist with respect to those establishments, we have to keep in mind that they may have made changes since the occurrence of those recalls and positives. And so one of the things that we're going to try to do is look back at food safety assessments for those. And that's only about -- off the top of my head, I know for grinding establishments, that was only about 16 recall establishments.

So we're not talking about going back to 1,300 establishments, but maybe 20 or so, trying to identify what changes took place to help us understand whether any differences we see in a checklist were due to changes implemented or possibly to -- or alternatively to conditions that were in place at the time.

DR. ENGELJOHN: Felicia, if I could, on the reassessment attachment 3 notice, there were five questions there. And, specifically, the inspectors did answer the question as to whether or not reassessment occurred, it did or it didn't. If it did, what did they do, and if they didn't, why didn't

they, and one of those answers could be because they previously did so.

And so that is captured. We didn't report it in this, but that would be information that ultimately will be part of the report. So we have the information that the inspectors were able to glean as to what the plant did as a consequence of our telling the establishments they needed to reassess.

MS. NESTOR: The reason I ask that question is, in slide number 10 in Chris' presentation, it says that 96 percent of the plants reassessed their HACCP plans due to adverse *E. coli* trends. Unless you asked them why did you reassess your HACCP plan, I don't think you can make that statement. And it's a very significant statement. I think if you ask them honestly, I think probably a good percentage of them reassessed their HACCP plan because they were threatened with an FSA if they didn't.

And consumers need to know that. We need, you know, we need to know whether -- what is triggering the food safety activities in the plants.

If it's a threat of an FSA, that's significant.

And, you know, Dan you were talking about finger pointing in the industry. And I'm assuming that was about supply plants taking action against smaller plants that tested, you know? Again, as a consumer, I have no authority, I have no impact at all whatsoever on the industry. But it is my job to have an impact on you. And if a small plant gets contaminated product, it is more incumbent upon the Agency to find out why contaminated product, why is it bearing the USDA seal of approval.

And when you describe, you know, what you're going to go back and look at, you know, that you're going to start to look at what the relationship is between contamination and what goes on in the slaughter plants, as far as I understand, that's basic HACCP 101. You're supposed to do an O2 procedure to find out through out the whole process if you had contamination at the end what happened. I mean, we're, what is it, ten years into HACCP, and inspectors have been telling me for years if there's contamination at the end, why don't they look at the

slaughter plant? Why don't they go back to the supplier plant?

I mean, you know, somewhere else you said this is the first time the Agency has evidence that primal cuts are being used and bench trim is being used. Well, maybe this is the first time Washington has had the information, but certainly the inspectors in the field have been well aware of it and have been talking about it, you know? So my recommendation would be that you listen to your people on the front line.

I mean, a lot of this, perhaps, illnesses, depths could have been avoided if the Agency were willing to step in and take regulatory action, set guidelines, set rules, as opposed to, you know, the incredible discretion that the industry has to -- you know, not to take proper steps to keep the product clean.

DR. GOLDMAN: Dan, do you have an answer to the question about the 96 percent? Do we have an answer to that? There was a question there about 96 percent --

DR. ENGELJOHN: Other than the Agency did ask why, and we have those parsed out. It wasn't part of the report. And we don't have that. I don't think it's going to say, though, because they were threatened with an FSA. But there will be a reason -- we'll report what the inspectors documented and we'll go from there.

MS. WALLS: My name is Isabel Walls with USDA's Foreign Agricultural Service. I just wanted to say 2007 really was a bad year, and I think, you know, it was unexpected and we don't really understand we suddenly got this series of outbreaks and illnesses. And I heard this morning some suggestion that it could be due to pre-harvest issues. And I think one of the things that FSIS did looking at the testing of the trim, pushing it back on the supplier was the right direction to go.

But I want to throw out for this audience just something to think about. Should we be pushing back further. And we heard a question this morning as to whether APHIS should be doing food safety on the job. Food safety is FSIS' responsibility. It's

not APHIS' job. And so I'm wondering again for discussion, is it time to think about FSIS asking for regulatory authority on the farm.

And I'm thinking this could include looking at the animal feed because there was some suggestion that changes to the animal feed are responsible. I'm thinking about the water that the animals drink, maybe the conditions, the housing conditions, maybe the control of manure. And so I ask is it time to start thinking about that?

DR. ENGELJOHN: From my perspective -- this is Engeljohn -- from the risk management point of view, I don't think anything is off the table in terms of what is it that the Agency needs to do and where do we need to apply those controls. I would say that we believe that the HACCP regs that we put in place do start at the slaughter operation, but they do, in fact have the provision there that what comes in the door needs to be addressed. And if there are effective interventions that could be applied pre-harvest, then we would expect that they would be incorporated into part of their food safety

system.

But in terms of the overall approach of us being on the farm, being FSIS, obviously, it's a legislative issue that would have to be undertaken, and we do think there's a great deal that can still be done under the current legislative authorities that we have.

DR. GOLDMAN: Before we get to Dr. Huffman, let me check again on the phone and see if we have questions there.

OPERATOR: At this moment, showing no questions on the phone line.

DR. GOLDMAN: Okay. Thank you. Dr. Huffman?

DR. HUFFMAN: Thank you. Randy Huffman, American Meat Institute Foundation. Thanks for the opportunity. Just a few questions about the checklist, some clarification for my purposes. And I guess the first one would be relative to slide number 14 when you asked the questions concerning -- of grinders concerning the use of validated interventions both in finished ground beef and in the

ground beef component. So I'm just curious what does the -- what interventions did the Agency expect with respect to those two product types especially with respect to ground beef? Was there an expectation that there should be -- I'm surprise -- not 100 percent.

DR. ENGELJOHN: Yes, there was an expectation on behalf of FSIS. There are interventions available at all points in the distribution. And the question had some specific interventions that may in fact have been used in terms of those validated points. And as I recall, it did identify the gaseous ammonia which we know to be an effective treatment against 0157 or radiation is an effective treatment against radiation [sic].

DR. HUFFMAN: Okay.

DR. ENGELJOHN: We know that there are other anti-microbial treatments that are used either on the primal cuts before the product is tenderized or enhanced. And so those were examples that we gave, and then we left an option for there to be an other to be filled in for which Chris is still going

to be analyzing that. But, yes, there is an expectation that there are interventions available. And we issued the questionnaire in the manner to find out what was being used since we don't have a means to track that at this point.

DR. HUFFMAN: Okay. Next question really has to do with how these data may be used in a risk assessment approach in the future or now, and maybe you have this data and it's just not part of this presentation, but I guess I -- the slides that Dr. Danielson asked about. How important or how useful is the information about number of establishments responding to some of these questions versus a metric such as the amount of product represented by those answers? Is that specific enough?

MR. ALVARES: Well, I think that, certainly, volume of product is an important factor. I guess there's two parts to that. In terms of number of establishments, I think it's important to understand whether a large number of establishments are using a component or not. If no one is using a

component, then it doesn't, in a general sense and maybe an analytical sense, it's not a significant factor if no one is using. But if a lot of people are using it, even if it's a small amount of volume that could still be something that needs to be considered.

Now, not necessarily -- I'm not talking -- you know, I'm certainly not here to say that we're going to make policy changes just because of the number of establishments, but I think when you get to that point, you're right. We do have to think about the volume that's being used as well --

DR. HUFFMAN: And is that captured in the checklist?

MR. ALVARES: Well, unfortunately, I think the checklist only captured an overall volume and did not break it down by component type. And as we mentioned, we are going to look at the strengths and weaknesses of this checklist as it might apply to designing future checklists.

DR. HUFFMAN: Okay. Thanks.

DR. ENGELJOHN: I would also add, Randy, on

the issue of -- this also is the first information the Agency has specifically on who produces what, which matters to the Agency in terms of, as we think about how should we construct our verification testing programs, and as I mentioned, we allocate a very large number to the grinding operations and a substantially smaller number to the trim operations in part because there are substantially fewer trim operations.

But the issue becomes one of how could and should the Agency be constructing its sampling frames for verification as one issue, what's the population of plants. And then the second issue being, in part, do we have the right type of information to our inspectors that perhaps are in those operations. As an example, is there special training that may need to be done as certain operations are being conducted.

And, again, the Agency is using this tool in a number of ways, one of which is to identify who produces what and then to the extent that we can identify what they're doing, how much they're doing, and what interventions and what level of control that

they have. So there'll be a number of uses for the information.

DR. HUFFMAN: One final, one, if I may, and maybe this is more of a comment or --

UNIDENTIFIED MALE SPEAKER: Okay.

DR. HUFFMAN: -- maybe you can confirm my clarification statement. But on slide 18 where it talks about grinders purchase specification requirements for each component class, I guess I would just like to make a point, and I hope I'm correct, that those values, which are relatively low responses on some of those particular categories don't necessarily infer that interventions aren't being used, for instance, at slaughter or at fabrication. It simply represents what may be in agreement between a supplier and a customer.

And so I assume the answers to those questions will be found in the checklist for the slaughter establishments? Is that --

MR. ALVARES: Well, yes, these are about purchase specifications. There are questions about the actual interventions and testing that are being

done. Those are other questions on the checklist. And off the top of my head, I don't recall which ones are specific to slaughter establishments. But they are available on the Web.

DR. HUFFMAN: I just want to make a point that I don't that -- you know, about -- I think it's 40 or 50 to 60 percent -- it's not this graph that's up now. It's further down. But I don't think that 50 percent of plants have slaughter intervention. I think it's much higher than that. And that's the only point I'm making. This just represents an agreement that may be in place between a customer and a supplier.

MR. ALVARES: It may represent that. And part of the issue, again, for the Agency, was to capture who has what as part of their food safety system in the operation in terms of a written requirement that may be there that identifies controls that are in place. And the Agency's interest was how well is the concept of prerequisite programs being used with regards to the control of this pathogen as product moves from the slaughter

floor where there likely is in many -- most plants a critical control point on trim fabrication, where there generally isn't the same level of control as in the slaughter floor and certainly lesser controls evidence at grinding operations. And that's what the Agency was capturing to these questions.

DR. GOLDMAN: Okay. Next question. Ms. Buck?

MS. BUCK: My name is Patricia Buck, and I'm with CFI. And I have some questions. Most of them got asked as I was waiting in line here, but I have a statement I think of sorts to make, and that is this. The system that we have right now isn't working, and we're seeing that evidenced. In 1982, 0157:H7 was discovered as an adulterant and in cow -- cattle feces. And since then it has been growing and growing and growing as a problem, as has the other O antigen *E. coli*. And we've discussed that.

The thing that I find amazing as the grandmother of, you know, dead kid is that we're not looking at this logically. These are enteric bacteria that come from cows or pigs or wherever.

But that's where they reside. That's where they live. We have got to start taking those steps back like the woman before me suggested and start looking at the farm and seeing what in the world is going on.

I have talked with one man. He has this marvelous, you know, system that all he does is apply to any hard surfaces and it acts like a bug zapper and will kill any bacteria. And I said you should take that FSIS. And he said -- or the industry -- and he says no. They're pathogenic load is too high. The animals are too infected. They're not sick. The animals aren't sick, mind you, but they are infected with this, and we have allowed it over the 30 years to become entrenched.

And now we have a problem. So I'm just wanting really, really very much for everybody in this room to do just as Dr. Raymond suggested and that is pull together to figure out what we can do. But industry is being given an impossible job. You are being given an impossible job because the animals are the source. I don't think you have a response to that. I'm not asking for a response to that. That's

just my personal observation on this.

As far as a question, what are the next steps? What are the barriers to coming together? Do you need more legislation? Do you need to have incentives for industry so that they can be compensated for the extra work their now going to be required to do? What are those barriers? Are you going to outline it in your report? I'd very much like to see that.

I'd also like to know what are the definitions. How are you going to define the adulterant in foods? This has huge implications for the future. If we don't get a handle on this now -- which is what I call food safety at the crossroads. If we don't get a handle on this now, what's it going to be like 30 years from now? I think that's something all of us need to keep in mind.

I find this meeting to be very encouraging. I agree 100 percent with Nancy Donley. It's very encouraging. But we still have a lot of work to do unless people are willing to roll up their sleeves and do the work. We'll be at the same place 10 years

from now where we -- you know, let's get together and do it. Thank you.

DR. GOLDMAN: Thank you, Ms. Buck. I will let Ms. Buck know that some of your questions about the animal loads, the live animal issues will be addressed in part tomorrow, not completely answered, but in this meeting tomorrow. So hope you can stay for that.

