MEASURING PROGRESS ON FOOD SAFETY:

CURRENT STATUS AND FUTURE DIRECTIONS PUBLIC MEETING

WEDNESDAY, JULY 21, 2010 - 9:00 A.M.

HYATT REGENCY
CHICAGO
151 EAST WACKER
DRIVE CHICAGO,
ILLINOIS

DR. FARRAR: Good morning.

THE AUDIENCE: Morning.

DR. FARRAR: Thanks for everyone turning out.

Welcome to our second Public Meeting on Measuring Progress on Food Safety. I'm Dr. Jeff Farrar. I'm the Associate Commissioner for Food Protection with the U.S. Food and Drug Administration. Again, thank you for coming. We appreciate your attendance and very much look forward to your comments.

Before we get started, a couple of housekeeping details. We do have sign language interpreters available, if needed. They are Nancy and Joshua.

Is anyone in need of a sign language interpreter?

(No response)

DR. FARRAR: If not, they will remain available through the morning, and if you need their services, please see one of our folks at the registration desk.

Also, if you've not preregistered to make comments and would like to do so at this meeting, please see an FDA staff member at the registration desk, and if there is time following those that had pre-registered, we will accommodate you.

Also, I want to call your attention to the packets that you received at the registration desk.

In addition to the agenda for today's meeting, you have a Federal Register Notice on this meeting and the next meeting we will be holding in Portland, Oregon. Enclosed with that are instructions on how to submit

written