Yes, sir?

MR. SMITH: Tom Smith once again. I don't know quite what to say after that last -- wow. Just real simply. Is tumble marinade considered not intact?

DR. ENGELJOHN: This is Engeljohn. I think it matters the conditions. If the marinade is injected below the surface, obviously, yes, it would be. Anything that jeopardizes the surface such that contamination gets below that, it would be.

It matters as well whether or not a vacuum is applied during the tumbling such that we know that a vacuum tumbler draws the contaminants from the outside into the interior. So if the surface is

manipulated such that product can be contaminated below the surface, then I would say yes.

MR. SMITH: The very idea of marinating is to bring what's outside in whether it's mechanical or whether it's -- we call it static -- or whether it's just soaking. I mean, anybody who marinates something obviously has in mind to bring the outside in. So, really, under that definition, would static marinade by the very nature of marinating be -- does any marinating leave a product intact --

DR. ENGELJOHN: Okay. Again, I think it matters on the circumstances. As the current definitions for what is an adulterant on whole muscle product is that if that product likely is going to be processed in a manner such that the surface is going to be well-cooked and the interior may, in fact, be raw, undercooked, that is an adulterant. So it matters on the circumstances. And I think you need to identify what your particular operations does. It's not a simple yes or no.

MR. SMITH: And just one more question, please, or a comment, I guess. That questionnaire I

think was a very good start. But I would -- you know, I think if Barak and Hillary and John can all get out there and beat the Bushes, I think it's hard to be able to learn to drive a car by reading *Car and Driver*.

I would invite anybody -- invite or hope that the folks here in D.C. would get out into the plants and see -- I mean, you can ask your IIC's, but until you go see and you see how these things fall down and affect the small businessmen, which this country was built on -- and hopefully -- you know, small meat shops are falling by the wayside and, you know, small hardware stores, blah, blah, blah. I would just, you know, almost beg you to get out there -- excuse me -- and get into some small plants and see how these decisions cascade downhill or the lack of decision.

I laid awake a little bit last night because I'm kind of a country kid, and I'm thinking I'm going to D.C. and I don't know, you know, whether they really care what I'm going to say or make a legitimate attempt. Honestly I think the last

presentation, while it did provide a lot of the answers to the questions I had, it seemed like I didn't have to ask them and you kind of brought them to the forefront. So I think that was a good thing, because I feel a little bit uncomfortable as a small processor asking some questions, whether they're totally warranted or not, and I was glad that you brought them up rather than me having to ask uncomfortable question --

DR. ENGELJOHN: We appreciate -- we do appreciate your input, and I will say the Agency makes a very specific and concerted effort to look at the operations that are large, small, and very small and those that produce a large amount of product versus a small amount of product versus a multitude of products differently. And we do not want to have a one size fits all. We do start there and then we work to enhance that, and we welcome any input you and your colleagues can provide the Agency on what we need to attend to. So we appreciate your input.

DR. GOLDMAN: Go ahead. Yes, Ms. Rosenbaum.

MS. ROSENBAUM: Yes, hi. Donna Rosenbaum with STOP, Safe Tables Our Priority. I had just a general question and then a couple of more specific questions. Do you intend to continue with these types of questions and do them over again as you incorporate information from seminars such as this if there are maybe topics you haven't touched about -- touched yet in the question set?

DR. ENGELJOHN: I will answer first, and Chris certainly can add because he's the one who is going to be analyzing it, but yes. The issue is we do learn as we go forward, and the issue will be what we missed, we will add, what we asked that was not clear will be clarified. And it is important to us to identify what are the most critical questions. And I think we look at this as a tool that will be improved upon and will be repeats.

MS. ROSENBAUM: Okay. There's some questions -- oh, did you want to comment on --

MR. ALVARES: Well, I guess from an analyst's point of view, you know, more data is always better, and I think, you know, the checklist

in itself I think can become more powerful if you can monitor these kinds of best practices and these kinds of activities over time and determine what the trends are, and I think that would lend more information and more guidance towards how to direct resources.

MS. ROSENBAUM: Yeah, I agree. Best practices are good to have as guideposts. There are some issues in looking over the agenda for this whole seminar, not even just this specific subsection, that from a consumer advocacy group's point of view we're sort of missing from the whole discussion. It was mentioned really briefly in Dr. Samadpour's one of his slides this morning, and that is the issue of employee turnover and workover turnover in plants themselves as a possible mechanism for interventions not working. And I was wondering if you have had any information like that or have gathered any information that could be useful?

DR. ENGELJOHN: I would answer -- this is Engeljohn -- that we didn't collect that kind of information and certainly can look into what it is that we can do. Again, it will be our FSIS

inspectors that are responding to these questionnaires. And I will identify that we did specifically make it clear to the inspectors if they were to complete it, that they were to share it with plant management in order to make sure that at least if there was other information to substantiate different answers, then the plant could provide that information. And then the frontline supervisors could look at it.

But I would say that there are other things the Agency is looking at. We announced last fall that we were going to begin looking at corporate information perhaps to better inform the Agency. And we are aware of some work that's been done from an economics perspective in terms of financial information. There has been some work to demonstrate that that may be a useful tool to identify whether or not the viability of a corporation is such that they may be changing practices as a consequence of their financial viability. And so it's those kind of things that the Agency is not just looking at what information we have available in the plants that we

regulate, but there are other tools available to us that we have expertise and the capacity to tap into, and we will.

MS. ROSENBAUM: Okay. Because it's our opinion that in many cases, the efficacy of the interventions depend highly on the skill level of the plant employee that might be applying them. And we've been led to believe by various people who have approached us in the course of the last few years that some of those key employees might, for instance, be subject to INS raids and such forth that they're losing a lot of people with a lot of good, in-depth, long-term knowledge on these types of interventions, and perhaps that's an issue here. Thank you.

DR. GOLDMAN: Thank you. Mr. Painter?

MR. PAINTER: Stan Painter with the National Joint Council. I'm wondering, does team inspection and risk-based inspection and/or risk-based inspection play a role in the reduction of the *E. coli* and, if so, how?

DR. ENGELJOHN: I'm sorry. I don't -- this is Engeljohn. I don't have an answer to that, nor

have we looked into it, nor has I think it actually been something that we would have focused on. The Agency's perspective is looking at what is in place in the operations, what do our own data tell us.

To the extent that we can look at our data to parse out what we think might be happening, we can, but I don't think that we have the intention or ability to look at that particular issue.

MR. PAINTER: Thank you.

DR. GOLDMAN: All right. Are there any questions from our call-in participants?

OPERATOR: We do have a question from Ilene Arnold. You may ask your question, and please state your organization.

MS. ARNOLD: Yes, Ilene Arnold here with Multi-Development Division. I've been -- listen to the questions and comments being made. I can tell you that sometimes it's pretty difficult. There is a lot of background noise. I apologize if someone has already answered this question. But the comments particularly associated with inspector and what they know or have known that headquarters may or may not

know or be aware of is of interest in the context of the checklist information collected. When inspection program personnel are assigned to verify regulatory compliance, if they certainly observe conditions that create unsanitary conditions or practices or certainly observe product adulteration -- observe conditions that -- from determining that product is not adulterated or mis-branded, certainly those inspectors have the authority to take regulatory control action.

With that in mind, the *E. coli* 0157:H7 was reviewed as Dr. Engeljohn indicated by the frontline supervisors, and that was actually directed by the OFO district offices prior to the electronic submission.

So this is my question. Has there been any feedback from the frontline supervisors associated with them documenting deficiencies of knowledge or deficiencies in execution in the inspection program personnel they supervise that would demonstrate that the checklist information was not appropriately collected or that would -- or any other FSIS program

area evaluating data to believe the data collected is not accurate?

DR. ENGELJOHN: This is Engeljohn to answer. I would say that, at this time, no, there has not been that kind of analysis, nor do I know that we've collected it, but it certainly is an issue for which we need to take attention to and address. But, to my knowledge, we have not.

DR. GOLDMAN: Okay. Thank you all for your questions and comments and participation in this session. We are at a break. If I could ask people to return in 15 minutes, we'll end the day with four presentations from FSIS. Thank you.

(Off the record.)

(On the record.)

DR. GOLDMAN: Before we begin this last session, it was pointed out to me that the opportunity for comments are specified as comments on issues and topics presented in the preceding session. So as is customary for FSIS, we want to invite anyone who has a general public comment to do so at the end of this session. So you will have an opportunity to

make a general comment if you'd like. There is a designated public comment opportunity tomorrow as well. But for anybody who may be leaving today and you'd like to make a general comment that's not relevant to a particular topic, you are welcome to do so.

Let me now move to the last session. Again, we'll have four relatively short presentations by FSIS and then we'll have again an opportunity at the end for about a half an hour or so for any specific comments or questions about these presentations, and then any general comments.

Let me introduce first Dr. Carl Schroeder, who is currently our deputy director of the Risk Assessment and Residue Division and was formerly affiliated with the University of Maryland. And Carl will talk to us about the two existing risk assessments related to *E. coli* and our plans for updating those risk assessments. Thank you, Carl.

DR. SCHROEDER: Good afternoon. As David mentioned, today I'll tell you about the risk assessment work that FSIS has done for *E. coli*

0157:H7, focusing on a risk assessment we did in 2001, one we completed in 2002, and two that we are currently working on. Next slide, please.

Before I talk about the risk assessments, before I talk about the risk assessments, let me take you through the process in general how we work. When we set out to do a risk assessment, we begin developing a risk assessment plan and gathering data for that risk assessment. We then work with our risk managers to formulate and refine risk management questions. We then develop a risk assessment model in an attempt to answer those questions.

When we're done with that, we have the model peer-reviewed independently so that we can get an understanding of what we've done well and what we need to improve. We then have public presentations. We receive comments from stakeholders. We revise our risk assessments in light of those comments and post them to the FSIS website. I'll stress that throughout this process, it's an iterative process especially when we work with our risk managers to refine our questions and our assessment. Next slide,

please.

In 2001, we completed a risk assessment for *E. coli* 0157:H7 in ground beef. And this was meant to give a baseline estimate and to help our risk managers see what mitigations might be effective for reducing *E. coli* in ground beef. On the next slide, the two questions that we were asked was what is the risk of illness for *E. coli* 0157:H7 in ground beef and what is the occurrence and extent of *E. coli* contamination at points along the farm to table continuum. Next slide, please.

This was one of the first models that we developed, and we developed what we call process model. Without going into depth, what that basically means is at every point along the processing chain from farm to table, we try to get data to inform those points and model them. The next slide.

Based on that model, we came up with the following results. In answer to the question on risk of illness, we predicted that in June to September, the warmer months, 1 out of every 600,000 ground beef servings cause illness. And in October to May, that

risk reduced to about 1 out of every 1.6 million ground beef servings.

Some of the risk factors for contamination of ground beef with *E. coli* included the prevalence of *E. coli* at feedlots, the occurrence and extent of carcass contamination, the effectiveness of procedures used to decontaminate carcasses, and the effect of carcass chilling. The next slide, please.

Excuse me. The conclusion from this is really the mitigations during cattle production and slaughter were predicted to be very effective for reducing the risk of illness from *E. coli* 0157:H7 in ground beef. So this gave our risk managers a beginning, a baseline from which to work.

On the following slide, in 2002, we did a risk assessment, a comparative risk assessment for 0157:H7 in intact or non-tenderized beef steaks compared to non-intact beef steaks. This was requested by our risk managers in light of some epidemiologic evidence that suggested steaks were causing illness and in light of a report from the National Advisory Committee on Microbial Criteria for

Food. Next, please.

The question that we were asked: Do non-intact, blade-tenderized beef steaks pose a greater risk to the consumer from *E. coli* 0157:H7 compared to intact beef steaks? Again, without going through it point by point, this is another what we would call process model, relatively complex, where we tried to model each step in the pathway.

And on the next slide, our results suggested that, in terms of contamination, about 2.6 of every 10 million servings of intact beef steaks were contaminated with *E. coli*, and about 3.7 of every 10 million for non-intact. And that translated to a risk of illness of roughly 1 illness per 16 million servings of intact beef steaks and 1 illness of roughly -- for every 14 million servings of non-intact beef steaks. And so from this we concluded that the risk of illness from *E. coli* 0157:H7 in non-intact beef steaks is not significantly higher than the risk of illness from intact beef steaks. Next slide.

So those are the two risk assessments that

we have completed. The two that we've recently begun I'll tell you about to close my talk. The first one is 0157:H7 pre-harvest risk assessment. We heard several questions in the last session regarding pre-harvest mitigations. And this is one where our risk managers want to know the effectiveness of various pre-harvest mitigation such as vaccination et cetera.

On the next slide, the objectives were to develop a screening tool to allow more rapid assessment of pre-harvest risk management options and to determine if pre-harvest intervention is a cost-effective food safety strategy under the most optimistic assumptions. Next slide, please.

This is one where I think we're learning from some of what we've done earlier, and many times to answer the questions that were asked, we probably don't need the types of complex process models that we create, and so we're trying to answer this question with a simplified model, but we're in the very early stages. On the next slide, please.

We hope to have the pre-harvest portion of this risk assessment completed in fall of 2008. I

would like to stress that in working with our risk managers, we anticipate expanding this risk assessment to look at all mitigation options not just pre-harvest, similar to what we did in 2001.

And, finally, on the next slide, we are updating the comparative risk assessment that I told you about for intact and non-intact beef where we essentially did not see a difference in the risk of illness. We're updating that in light of some epidemiologic data in the past several years that suggests that needle tenderized steaks might be a risk of illness for *E. coli*.

Our objective is the same, to estimate the risk of illness from *E. coli* 0157:H7 in intact versus non-intact beef steaks. And the proposed model, we plan on using a model that's very similar to the one we used in 2002, but we're working with our partners at the Agricultural Research Service to get new data so that we can use those data to inform the updated model.

We're looking at studies that would tell us about translocation and distribution of *E. coli* in

mechanically and chemically tenderized beef, data for the growth of *E. coli* in non-intact at various temperatures, the effect of cooking on *E. coli* in non-intact steaks, and the effect of sanitation processes on removal of *E. coli* from blades and needles that are used to tenderize beef. And we're in the preliminary stages. We would hope to have that completed by the fall of 2009 once those new data become available.

And so, lastly, to summarize, in addition to the two risk assessments that we've completed, the one in '01 and '02, we're conducting a risk assessment to look at pre-harvest interventions for *E. coli* and beef. We will then expand the scope of that assessment to look at other mitigations. We are in the process of updating our comparative risk assessment for *E. coli* in intact and non-intact beef.

And, lastly, all of our risk assessments are response to comments, public comments that are submitted, and so forth. We make available at our website that you see listed there. Thank you very much.

DR. GOLDMAN: Thank you, Carl. Next up we'll hear from Mr. Loren Lange, who is my deputy in the Office of Public Health Science. We're glad to welcome him back into public. He's going to sit up here to deliver this presentation.

But Loren has been the executive sponsor for the baseline programs in our Agency for a number of years. And most of you are very familiar with the trim baseline study, which was conducted largely over calendar year 2006 and ended early in 2007. It is continuing to undergo various forms of analysis, and Loren is going to present with you -- to you the early results of this trim baseline as well as the plans for future analyses. Thank you, Loren.

MR. LANGE: Apologize for sitting, but I can say I'm very happy to be here. This is my sort of first day out except for things like physical therapy since February 1st. So it is good to be here.

The data I'm going to present briefly today hopefully will be available in the first of two documents that we will publish on the beef trim

baseline. In preparing this presentation, I did finally get all my comments to Dr. Goldman, handed them in today as I got here. So we will be making some revisions in the report that I'm summarizing today and hopefully get that into Agency clearance by the end of next week. So I would hope that this within a month will be posted on the Web.

The second paper I'll talk a little bit at the end about some of the types of analysis that we'll cover, but the main thing, the second analysis, which is still ongoing, is taking a lot of production data that we have collected and doing the statistical analysis that turns the actual laboratory findings from the study into estimates of national product prevalence, accounting for non-responses and accounting for plants that are currently under production that weren't included in the baseline study.

So with that I'm going to just briefly sort of give you an overview of what the baseline study was and then talk about some of the major policy decisions we made or design decisions we made that

sort of kind of were relevant to a lot of the discussion earlier today. And, lastly, then I'll present the results.

On the overview, as Dr. Goldman said, these samples were collected really from late December 2005 through early January of 2007. That was essentially a calendar year baseline. The last analyses were completed in early 2007. The design was based on getting at least 2000 samples to make further analyses of the results. These samples were analyzed at our three laboratories, which are in Athens, Georgia, St. Louis, Missouri, and Alameda, California, and at a contract lab, Food Safety Net Services, Ltd., at San Antonio, Texas.

It was a management decision that even though our contract lab is an ISO 17025-accredited lab for analyzing for *E. coli* 0157, because those were, you know, regulatory findings, the management council decided that we would, you know, do all the 0157 analysis at our labs, so that also created complications. At each sampling event, we actually had our inspectors collecting two samples, one for

0157 in our labs and one for the contract lab.

The analyses that were conducted were basically sort of what was recommended by our National Advisory Committee for Microbiological Criteria for Foods is that we would do both presence, or prevalence and onification (ph.) for *E. coli* 0157:H7, *Salmonella*, generic *E. coli*, coliforms, Enterobacteriaceae, and aerobic plate count. Existing laboratory's methods would be used where they were available. If not, they would be AODC-approved methods if there wasn't something that we actually did in our labs.

Now, I mentioned there were a lot of design issues, and some of them certainly have been related to -- the questions that have been raised today on, you know, how to collect samples of beef trim. So we'll go a little bit over where, when, how, and what.

First topic of where, by where I mean at what type of facilities. There was a decision made that we would collect these samples, the beef trim baseline, at the plants were carcasses were -- no --

cattle were slaughtered, turned into carcasses, those carcasses were chilled and then fabricated and produced the trim. At that time, we -- in the initial design, we wanted to collect data on the interventions that were used in the slaughter facilities and samples would be collected at facilities where at least those facilities had an opportunity to make adjustments on the kill floor to, you know, adjust risk.

We recognized at the time there were -- the trimmings are produced, as they've been called today, bench trim, where people by primals and cut steaks and roasts and produce bench trim, trimmings -- also produced at retail. Just baseline, though, the trim would be those trimmings produced at the slaughter facilities.

The major issue at that time for not even attempting to try to deal with those downstream trimmings was a microbiology decision in the sense that we knew we could collect the samples at the slaughter facilities essentially the day after the carcass was slaughtered, chilled, and then produced

the next day. We have no real feel for the time for when those downstream trimmings are produced.

So, you know, people in the audience know a lot better than me about that. Some could be a week later. Some could be two weeks later. We may or may not be able to capture, you know, how long it had been since, you know, those trimmings or the primals were produced. And so there would be a lot of questions raised about handling temperatures and handling. So, you know, when microbiology weighs in on a baseline, they want every sample collected at the same time, shipped at the same time, arriving at the lab at the same time, all under the same conditions. So was actually the major situation there.

The when. We really have a lot of discussions within the Agency on two major options. One would be collecting beef trim at the end of the boning line where the carcasses, you know, finish fabrication, and the other after the product was accepted for use in raw ground beef. Proponents for the end of the boning line argue that, well, then our

baseline would be a really good measure of how well the slaughter process was working in keeping down both indicator organisms and pathogens.

But our risk assessment, which is one of our major clients of baseline information really wanted data on the contamination levels in trim that was available for use in raw ground beef. So the population that we were really measuring in became beef trimmings produced in slaughter boning operations that had passed existing food safety systems and had been cleared or were available for use in raw ground beef production.

The how. We had a lot of discussions with both industry scientists and ARS scientists from the early days before we even started this baseline. We had discussions about, you know, the pros and cons of collecting purge, poor drilling devices, and various amounts of surface slices. We've heard a lot of references to N-60. There were people talking N-25, N-30 at that time. I think those were the three major sort of numbers of surface slices. The decision was made to use what people have been

referring to as the N-60, a sample of 60 thin surface slices from a production lot.

Comment on purge, we were collecting samples from where the trimmings are going into these big 2,000 pound combo bins. Purge wasn't available at that time, or, you know, they're big, heavy -- most of the time they're heavy plastic liners, so if there was purge, it was the bottom. But we were collecting as they were getting filled and getting ready for use, shipping out of the plant or -- so, I mean, there really wasn't an opportunity to find at that time for us, baseline, you know, a purge from the, you know, bottom of the container.

One last comment on the N-60. I said the number 60 was based. Well, it references the publications put out by IC-MSF. 60 is probably the most intensive sampling program in those publications and really is sort of referred to as, you know, a sampling program to use where you have a severe hazard and the conditions are, you know, such that you might have an increase in the hazard.

As I think Dr. Samadpour pointed out, it is

sort of in the text if you go there. It talks about 95 percent probability of detecting, you know, a organism that's present at a certain level. So it's not -- you wouldn't go to either I think there's actually three different publications that talk about the 60 samples. They're not going to say, oh, this is the sampling method we recommend for beef trim, but they are the sampling method sort of for a severe hazard and other conditions. So it was more -- it at least has its tie-in to sort of the most intensive, you know, sampling program that's referenced in those documents.

The what. We defined the term beef trimmings at that time to also include the subprimal cuts, such as boneless cuts, if they were being produced and used as components of all ground beef. I think in our development of the instructions, you know, if we got a question from the field on, well, when the sample of the subprimal not a subprimal, is how is it being processed in the plant. I mean, so if a combo bin of boneless chucks is right there with a combo bin of small trimmings, large trimmings, and

it's being handled as trimmings, then it was part of the baseline. If it was handled more how the primals and subprimals were going out, then it wouldn't have been included in the baseline.

We had a lot of discussions on whether or not to try to characterize the fat content of the trimmings we were sampling. And there was interest at that time. There was concern that, you know, high fat trimmings might be different. That was about the first time we were hearing about that.

But two considerations weighed in. One is we didn't think it would be always available to our inspectors. And, as I know some of the staff pointed out, someone could go to a 70/30 combo bin and actually collect a 50 percent fat trim and someone could go to another one and -- we had no control over, you know, really the ability of the people to sort of say, well, if the combo bin is 30 percent fat and you know that, make sure that your 60 slices are 30 percent fat.

So it was just deemed to be beyond the scope of the ability for us to really carry out at

that time. And this baseline study did not include any of the other components that you've heard mentioned today, the head meat, the organ meats, the AMR product, the very high fat content, you know, trimmings that would be destined for finely textured beef or partially defatted, you know, product and stuff that aren't really used as an ingredient in raw ground beef.

So that sort of covers some of -- a lot of the issues we went into. I've summarized the results in this publication that will be coming out soon on the next slide for the prevalence results. People seem mostly interested first in what did we find on the pathogen levels. Out of 1,900 samples analyzed at FSIS labs, we had 13 positives, .68 percent, which is a percentage of positive samples, not our estimate yet of national product prevalence. Wanted to make that clear. *Salmonella* findings, out of 1,719 samples, there were 22 positives or 1.28 percent.

Why the difference, the 1,900 and 1,719, I don't think it's entirely attributable to how FedEx delivers samples in Texas. The main reason was we

did have a higher temperature allowance. We allow a sample to come in for 0157 analysis at our regulatory labs at 15 degrees centigrade. For the analysis that was going to be conducted at the contract lab, microbiology determined that we didn't want samples coming in over 10 degrees. So we probably had some samples rejected at the contract lab because of temperature that would have been acceptable for our lab. So that is one reason. It may not explain all of them, but we're still kind of looking into that.

I will point out on this slide the one thing that was mentioned, that there's a lot of zeros with generic *E. coli*. Yes, we found generic *E. coli* only in 15.7 percent of our samples. Just our look back at history is sort of -- 15.8 was the percentage of on the cow/bull baseline study back in the '90s. I think steer/heifers were somewhere around 8 percent. So, you know, there are still a lot of zeros when you're looking at generic *E. coli* in beef trim or on carcass samples. Those earlier baselines were not sponges like we do today. They were actually incision type baselines.

The reason we added Enterobacteriaceae was because we thought it would be, you know, present a lot more and may be a better indicator of sanitary dressing procedures. And, yes, we found it 59 percent of the time. So that is a positive indicator organism that, in the sense of each criteria, is it present a lot? Yes, it was present a lot in the beef --

Now, the next slides briefly summarize what we found in our quantification. And I do apologize. We have to sort of imagine yourself that your down at the ground level looking through a three-dimensional bar. So the first one is really six although it looks like it's about 5.6 on the stuff. It's a projection back to the line. So if anyone -- it's confusing.

This slide shows 6, 3, and 3. As I mentioned, we had 13 positives. We were able to quantify or run our MPN number on 12 of those. Six were below our MPN level of detection. That doesn't mean they're zero. I mean, you got two things that could happen. If we take 325 grams and we analyze

five 65-gram subs to determine prevalence, take 325 grams for the MPN method, but you don't -- you really only get 65 analyzed at the same original method. So the level of detection really does change. So those six in the first graph that quantify, you know, they could actually be negatives because it's a heterogeneous, you know, distribution of the product or they really were below our level of detection.

The six that we quantified, the average was .56 colony-forming units per gram. It's always good for me to think in terms of a quarter pound hamburger. That's 113 grams. The .56 is 63 to 64, you know, colony-forming units in a quarter pound of ground beef although this is trimmings, just to sort of put it, you know, in a perspective that, you know, is easier to sort of visualize.

The range was from 4 to 170 if we put it in this. And, as I said, one sample wasn't positive. Generally, I guess we would say that the levels were pretty low. The highest level we found was 1.5 CFU per gram, which, as I said, in a quarter pound, that equates to 170 organisms.

The next slide is just for comparison. We started in about July quantifying our raw ground beef samples coming into the lab. We had nine results from July to the end of the year that were quantified. Again, six of those, six out of nine of those were below our ability to quantify our MPN method. We did find one fairly common, you know, contaminated ground beef sample that had a result of 43 colony-forming units per gram. It was a raw ground beef sample collected in late September. So that's sort of -- since we've been trying to quantify *E. coli* 0157, that's certainly been our highest number.

The next slide, as I mentioned earlier, we had 22 positives for *Salmonella*. We were able to, you know, quantify all those 22 positives. Well, we ran the MPN method on all of them. Our level of detection here is higher in order of magnitude than it is for 0157. So 13 show up as less than 0.3, which for our method at the contract lab for quantification was there. The average was certainly higher when we did find positives in 0157, where I

said it was .56. The average was 12.6 colony-forming units of *Salmonella*. And it ranged from up to 46 was the high, 46 CFUs per gram bundled up.

Staff wanted me to just sort of make one comment. There's been a lot of comments about our level of detection, what's on -- are posted on the Web. There's a lot of sort of level of detection, and there's a lot of sort of art and uncertainty to it, level of detection and looking to these organisms can vary on the fat content for the sample. It can vary on the competing organisms, what's the microbial flora in the sample. It can vary. We use 0157 for, you know, fermented sausage and raw ground beef, that that now changes.

We post an LOD because our crediting body wants us to post an LOD. So the one that's referred to there is .23 colony-forming units per gram is something we demonstrated in our lab validation studies. If you ask the question do you think we ever find one unit at one of these samples? No, because it is enriched. Yes, I think our microbiologists will say sometimes we get, you know,

one of our positive samples may be -- grow out of a single organism.

Do we always find one organism in a 65-gram sub? Probably not. You know, there just isn't enough resources around to sort of generate the types of study you would really need to sort of say what is our level of confidence of finding one, our level of confidence of finding two, and then you'd have to do it across different products, different fat content, different background levels of competing organisms.

So I promised our micro division I would at least comment on what looks like a high LOD isn't necessarily what we do find in our lab on our regulatory samples. We believe most of the time we find very, very low levels.

The last slide -- well, next to the last slide here I put up just as illustration when the report comes out. We did this type of chart and this type of distribution for all our indicator organisms. This one happens to be for the generic *E. coli*, where we have 270 positives. What was -- 50.7 percent. I forget exactly. We did get a quantification on all

those, but as you see here again, over 84 percent were negative by our method. You can see there are a few out buyers, the last 20, 10, and 1 are fairly high levels of indicator organism. We're going to be looking a lot more at the data, the levels -- and the different indicator organisms.

And I'll finish with our sort of what our next steps are. Well, first you will see a summary of these results, hopefully, very soon on our Web. We need to complete the analysis of, you know, the data to generate our estimates and national product prevalence. Just so people know what we did collect when we collected the samples, we've collected a lot of data on the interventions that were used. We've collected data on the age of the carcasses, whether it was a line kill versus a bed kill, and we tested whether or not the plant was doing routine testing for 0157 and a lot of information on the lot size that was sampled and the daily production on the plant.

So we've got a lot of work to do with policy and looking at the types of, you know, further

analysis we want to do in our second report we'll put out on the baseline. The reports will try to look at pathogens versus indicator organisms, but, probably, if you find the pathogen so few times, it's, you know, it's really problematic to sort of say you're going to be able to demonstrate sort of a relationship between the indicator organisms.

We think there's a lot more promising analysis that's going to be done in terms of, you know, the data that we collected on interventions and the levels of indicator organisms. And, of course, we will be looking at the full analysis of this baseline and exploring implications of policy changes. I thank you and sorry I had to sit.

DR. GOLDMAN: Thanks very much, Loren. Next, we'll hear from Dr. Ken Petersen who is our assistant administrator for our Office of Field Operations, and he is going to discuss his conclusions from some of the finds related to FSAs that were conducted last year in plants that may have had a positive *E. coli* 0157s. Dr. Petersen?

DR. PETERSEN: Okay. Thank you. Good

afternoon. Good to have everybody here with us today. Actually, I've got two things I want to talk about. First, to go over some of the information we've seen in our recall data over the last few years particularly related to *E. coli* and then also illnesses, and then we'll get into some activities we did for food safety assessments related to *E. coli*.

So last year -- we touched on some of this, but I don't think all of it -- 21 Class 1 recalls due to *E. coli*, which as you'll see in a minute was a rather significant trend in the wrong direction from what we've been seeing in recent years. Total poundage, over 33 million pounds. Some of that was driven by several large recalls multi-million pound recalls which we had not seen in a while.

Not unusually, most of them were ground beef-related. We had one or two, or really one kind of odd one that we hadn't seen in well over ten years, a pepperoni-related 0157 recall and then one or two, I believe, related to mechanically tenderized steaks, which was an issue we thought we had addressed several years earlier, really, for similar

reasons, where we were seeing outbreaks and folks were not adequately considering potential hazard with that product and that pathogen.

So breaking them out, how did we come to find these 21 *E. coli*-related recalls? Eight of them due to FSIS testing, which, given the fact that there's a recall by definition means the plant did not hold the sampled lot. Three were due to industry sampling, where either they got a late result or something else happened and the product was already in commerce. These would be the results they brought to us. Ten were due to some kind of outbreak-related activity, and that's kind of the big changes we'll see. The next slide.

I think we don't need to get so much hung up on the numbers on this slide. For one, you probably can't see them in the back. But look at the colors of the bars, and I'll kind of tell you what you're looking at here. The far left side, the high bars, the purple bars, are total recalls by year. And, again, the trends are just important. They're important here. Not the raw numbers. The far left

side is the 2000 calendar year. The far right side is last year calendar year '07.

And so we see the first three bars, the purple bars, 2000, 2001, into 2002. 2002, 113 recalls, lots of outbreaks, *E. coli*, deaths, *Listeria* recalls, a very bad year for public health. The next colored bar down, kind of the reddish bars, are the recalls in that year that were related to *E. coli*, and then the beige bars down at the bottom were the recalls that were due to some kind of outbreak.

So when you get past 2002 -- and, of course, in the fall of 2002, specifically October, is where we pushed out policies expecting plants to reassess due to *E. coli*. Coincidentally, fall of 2002 is when we graduated our first class, I believe, of the EIOs. So we had a new capacity to really assess what was going on as far as food safety systems.

Then, in subsequent years, obviously, the number of recalls went down quite markedly, 68 the next year, 48, 53, and then 58 last year. But you also see the recalls related to *E. coli* down

significantly. Twelve in 2003, then 6 in '04, 5, 8, and then spiked up to 21. Similar story for outbreaks, down markedly. And that parallels some of what we've heard here earlier.

Agency pathogen *E. coli* results in products we were testing was down and largely became flat during that period, in the .17 to .2 percent range we were testing. Our strategy was to focus on product that was going into the marketplace in its raw state.

And then so it would be reasonable to conclude that things were -- could be improved, but things were static at a low level in the time period from 2003 to 2006. And then things became somewhat undone last summer. And then that's obviously why we're here today, with both *E. coli*-related up from 8 in '06 to 21 in '07, *E. coli*-related outbreaks zero that led to a recall in '06 and up to 10 in '07. Okay.

Then moving on to the food safety assessments-related notice 6507, which was put out last year. We've had some discussion on this. FSIS personnel did awareness meetings with the plant, said

here's the notice, here's kind of what's in it, here's what we expect you to be doing, ascertained whether and how the establishment had reassessed, and then, as was described earlier, walked through the checklist. Okay.

And collecting a variety of information, identify operations that were not employing certain multi-point strategies to deal with *E. coli* 0157:H7. The converse of that would be finding plants that were doing things well. Capture production control practices so that we can analyze that data. It would help us prioritize food safety assessments, and we'll see how we did that in a minute. And, then, ultimately, use the data to inform our risk-based strategies, including which -- how to focus our risk-based testing.

The constellation of plants that were subject to the reassessment -- we saw this number earlier -- was about 2,322. There's about 5,300 plants in the federal system that are subject to HACCP and SSOP regulations. So out of the 5,300, just over 2,300 were under 6507. Then on the far

right side, I gave some percentages, I think, to give some frame of reference here.

Of the 5,300 plants that we have nationally for all, you know, all products, again, HACCP and SSOP, about 51 percent of the overall population is very small plants in the big pool. Here, it was a little bit above that. About 58 percent of the ones under the *E. coli* reassessments were very small. So a little bit above the 51 percent in the broader pool.

Small plants here was about 39 percent. They make up about 40 percent of the overall pool. So that's pretty much spot-on. Because very smalls are over-represented, somebody has got to be under-represented in this particular survey, and so the large plants, of which there were 61 making up 3 percent, they make up about 7 percent of the overall 5,300-plant population. Okay. Next slide.

Then, in mid-November, after the survey had been out for a while, we started initiating some food safety assessments at certain beef-producing plants to assess the outcomes of their reassessments. And

we established some criteria for prioritizing how we were going to work our way through the food safety systems. And basically a two kind of pronged approach.

Starting out with large volume plants that slaughter and/or processing moving down to small/very small slaughter operations with low volume, focusing on slaughter because, obviously, that'd be the entry point for the pathogen and then moving down to small/very smalls that grind or produce non-intact steaks with a large volume and then very smalls that grind or produce with the low volume.

So each district would work their way down. Some districts don't have a lot of large plants, so they, you know, end up with a second tier. Some have a lot of large plants, so they'd perhaps be spending some time at the upper tier. Then we gave the districts basically two distributions. One was large beef slaughter, the top 100 beef slaughter plants in the country. That would help them obviously with large slaughter volume. Once you get below the top 100, those plants below that slaughter are less than

20,000 a year. So 20,000 and above pretty much makes up the top 100 beef slaughter plants in the country.

Then we gave them a list of the top 40 or 50, I believe it was, grinders. So that was kind of their metric to start working their way through. Okay.

Then, within each of those categories -- again, they kind of worked their way down it. If I don't have any large plants, then I go to the small plants, and on. They worked through this prioritization. First of all, first of all, did the plant not reassess? Obviously, that'd be a good candidate to do a food safety assessment. As we saw earlier, very few plants were in that category, but there were a few. And we had made it known early on they would expect to see us pretty soon. And they did.

Then, those plants that reassessed within the last six months. Some plants, which is good, saw the difficulty that was occurring earlier in the summer, June, July, and so they reassessed then. They didn't wait for the Agency to tell them, hey,

you need to reassess. So some of them that's why we came up with the six-month window. When we saw trends in 0157, did some, you know, come out of the box early?

But if they did reassess, did they make no changes? That could be a perfectly appropriate decision, but it might not be. And if they made changes to their HACCP plan or prerequisites or SSOP, those with inadequate support were a focus for a food safety assessment, meaning they made some changes. It's difficult to understand why they made those changes or those rationale for making those changes. That leads us perhaps with some questions about the integrity of the plant.

And then plants with either no interventions or using measures that were inconsistent with the best practices. Again, the best practices were not a requirement, but they did -- they do kind of lay out a consistent way of controlling the pathogen. Okay.

So then, with that, our EIOs went out and conducted food safety assessments using those

criteria, and between mid-November and a couple weeks ago, we did 224 food safety assessments pretty much related to this activity. 95 plus percent, probably closer to 98 percent were driven by one of these criteria. We also in this time window had about 13 *E. coli* positives through Agency sampling. So some of those would have been caught up in this. We didn't list that as a priority, but it's already a priority. If you pop a positive, we're going to be in there looking at what you do. So 224 was the number that we did. Okay.

So what did we find? All 15 districts were involved. Obviously, beef production, certain slaughter is focused in certain geographic areas, but some parts of the country do more, some do less. 34 of the 224 food safety assessments basically resulted in no action, acceptable findings, the plant had a well-articulated program, and they were implementing it effectively.

190 had various actions, kind of, you know, moving from least severe up to most severe; 9 of them we issued what we call a reassessment letter, used to

call it a 30-day reassessment letter. That basically is we think your plant looks pretty good, looks like you have everything there, but we didn't quite understand a few things, and so we give you 30 days to kind of re-articulate to us what it is you're doing; 122 the outcome was one or more non-compliance records, where there was some individual non-compliance, the aggregate of non-compliance did not rise to the level of a actual enforcement action, and so that was the appropriate outcome. 55 resulted in a notice of intended enforcement, which is where looking at their program in aggregate, we have sufficient questions that we give you basically 72 hours to make some revisions or we'll move you into a suspension, and 2 of the 55 resulted in a suspension. So 55 out of 224 basically resulted in an enforcement action. Okay.

And this breaks it out a little bit by plant size. So of the 224 food safety assessments, we had 55 NOIEs. Six of those NOIEs, those enforcement actions, or just over 10 percent, 11 percent, were in large plants. Of the 55 NOIEs, 25

were in small plants, about 45 percent, and of the 55 NOIEs, about 224 were in very small plants. And then one small plant was suspended, and one very small plant was suspended.

The overall kind of NOIE, 55 out of 224. This was kind of a biased sampled, you know, if we worked through the prioritization here. So that's about a 24 percent, or so, overall rate of enforcement actions taken as a result of these food safety assessments. That's higher than we see, you know, on average.

On average, over the course of a year, we do however many food safety assessments. Some are for cause. Some are not for cause. Some are for some pathogen-related programs. On average, we usually -- outcomes of a food safety assessment -- 8 to 9 percent tend to result in an enforcement action, meaning an NOIE. So, here, it's significantly higher than that, 24 percent, but it was a biased population because we hit them based on, you know, information we got from their questionnaire. Okay.

So common findings. Before we get -- kind

of work into these, let me make sure we understand kind of what we do in a food safety assessment. In a food safety assessment, really, it's called a comprehensive food safety assessment because I look at the entire system, the entire relationship of what the plant theoretically wants to do, what is their scientific support for what they're doing, are they doing it on an ongoing basis, and are they assessing and correcting as time goes on. So what's your theoretical plan and are you implementing your plan?

And some plants have -- not necessarily these ones. But you look at plants across the board. Some plants have one HACCP plan. Some plants have 60 HACCP plans. So the complexity is all across the board. Some of these plants no doubt had ready-to-eat products, and that would be part of the food safety assessment, because we look at everything. Sanitation performance standards, SSOPs, HACCP, what are you doing, and how is it working.

So these are kind of common findings that kind of rose to the surface, meaning we saw them more than once. And, typically, as we work through I

think there's five or six of them, you would see these things in aggregate. You'd have to have multiple kind of issues. I wouldn't want you to be sitting there thinking one of these just gives rise to, you know, an enforcement action, meaning a suspension. But they give you some insight into kind of what we found because, again, they were consistent.

Failure to conduct hazard analysis or identify the hazards associated with key steps. You have points, you have steps in your process, receiving, you know, marination, grinding, whatever. If you don't understand what your hazards are at each step, then there's no way you can decide how you're going to control that hazard, much less, know that you're doing it effectively. So you have to know the steps in your process. You have to know the hazards that may occur so that you can then decide how or whether you need to control those particular hazards.

For example, not articulating the hazards for a mechanical tenderization step to produce non-intact cuts. We addressed that issue years ago.

You're penetrating the surface of a steak. That's introducing a potential hazard. You need to think about how you're going to prevent, reduce, or eliminate that hazard from being reasonably likely to occur. So that didn't occur in several firms.

Failure to provide supporting documentation for decisions on selection of CCPs and critical limits. Critical control point is to prevent, eliminate, or reduce the hazard. And critical limits are your parameters for executing that.

So, for example, and there's a variety of these, but concentration of lactic acids. A plant would say our concentration of lactic acid is 2 percent, and that controls the hazard. Well, how do you know that? What science tells you that that works on that hazard at that point in your process? And they're unable to articulate that. And we see that through other interventions, other critical limits, failure to understand or have adequate support for what it is you're doing. Okay.

Failure to carry on monitoring or verification procedures according to your

prerequisite program. And a prerequisite program is designed to show that the hazard is not reasonably likely to occur. In this case, *E. coli*.

For example, certificates of analysis. Are you receiving them on every load? Do you receive different rigor of analysis from different customers? Is one customer -- we talked about N-60 earlier. There is N-15 testing. There is N-25 testing. So why would you receive different rigor of samples, results, from different firms? You can perhaps describe why. I can't think of it offhand. But why does that make sense in your program, that this supplier is an N-15, this supplier is an N-25? That's going to lead to some questions. So certificates of analysis.

Then what do you know about what that supplying firm is doing on an ongoing basis? What do you know about validated interventions that they're using, that it's effective, supplier letters that could be, you know, provided at a lower frequency.

And then basic monitoring or verification? Are you doing what you said you would do? You said

the hazard was not reasonably likely to occur. Fine. How do you know that and know that that is true on an ongoing basis? Okay. Next slide.

Failure to take appropriate corrective action according to your HACCP or exit program? We want you to -- all plants should assess what they're doing. Things can go wrong. That's perfectly understandable. Then you react appropriately and make a determination on whether it was something isolated or perhaps something structural or systematic. You got to assess kind of what's happened. What does your information tell you?

For example, failure to reject and control incoming beef with positive *E. coli*. If your plan doesn't provide for receiving positive samples, how is it that you did receive it? Whether you processed it is a whole different question, but even if you allow that to come into your plan, that's a failure. How did that happen? What was your corrective measures? How did you keep it out of your process? And so that was something else we saw.

Failure to maintain proper HACCP or -- show

CCP monitoring. Calibrations, frequencies and corrective actions are taken according to your plan. We can have a very good plan, well designed. I'm going to monitor at this frequency. I'm going to make sure my monitoring instruments are accurate. But how do you know that's true yesterday, today, next week, next month? Can you do that through monitoring records following your plan? And if we have a plan and we don't follow it, then we get back into questions about whether you're controlling the hazard of concern, which, in this case, is obviously *E. coli*. So that's not at all uncommon, failure to follow a plan, which doesn't make any sense. I spent time to design it, so why not execute it? Okay.

Failure to validate and verify the ongoing effectiveness of interventions designed to control the pathogen, including failure to describe procedures used in the application of the intervention. We'll use the lactic acid example, 2 percent. Well, what does that mean? What pressure? What temperature? We have the concentration. There are different parameters. That's part of validation.

I mean, you've got to execute them on an ongoing basis. Now, you can use as a safe harbor, a scientific study as long as you follow that study the way it's written. But then that study, you have to decide if it works in your facility. And that's ongoing -- that's initial validation. And then verify that what you set up last year is still working, that it's still doing what you thought it would do.

So initial validation is a problem. You're verifying that it's still working on an ongoing basis, some kind of verification activity, and that you're monitoring the right parameters in the predicted intervention if that is what you're using. So that's, again, not at all uncommon.

Failure to consistently implement segregation and disposition procedures to control product intended for grinding that is untested or that test presumptive positive or positive. You don't have to test the product. If you don't, and it's for raw, we're going to think that it's really intended for grinding -- I mean intended for cooking.

So failure to understand. Some of my process I'm testing. Some I'm not. What are you, you know, what are you, what are you doing? What are you doing with that product and are you implementing it correctly? You don't have to test it if you want to divert to cooking. That's fine. But you need to understand the segregation, the separation between those particular products.

Or if you do the right thing -- and, actually, this was a recall or two -- doing the testing, getting a presumptive positive, and then diverting that product to where it should go, which is for terminal leave alley, failure to do that. Or getting a presumptive positive, maybe holding that product for some period of time, which is fine as long as you control and segregate it, and then golly, gee, lose track of it, and it makes its way into the raw grinding stream. That's not a good thing. So it can go both ways. Understanding kind of what you're doing in your system or errors in a plan that was really well-designed -- you look at the pathogen, but failure to control it when you did pop a positive.

So that happens. Okay. And I think that's it. Okay.

DR. GOLDMAN: Thank you very much, Ken. All right. We're almost there.

Our last presentation today will be from Dr. Sally White, who is currently the director of our International Equivalence Staff in the Office of International Affairs. She is both an attorney and a food scientist by profession. And she has responsibility for determining eligibility of other countries to export products to the U.S., responsible for equivalence determinations, and prior to her current position in OIA, she was on the -- director of the Regulations Development Staff in our Policy Office.

Prior to joining FSIS, she served as a senior trial attorney with the Office of General Counsel at USDA and was also at one time counsel to the IG for USDA. She also is an adjunct instructor for those in the State Department's Foreign Services on international negotiations. Please welcome Dr. White to talk about our efforts with imported

products.

DR. WHITE: Thank you. I've been asked today to talk to you about the developments that we have been making with respect to implementing FSIS requirements in the countries that ship these products to the United States. And so today my discussion will be very general. I will go over some general areas such as our notification procedures, the status of our reviews of those country's systems, compensating controls that we've put in place, the equivalence process itself in general, and then also I'll touch on some port of entry issues.

Let me say that I don't have any charts for you today.

(Laughter.)

DR. WHITE: I'm sorry. But I think you've had lots of charts and lots of data and lots to think about from the other speakers. And, of course, all of this information will apply, if doesn't already, eventually to the countries that ship to us. Next slide, please.

These are the countries currently that are

shipping the products of interest today in this discussion. In the calendar year of 2007, these countries ship nearly 1.3 billion pounds of these products to the United States representing 22 percent of the total U.S. production of these products. There were five of these countries that shipped 1.2 billion pounds. And those countries were Australia, New Zealand, Canada, Uruguay, and Nicaragua.

Now, you'll notice that there are some countries that aren't on this list that are eligible to ship meat. They're simply not eligible because of animal disease restrictions to ship these particular products at this time. And those countries, when and if they become eligible, will also have to put the requirements in place. Next slide.

I want to talk a little bit about notification. We notified the countries by letter in October 19th of 2007. We let them know that we had this new control program that we're going to put in place in the United States and advised them that they had to implement or an equivalent process. Next slide.

On October 23rd, a few days later, we sent them another letter. And in that letter we advised them that we planned to extend our sampling at port of entry for *E. coli* 0157:H7 to the products. And, later, we also notified them through the WTO process of our new requirements, what it meant to them, which gave them an opportunity to comment within 60 days. This is a separate type of notification process we have to do for foreign countries that we don't do here domestically within the United States. These countries had until February 20th of this year to put our requirements or something equivalent in place. Next slide.

Now, part of our notification process was not merely just sending out a letter with a list of notices of the requirements for them to put in place. But we actually had conference calls with each of the chief veterinary officers and their scientists along with our scientists in order to explain just what this program meant. At these conference calls -- sometimes they were multiple calls to countries -- we had representatives from our OPHS, from our policy

office, as well as our office to discuss the various issues and how it would impact their programs. Next slide.

Well, this is the status. This is the next area I'd like to cover is the status of where we are with respect to reviewing these requirements. The countries were requested to send in the documents that demonstrated that they had, in fact, implemented these programs, and that is the first step usually in an equivalence determination. You look at the paper. And as most of you know, that's just the first step. There's usually two other steps that follow. The second step would be an audit of some sort during the year. And also, of course, continuous port of entry testing.

In the case of the document review process that we are now currently undergoing, there are four countries that we have completed, and they have been found to be equivalent. These countries have actually put in place our program, and in some cases, they have put in additional testing and verification programs that exceed our levels of testing. Next

slide.

That leaves us with the following countries on this slide which we are still reviewing. As you can see, these countries are all Spanish-speaking countries with the exception of one, which means that when we receive the thick packet of documents, these are translated, reviewed, and in some instances in order to clarify points within their program, we have to institute conference calls or meetings in order to make sure that we fully understand what it is that they're implementing. At this time, we have not completed our review, but with respect to most of these countries, it appears that they are adopting exactly what we have adopted in the United States. But we will not know that for sure until we've completed the review.

I want to mention at this point that it's not just the control programs itself that we look at. We also look at the methods that they use to test for *E. coli*. We look at those issues related to the control programs. Next slide, please.

Now, you've probably asking the question,

well, if you're reviewing these countries, what have you put in place to ensure that, in fact, there's protection for public health with respect to shipments from those countries. And until we have been able to make our final equivalence determination, we put in place compensating controls. And compensating controls simply means those measures that the Agency determines is necessary to put in effect until the process is completed.

In this case, what we decided to do was to increase the sampling at port of entry for these countries until we completed the review. So as each country is found to be equivalent, then the testing, the compensating control testing would be eliminated. I want to clarify that this is additional testing in addition to the routine port of entry testing that we're doing now for *E. coli*, which we will -- which I'll describe in a few minutes. Next slide, please.

I'd like to talk a little bit generally about the equivalence process. I mentioned before that there are three parts to equivalence process. But what I want to talk about now is that part of the

document review and just give you a flavor for exactly what it is we're doing with the countries' submissions for those of you who aren't familiar with the process.

Usually, when a country submits their program to us to demonstrate that they've implemented a requirement, in most cases, they're doing the same thing that we're doing. And that is a form of equivalence. That's compliance equivalence. But in some cases, countries will, in fact, submit something that is different, and they're asking for us to accept that as equivalence.

So we have a process whereby after the country sends in its request that we put together a team of experts the particular documents. And, as this slide indicates, we've done that with a team of experts with people from the Office of Policy and Program Development and the Office of Public Health and Science, and in some case others in order to review the documents and ensure that, in fact, they are equivalent or they are the same. And, if necessary, we develop criteria to apply the

particular facts at hand. Next slide, please.

Once that process is done -- and all of that, by the way, is documented in a file called an equivalence file. It's documented, minutes are taken of the meeting, decisions that are made within those meetings are documented, and, finally, then, when a determination is made based on those experts' recommendations, that, too, is documented and then of course -- next slide, please. Then we notify the country of equivalence decision.

And I think it's important here that you remember the terminology. This is not an equivalence agreement. This is a equivalence determination based on sufficient scientific evidence that's presented by the country and reviewed by our experts. That's what the process entails, and that's what we're doing here with respect to these countries and with respect to the methods that they're using. Okay. Next slide.

All right. I'd like to talk about something else here for a few minutes. In this particular instance, with respect to *E. coli* and port of entry testing, there have been some countries that

have come to us and asked for a risk -- for a reduction in the testing at port of entry. And we have developed some risk reduction criteria in that case, in any case that those countries would request it. And here are the criteria set forth on the slide.

First of all, there's an indigenous risk reduction. And if a country meets that -- and that means that there's a reduced risk for contamination compared to the United States because of indigenous factors; for example, 0157:H7 is not as prevalent or the animal-raising practices make it less prevalent, whatever factors are in place. If a country can demonstrate that, then they get a 50 percent reduction in sampling at port of entry.

There also is the enhanced testing program. And that means if a country decides to do additional testing, more than we require and more than we do in the United States, they have a more robust program, then there's a possibility for them to further reduce that number by another 50 percent.

And, finally, if they have an enhanced

government intervention program, they can reduce that testing even further. I'd like to use as an example one particular country -- well, two countries actually.

Australia is one of the countries that their program has been found to be equivalent, but they met all three of those criteria. So they have a further reduction for all three of those points. But it's very important to understand that even with the reduced levels of testing that it never gets to zero. There's always some port of entry testing. And, of course, it can change based on any additional information we receive from the country, if factors change in any way, audit results change the situation. That can change as well. So it's a continuous -- we do a continuous review.

One of the important things that Australia and New Zealand did for us is that they're forwarding their PFGE results to us so that we have that information. They're also going to be sharing with us their testing in their country. And they have a significant amount of testing that they do both from

the industry and from the government. They're making that information available to us. And we think that that will be very helpful for us in the future in terms of public health implications. Next slide.

Okay. I want to speak just briefly about port of entry activities. I'm sure there will be a lot of questions about this during the questioning period. We began our port of entry testing for these products on Tuesday, January 22nd, and to this day there haven't been any positives with respect to this testing. The products that are subject to testing are listed, of course, there on the slide. Go to the next slide, please.

The number of samples that are collected per country have been determined, a statistically based program. It's been determined by our Office of Food Defense and Emergency Response along with the Office of Public Health and Science. And, of course, that number is fluid is as it's increased or decreased based on circumstances or information we get about the country. For example, compensating controls. We add in another layer. Next slide,

please.

Basically, what we do is we assign a task to test for this organism. The import inspectors use the N-60 method to collect the samples, and we use the labs with the same methods to test for the organism. Next slide.

We recommend that the product be placed on hold at the port of entry until a test's results are received. And that usually happens. If a positive test result is received and the product is held, obviously the product will be refused entry. Next slide.

We will at that point, either one of those situations, we will be going back to the country to request information on other like products that may have been exported to the U.S. under the same production lot code. And I'd like to mention at this point that this is based on a presumption of positive. It's not the final positive. We go immediately back to the country.

If a positive test result is received and the product is not held, the product with the

positive test result and the product produced under the same production lot or code will be subject to recall. Next slide.

And, of course, the foreign establishment will be placed on intensive high inspection, and that means that the next 15 lots are sampled and tested and that those 15 lots that come in must be held at the port of entry while, in fact, they are being tested. And, of course, there is a variety of the regulatory actions that we can take depending upon the circumstances.

Basically, what I've talked about just generally for you today, having the notification procedures, the status of where we are in our review, the compensating controls that we put in place until we finish the review, or equivalence process in general, how we do that, and then some of the port of entry issues, I'd like to say I did receive some information before I came.

We've been starting the audit process, and I thought it would be of interest to you to know that we are doing that. And the first country that we

have been able to go into and verify what the country has said to us has gone very well. And so that information as we go through the countries on audit, along with what we're doing with the documents, they would be all part of the final picture and final report that we would do at the conclusion of this process.

So even though we are not through the process, I'm hoping that that gives you some information as to where we are and where we're going and what we hope to achieve. Thank you.

DR. GOLDMAN: All right. Thanks very much, Sally, and to all of our presenters in this last session of the afternoon. We do have time now for your comments or questions about this presentation. We'll start there first, and then if there are any outstanding general comments you'd like to make, we can do that. We'll hold those until the end if you will.

And why don't we start in the room? Go ahead, Mr. Smith.

MR. SMITH: Thank you. Tom Smith once

again, in case you don't remember. Hard to remember or hard to forget, one of the two.

Dr. Petersen, I was under the impression that four years ago there was supposed to be a reassessment that had to do with mechanically tenderizing or penning followed up by an FSA. That didn't pan out. I had personal experience that really never was about -- all the information I can gather, it was supposed to be about mechanical tenderization or non-intact beef cuts. And through personal experience and also some verification from some former very high up folks in your organization, that never happened. And if it would have happened, we might not be here today.

On the other hand, the most recent round of similar information gathering seemed to work very well. I guess a couple of things are giving me a burr under my saddle here -- is that why isn't the FSIS a source of the information or -- you know, we don't all kill 40,000 head a day or grind 100 -- tons and tons of ground beef. And I don't see the Agency as an authority.

You bring up, well, how do you know that your 2 percent lactic acid is doing what it's supposed to be doing? I mean, we got enough people to get the job done. We don't have statisticians and biochem majors on staff. Why is that -- why are you not a source of information for us rather than having your inspectors be document proofers and sample gatherers, because, to me, that's -- and no disrespect. It seems like that's what they've been relegated to.

DR. GOLDMAN: Okay. Can we --

MR. SMITH: And, additionally -- go ahead.

DR. GOLDMAN: You want to take that?

DR. PETERSEN: Sure. Okay. Well, a couple things in there. As far as the source of the information, I mean, we'll start today and maybe work back, but today I think we're doing -- I mean, you're the customer on this -- a pretty good job of getting the scientific information out. This has been one of Dr. Raymond's interests really the last year, year and a half. Small plant outreach. Getting the materials posted on the Web so you can access

materials. And not just throw everything on the Web. Somehow structure the information so if you're a grinder, you can go there. If you're a slaughterer, you can go there. If you're ready meats, you can go there.

Then we have, you know, a variety of course for our inspectors. With every one of those courses, the FSRE courses, we do have an industry regulatory education session. They're all over the country. I think they're pretty well attended. So, you know, that's good.

But you do go back -- I do have to go back a long time ago. 2 percent, if you're applying some kind of intervention to prevent -- or eliminate the pathogen, it is your responsibility to understand what you want to do, is it the right agent, and is it working correctly. Now, we can certainly help you with some information, but it is your responsibility.

There are different ways to do that. There are scientific studies. There are some studies designed for small businesses that don't involve some high-tech applications. If you follow the parameters

of the study, that is a good safe harbor for you. And then you validate it on an ongoing basis, that it is working for you.

I agree that sounds, you know, unusually simple, but there is I think a lot of information, you know, out there that can help you do what you need to do. But at the end of the day, you have to understand what you want to do on your plan. And then you have to understand to execute it because what we do see is some HACCP plans that get developed outside of the plant business, handed to the plant. They try to implement it, because they never really understood it in the first place, and they're the ones, frankly, that are getting in a little bit of jeopardy. So the ones who kind of understand what they want to do and understand when things perhaps get off track a little bit, they tend to be the most successful.

MR. SMITH: Thank you. Just to further that a little bit. We're approached by chemical salesmen, and they all have a song to sing. Everybody says, hey, this works best, this works

best, this works best, and who are you left to believe? I mean, you can read -- you can get swamped down in studies and try to figure one from another, but at the end of the day, you're taking somebody's word for it. And it has been my experience that the Agency is very non-committal in -- I'm not saying you should endorse somebody's product. I understand the implications of that. But the Agency has been very non-committal in saying, well, you know what, if this was my plant, this is what I would do. And that's it.

DR. PETERSEN: We do also have -- I mean on this thread, and I'll leave it at this -- a new separate office of outreach to help people like you, small businesses who don't have all day to find a bunch of information but who need the information. And so their job is to get it in a format that you can understand and not in the format that necessarily we understand. And that's led by Dr. Karlease Kelly. So that's a good resource for you. But as you get down the road, if that's not working for you, we want to know so we can make it better.

MR. SMITH: Ms. Kelly approached me, so I appreciate that --

DR. GOLDMAN: Let me just add one thing. I think, hopefully, if you're in one of the industry associations, your leaders are here. And they can help you. We work with them, and, certainly, they should be a resource for you as well. Randy?

MR. HUFFMAN: Thanks, Dr. Goldman. Randy Huffman, American Meat Institute. We'd be glad to help if we can. Get in touch, Tim [sic]. I've got four questions. I'll make them as concise as possible. I think we can get through quick, very quick.

DR. GOLDMAN: Long line behind you.

MR. HUFFMAN: First three are for Carl on the risk assessment. Why is the Agency not updating the original risk assessment questions and I think there were two primary questions in that, and maybe I missed it in your presentation. I missed the very beginning of that. And my reason for the question is the majority of the data used in that was pre-2000. We've got a lot better data now. And then a follow-

up to that is, has the Agency conducted a risk assessment on intact primals?

DR. SCHROEDER: To your first question. We're just at the beginning stages of the new -- sorry -- we're just at eh beginning stages of the new risk assessment, and we've begun with the pre-harvest stage, but we will certainly update, work with our risk managers and I suspect ask questions very similar to what was asked in the original risk assessment. And you're correct. There are a lot of new data out there now that will I believe let us come up with an improved risk assessment.

To your second point, yes, the comparative risk assessment that we did also included intact steaks, and so it was two-part, non-intact versus intact, and that's one that we're also in the process of updating.

MR. HUFFMAN: Okay. The questions that are in your slide don't necessarily address the risk of the intact products. I just wanted to point that out. Before that risk assessment, you mentioned -- I think it's in the third to last slide -- some of the

factors and the data that would be addressed. And I guess I would recommend, with respect to the use of intact products that are typically in a vacuum package that you consider the effective packaging and the packaging environment.

There's some new data that will be published soon, this summer, with respect to packaging treatment and the effect of the anaerobic conditions on 0157 over time through the shelf life. I think that could be a significant factor. Competitive microflora would play a role. So I would recommend that being considered. So that was a comment more. Not a question.

DR. GOLDMAN: How many questions?

MR. HUFFMAN: Just two more. Again, on that risk assessment, I strongly recommend that you consider the concept of integrated lethality as you evaluate the effect of cooking temperature rather than an end point temperature at the center of the product. It's important to capture the effect of heat throughout the process. I don't know if that's in the plan, but I think it's important. It was

talked about it at our BIFSCo best practices session. I think that Dr. Engeljohn attended, and we've got plenty of data to share on that if needed.

The final one is real quick. For Loren, with respect to the methodology described on identifying the trim and what products were included in trim, you mentioned that chucks or primals that were destined for raw ground beef production were considered and sampled as part of that baseline data. Did you separate out the percentage with positives that were primals in that baseline and is that data available?

MR. LANGE: That's an easy one. No, we didn't. Same as we didn't try to capture 90/10 versus 70/30 versus 50/50, we didn't identify things as subprimals because they all would have come into the lab. I mean, we would have had to have it done on the form and we didn't.

MR. HUFFMAN: So --

MR. LANGE: There's only so much space on the sample collection form, and when it came into the lab, they should have all looked like similar -- like

the pictures that Dr. Samadpour showed that they should be coming --

MR. HUFFMAN: Right.

MR. LANGE: So simple answer is no. It's not there.

MR. HUFFMAN: Final follow-up, then, does the Agency have any data on intact primals and the prevalence of 0157?

MR. LANGE: Not that we --

MR. HUFFMAN: To support the positions that we heard earlier.

MR. LANGE: If we have data, it's from ARS or some outside -- I'm not aware. We certainly haven't generated it from our own testing.

DR. GOLDMAN: Okay. Thank you.

MR. DANIELSON: Thank you. Dean Danielson, Tyson. Dan, you may have to help me out on this in a definition standpoint. If you've got a positive piece of meat or positive combo trim, is it considered to be adulterated at that point or is it adulterated if it's not disposed of properly or cooked?

DR. ENGELJOHN: This is Engeljohn. It's adulterated unless there are controls in place that demonstrates that it will be under control --

MR. DANIELSON: Okay.

DR. ENGELJOHN: Appropriately disposed of.

MR. DANIELSON: Okay. Good. So a lot of times, there's systems in place that we utilize that goes through a cooker, and we have under control, and there's seal issues.

So going, Sally, to the imported product, you said that if it's positive, it's rejected. If it's not really adulterated, if you're going to be able to manage controls, bringing it into a cooking operation downstream that's under your control, why aren't we allowed to do that?

DR. WHITE: The reason for that is that our regulations in Part 327 of the Title 9 C.F.R. does not allow us to do that with respect to imported product. We consider it adulterated and it's rejected. Now, there is a way to get around that, and that would simply be that the regulations would have to be changed.

MR. DANIELSON: I --

DR. WHITE: Because at this time that's why.

MR. DANIELSON: Perhaps that might be an interpretation, because is it really adulterated at that point if there are controls in place?

DR. ENGELJOHN: This is Engeljohn. And I would just clarify a bit on what Sally also offered there is that when it's presented to FSIS, it's as if it's a completed production lot. It's as if in this country it completed it's pre-shipment review and was released to go into commerce. And so from the perspective of the U.S., it is adulterated and we don't allow it to come into the country to be further treated to remove the adulterant. So the distinction is, it's imported, coming into the country as adulterated. So there is a distinction between the domestic where there is controls in place versus what can come into the country. So we would not allow it.

DR. GOLDMAN: Okay. Let me just check on the phone for a moment and see if we have any questions from our callers.

OPERATOR: Yes, thank you. Barbara Kowalcyk -- please state your organization --

MS. KOWALCYK: Hi, this is Barbara Kowalcyk. I'm with CFI. And I have a comment and then a few questions for Loren about the baseline trim.

First of all, I just wanted to comment on something that the first commenter mentioned, and -- his concerns. But I think FSIS should be a source of information for small plants, in fact, all plants, and should, in my opinion, be undertaking all sorts of validation studies, looking at the effect of the -- interventions and sampling methods. That was a very good point and I just wanted to reiterate it.

Now, onto the baseline trim study, as you know, I'm very interested in the baselines, and I have a few questions for Loren. First, according to the one slide, and it is difficult to hear when you're on the phone, you have a slide where you said how the samples were taken, and then you indicated that when the study was -- there were a wide variety of methods for sampling beef trim, which included --

purge, core drilling, and various amounts of surface samples, surface slices.

Did FSIS actually collect trim samples using all three of these methods? And, if so, did you have a sufficient sample size to compare these sampling methods, and if not, why not, because it's an excellent opportunity for FSIS to get more information -- the best way to do sampling.

The second question I have is could you define what it means to -- what FSIS means by randomly selecting samples?

And, thirdly, in the one chart in your presentation where you present the positive/negative results for the beef trim, there are more *E. coli* than there are samples in all the other categories. And it's about 200 samples more. I was just wondering why the sample size was larger for 0157 than it was for the other category.

MR. LANGE: I'll start with the last question. I did mention that there may be several reasons. But the primary one was the *E. coli* 0157 samples were shipped to an FSIS laboratory and they

were accepted at 15 degrees centigrade. At the same time a sample that was collected that went to FSIS, we debate whether to call that -- sometimes a companion sample -- it isn't the same sample. It is a separate sample collected from the same lot at the same time. It went to the contract lab food safety net, and it had an acceptance criteria for the analyses they were going to do of 10 degrees.

So we think one of the primary reasons we had more samples lost because of arrival conditions at the contract lab. That was a common cause for that, but we're still looking into the -- we will sort of summarize the details on what were the different reject criteria. But we think that was the primary one.

Back to your first one, no. I mean, for the baseline study, we wanted to extent possible a single sample collection method. We haven't done any comparisons ourselves. We have seen I think some limited -- this goes back to 2002 when we met with ARS. They had some data on different sample collection methods and results that they shared with

us. We had seen some industry data on the different sample collection methods, but we did feel we had to pick one and have it consistent across all the baseline samples.

But, I mean, your question sort of does raise something I didn't sort of mention. When you present the results, it's not an absolute. A baseline study is not an absolute. Those are the results we found with a specific sample collection method, with a certain packaging and shipping method, and with specific laboratory analysis. So you really can't separate out the numbers and sort of say, well, this is what beef trim is. It's beef trim collected at this point in time, you know, with this method of sample collection, shipped this way, and analyzed this way. And you change any of those variables, yeah, it is true. You could easily change the results. So the results are sort of, you know, part of an overall comprehensive definition of what was the baseline.

The question in the middle I can't remember exactly. When we ran this baseline, we had a

sampling frame, and we had it stratified. And there were a certain number of establishments in each stratum, and each month, you know, there was a program run to, you know, schedule the samples from each of the different categories of size.

When we do let's say our regulatory sampling, we always start with a list of plants that produce a certain product and each month -- it actually is done each week -- you know, there is a program that randomly select from the establishments that are part of a sampling frame.

DR. GOLDMAN: Okay. Thank you. And --

MR. LANGE: And, I mean, I guess the question is we've always had a general instruction for the inspectors to sort of randomly pick, but, you know, we probably don't focus on that. We do instruct the inspection program personnel to, you know, randomly pick a sample from what's available in the establishment.

DR. GOLDMAN: Thank you. Okay. We'll move back to the room now.

MR. CORBO: Tony Corbo, from Food and Water

Watch.

Ms. White, are the equivalence determinations on the 0157:H7 posted on the FSIS website? If not, do you plan to? Because I think it would be interesting to see what these other countries are doing either to keep the levels down or whether there are animal husbandry techniques that are different from ours that are keeping the levels down?

DR. WHITE: At this time, they're not posted. That's a good suggestion. We should look at that suggestion. I think at the end of -- when we've concluded our complete review would be the time to make a determination to do that.

You brought up a very good point, and that is that in many times when we review some of these countries' submissions, we see some very good inspection methods and some very good suggestions that our scientists can look at as well. That is one of the benefits of looking at different countries' inspection systems and being transparent about it.

MR. CORBO: Thank you.

DR. WHITE: Thanks for the question.

DR. GOLDMAN: Okay.

MS. DONLEY: Nancy Donley from STOP. I really appreciated your presentation, Sally, about the imported trim. And it's something that kind of brings this full circle back to where we started today, and that is non-0157 STEC. And I have seen studies where countries that export to the United States their trim, the pathogens of concern are not -- is not 0157 STEC. It's different STECs. My question to you is do you see -- and those countries test for the pathogen, that particular STEC of concern. Do you have any access to those records where they are dealing with a different bug than the bug that we're dealing with here?

DR. WHITE: That's a good question. Generally, what happens is when we are on site during an audit, part of the oversight that the auditor does, the interviews that they do, they do talk to the countries about any potential outbreaks or public health concerns. So at that point we if we're going to have any information, that's where we would have

it. I think that, more importantly, and related to your question is that this meeting today where we're talking about future decisions on policies on these other organisms that that information definitely would be something that we would have to look at.

MS. DONLEY: I guess I have a concern. I know you ask questions, but do they when they do their microbial testing, do they share any of that with you? So are you made familiar with levels of 0111, for instance, or any of the others?

DR. WHITE: Normally, what happens is that the auditor, when they're auditing, they audit against the equivalence determinations and our requirements. So they wouldn't be usually looking at something that's outside the requirements for our country.

MS. DONLEY: So I just want to post a hypothetical situation here that gives me concern. You could have a country that is dealing with a non-0157 STEC. And let's just say they've tested it, and it came up hot for that other STEC. And it would not be a problem for the United States because that's not

something that we've looked at as necessarily being a problem, and it would have been tested negative for 0157. Can that be shipped to us?

DR. WHITE: Product that is adulterated cannot be shipped to us. With respect to any information that we receive from that country about adulterated product, we make sure that it's refused entry --

MS. DONLEY: And I guess to that point is that -- and that's the crux. That is the crux. Right now it is not adulterated in the United States definition of adulterated product. And we know that those pathogens do cause illness here in the United States, and we are importing 1.3 billion pounds in 2007. My point here is we've got a huge loophole here, a huge gap in public health and safety.

DR. ENGELJOHN: And this is Engeljohn. And I did want to just follow up as well. And we recognize that as part of the purpose of the meeting today. But I would also say that we do take into account what is considered adulterants in other countries. Countries can't ship us product that

would qualify as adulterated in their country as well. So one of the factors that we look at as well is what is, in fact, adulterants in other countries. It may not be here, but there it still can't come to the United States if it qualifies as an adulterant there. It's just another consideration.

MS. DONLEY: But how are we looking for it? How are we knowing that? Are we waiting for them to say, yeah, we're shipping this to you? It's fine for 0157. What's the mechanism in place to make sure that's not happening? That's my question.

DR. ENGELJOHN: Okay. It's the same as what's here domestically. And at this point in time, the Agency does not consider the other non-0157 STECs as adulterants. It's the reason why we're here today to talk about where do we have to go to go forward on this particular issue.

MS. DONLEY: Okay. And I just, as one last point, and this is with our first presentation, is that to this point where you -- for the risk assessment, where you looked at seasonality, is that these countries that do export trim to the United

States, of course, their seasons are opposite from us. And so I really think you might -- I don't know if you've taken any of that into -- I know your risk assessment was for 0157 specific. But have you taken any consideration of that into -- consideration of that opposite seasonality issue when you put your numbers together for the U.S.' fall and winter season?

DR. SCHROEDER: It's an astute point. When we do our risk assessment, this particular one, it was for product produced in the U.S. But we will -- I'll take that point back to my colleagues. It's a good one -- considering seasonality if we include in our risk assessment imported product.

MS. DONLEY: Thank you.

DR. GOLDMAN: All right. Thank you. Felicia?

MS. NESTOR: Felicia Nestor, Food and Water Watch. I don't know exactly who this question is for, but I'm glad Dan is up there because I figure in between Ken, Loren, and Dan, someone will probably be able to answer this.

We heard earlier today that this N-60 method gives you a 95 percent confidence rate if the contamination is 5 percent in the product? Right? Is that the estimate?

DR. PETERSEN: That's the statistical basis of it, yes.

UNIDENTIFIED SPEAKER: Yeah, yeah, yeah.

MS. NESTOR: Yeah. Okay. What's the level of confidence if the contamination rate is .68 percent, which is what Loren found on the trim?

DR. PETERSEN: Dan's group -- this question had come up quite some time ago -- not too long ago -- in a food safety assessment some time last summer. And we asked the policy office to look at that, and they did some pretty good analysis on looking at sampling over time. And I presume that's --

DR. ENGELJOHN: Yeah, I don't have the -- this is Engeljohn. I don't have the numbers, and I don't remember that. But it is in the form of guidance that, actually, Dr. Kelly's group is also working on to make available to small plants. So

that gives them some perspective as to if they're using something other than N-60 or they're using N-60 over time, what does that tell them about their production process and the statistics behind that. So we have crafted what we think is a fairly simple way to look at statistical data in various types of sampling programs. And that should be ready to come out to industry here very shortly. But I don't remember the numbers offhand.

MR. LANGE: I'll just add, obviously, if you have a lower true prevalence, which we haven't -- .68 is a percentage of positive samples, as I said, we will have an estimate of prevalence. But it's going to be less than 5 percent. So, yes, if it's less than 5 percent, your probability of finding the organism there certainly is going to be less than the 95 percent than it was when it was -- if it was prevalent at 5 percent. So --

MS. NESTOR: Any way to --

MR. LANGE: That's why I tried to sort of qualify is if that's sort of the -- at that time, that was sort of what was viewed as the most rigorous

sample, surface sample collection method. You know, you can't test the whole lot. So we have seen data presented to us where, you know, where people have taken lots that -- pass a good N-60 and then sample the ground beef made from those. And, you know, it seems to be a pretty effective, you know, sampling program from what we have seen. You know, is it perfect? No.

MS. NESTOR: And you say you've seen data meaning this is data you got from the industry?

MR. LANGE: Yeah.

MS. NESTOR: Okay.

MR. LANGE: We've seen industry data showing tests done on negative N-60 lots.

MS. NESTOR: And we saw this morning that, you know, not all N-60 is equal depending on, you know, who is doing it and what little -- I mean, I think it's very important because the Agency is using N-60 for the baseline. If I'm not mistaken, the Agency uses it for follow up testing whenever there's a positive. The Agency is using it to determine when trim is okay to carry the seal irrespective of

whether the 2,000-pound or ten of the 2,000-pound combos prior to this combo -- if all of those tested positive but this combo tested negative under N-60, it's my understanding the Agency will allow that to carry the seal because you're saying that N-60 is reliable. You're relying on it. And it's also used for import sampling.

So, Dan, when you are going to give us this, are we going to get studies -- I mean, for instance, Ken just told a small plant own that, you know, the small plant owners get in trouble if they get some kind of method from someone but they don't understand it and they don't really understand why it's being used. Are you going to be able to give us documentation to show that the Agency understands this, understands what the limits are, understands why it's being used? I mean, I would like to know, if there's .68 percent of contamination on the product and you're allowing plants to use N-60 to release product as raw product, I would like to know that the Agency knows what the confidence level of that is.

DR. ENGELJOHN: Yeah, this is Engeljohn --

MS. NESTOR: I would like someone to know.

DR. ENGELJOHN: Yeah, the Agency does know what those confidence levels are. And we accepted that back in 2003 when the Agency began focusing on point source contamination and accepting industry-negative results. It is a practical means that industry was able to conduct their testing of their production lots. And we accepted that. And that has become, to some extent, the industry standard today, in that it is a level of testing that is giving us what we consider to be a removal of a substantial amount of positive product in the marketplace.

But I would say, Felicia, on your point about the prior positives and just accepting those that are negative, we also said in the re-assessment notice from 2002 and again in 2005 that it matters about the relatedness from one testing production lot to another. You cannot ignore the fact that you have positives and go unchecked. It's not acceptable to just divert product.

And that's why any time that we the Agency

talk about sampling, it is in conjunction with a program that's designed to have in place to the best extent possible sanitation and dressing procedures that are verified to be effective coupled with a testing program that is, in fact, diverting product and that there is an understanding of what is the expected positive rate in a facility and then a reaction if, in fact, there's trendings towards exceeding that.

So it is a combination of multiple things. But we have accepted that N-60 from a practical implementation perspective is, in fact, acceptable from the Agency's perspective of a release of product.

MS. NESTOR: Okay. That is not a scientific basis. The fact that it's practical is not a scientific basis. And consumers need to understand that you've accepted it just because it's practical. But if you do understand what the confidence level is at .68, maybe you can tell us tomorrow morning what that is because that would be interesting in a discussion. You know, since N-60 is

such a cornerstone of your program, it would be interesting to bring that information into this discussion.

DR. ENGELJOHN: Okay. Just one follow-up on that is that, again, because we consider that the trim-testing program is a critical element to what we modified the program last March to accomplish, which was to remove manufacturing trim from the market that could be used for raw beef production is that we did design the sampling program that we have, the 3,742 samples, or so, that we take a year, is designed for us based on what we believe to be the positive rate in trim that we found in the baseline study and that would give us a discernment as to whether or not the trends that we see in the positive rate are statistically significant.

So we did design the program so that we ourselves through our verification can make some assessment as to whether or not if we see more positives than as usual what the statistics are behind that. So we have, again, the percent positive rate is very important to the Agency because it tells

us to some extent whether or not the changes we are significant.

MS. NESTOR: Right, but that's the not the only way you're using it. So I'm hoping you can give us -- you know, it doesn't have to be .68 -- 1 percent, 2 percent. I would be interested in that information.

DR. GOLDMAN: Okay. Thank you.

MS. NESTOR: That leads to my second question.

DR. GOLDMAN: Felicia, can we ask you to hold that possibly unless it's a burning question. We have --

MS. NESTOR: It is a follow-up, okay?

DR. GOLDMAN: Okay.

MS. NESTOR: Dan, you talked about the trends, the number of combos that would be positive before you wouldn't accept that N-60. Can you tell me how many combos would have to be positive before you would not accept the N-60?

DR. ENGELJOHN: The Agency doesn't have that information that we react to. We react to the

individual establishment's data that they have and the rationale for why they allow product to be produced and shipped. And so it's on a plant-by-plant basis and the rationale that they would have to discern whether or not positives from one production lot to another have relevance.

MS. NESTOR: But you're putting the seal on it. You can't put the seal on it until you have determined. So it doesn't matter what the plant determines. You are making a determination when you put the seal. So I would expect that there would be some articulable standard.

DR. GOLDMAN: All right. Thank you. Mr. Wood?

MR. WOOD: Yeah, I'm Richard Wood. I'm with Food Animal Concerns Trust, and my questions I think are more to Carl Schroeder than to others, and I know we're running short of time. I'd be glad to chat more afterwards.

But we're very supportive and very interested in the 0157 pre-harvest risk assessment that you presented to us today on slides. When I was

at the table in 1995, or whenever it was, when HACCP was being put together, we were hoping there was going to be some kind of specific kind of intervention that would be a part of that plan, and we're glad to see that you've come back to that point now and are looking at that.

But I would like to just better understand that risk assessment and what all is being planned and hoped for. I have three quick questions. Is that plan going to follow the risk assessment process that you identified in one of the earlier slides, you know, developing a plan, formulating questions, peer review, and then what I'm most interested in is the one that says public presentation. Is there going to be any kind of stakeholder involvement feedback reality check in that process.

Secondly, with the risk assessment, how will the selected risks and interventions be identified? What kind of criteria are going to be used? And in one slide, you went on to say that you anticipate to look at all the mitigation options. Are you going to be looking at them, you know, in

global terms, in very specific terms, and what's going to shape that kind of query?

And, finally, something that's been reflected here in a couple of other questions earlier in the day, will the risk assessment be limited in any way by the lack of FSIS authority to go on the farm, particularly as you're looking at mitigating steps or risk assessment to come? Is that going to in any way skew or limit the range that this risk assessment might take a look at?

DR. SCHROEDER: Yeah, in answer to the first question, yes, sir, we will do our best to follow that process that I outlined.

In answer to the second and third questions, the one regarding scope and the one regarding where we could potentially use those mitigations, what we do as risk assessor is really stay focused on answering all the risk management questions. And so we're just developing this risk assessment. We'll work very closely with Dr. Engeljohn's group to see how that progresses. I think on your third question, specifically, I'm

probably best served to defer to Dr. Engeljohn on that.

DR. ENGELJOHN: Remind me what the last part of it, but I can answer the issue on there is a common period associated with this process. And as the risk manager responsible for identifying those risk management questions we need to answer, I would welcome any questions that you think would be appropriate for us to consider. So just think of that as you --

MR. WOOD: And that would happen -- those comments would be in a public forum where we could see what is on your plate that others are asking from other sources as well or how transparent is this whole process I guess is my question.

DR. ENGELJOHN: Oh, okay, well, the process that we have for risk assessment at the Agency has traditionally been that we do put together the risk -- and Carl can certainly go back over this, but it is a public process in that we do craft the risk assessment, we do identify the risk management question, we generally have a public meeting that

presents what it is that we're working on. We ask for input. We get a peer review process of that. We address the peer review comments, and then redo it. And then from that we use the results from it. So --

MR. WOOD: Very good --

DR. ENGELJOHN: So there will be a very public process.

MR. WOOD: Okay. Great. I was at the very first risk assessment at USDA I think in the beginnings of *Salmonella*, and that was the case then, and I'm glad to see that it's continuing.

DR. GOLDMAN: Thank you. Mr. Painter?

MR. PAINTER: Stan Painter with the National Joint Council. My first question is directed to Dr. Petersen. And in the slide that was showing some criteria for prioritizing FSA at a beef establishment, number three, more specifically, spoke to small and very small plants that produced a large volume. I'm wondering what's considered a large volume at a small and very small plant?

DR. PETERSEN: Well, we have some "small plants" that produce a whole lot of ground beef as

you well know. So what we gave them is what I suggested in my talk. We have the top -- we gave them a list of here's the top 100 slaughter plants. Most of those slaughter plants tend to generate trim. Then we gave them a list of here's the top 40 or 50 I think was the number of grinders. So that was just the metric to get on with the food safety assessments because it was a procedural thing. So we didn't go into the data and say this plant does 1,000 pounds, this plant does 10,000 pounds. That was kind of the cut off. For prioritizing the food safety assessment, that was kind of the metric, as I recall it.

MR. PAINTER: Am I hearing you say that a large volume is subjective?

DR. PETERSEN: For the purpose of just those food safety assessments. Again, I entered into those with questions about the process, and some of them, they answered the questions. So for the purposes of doing that work, those were the benchmarks, top 50, top 100.

MR. PAINTER: Okay. And the next part goes

to the imports of the approximately 1.3 billions of pounds of product that was imported. Do we know how many samples were taken and if so how many of those samples resulted in a positive?

DR. WHITE: We do know how many samples were taken per country and whether we had positive results were not. I personally don't have that information. Mr. Lange, do you have that? But my understanding was if they were either zero -- minimum for the countries.

MR. PAINTER: Okay. And then my last question was how many inspectors do we have that's sampling that 1.3 billion pounds?

MR. LANGE: We have 70.

DR. WHITE: Seventy.

MR. PAINTER: How many of the positions are filled?

MR. LANGE: It fluctuates. It depends, you know, on the vacancies and --

DR. WHITE: This is Mr. Loren Lange who is the deputy director of the Import Division, Inspection Division.

DR. GOLDMAN: You want to repeat the answer, Sally?

DR. WHITE: Yeah -- we'll bring the answer tomorrow.

DR. GOLDMAN: Okay.

MR. PAINTER: Okay. Thank you.

DR. WHITE: Yes.

DR. GOLDMAN: I want to thank Stan. I think in every line of questioning, he's been the closer. We need a closer, and we appreciate that.

MR. LANGE: Yes. In response to one thing, I misspoke a little bit. Dean Danielson's question. When we implemented -- 53 or 54 -- the components in addition to trim, we are starting to collect FSIS data on components that include boneless chuck, cheek meat, and -- but that started in late December, so I wasn't thinking of that when you asked the question do we have any data on the primals. We probably have few samples that have come into the lab identified as samples of boneless chuck now.

MR. DANIELSON: I know -- Randy Huffman, but he's the one that asked that question. I can

understand you getting confused.

(Laughter.)

MR. LANGE: I thought you asked it. Okay. I'm sorry.

DR. GOLDMAN: Let me just last one last time if there are any questions on the phone since we've exhausted the questions here.

(No response.)

DR. GOLDMAN: Okay. Great. I do want to thank everyone for your time and attention today. We will resume at 8:30 tomorrow morning, and we hope you'll return for that session.

(Whereupon, at 5:09 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:

SHIGA TOXIN-PRODUCING *E. coli*

ADDRESSING THE CHALLENGES,

MOVING FORWARD WITH SOLUTIONS

Washington, D.C.

April 9, 2008

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

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Dominico Quattrochiocchi, Reporter

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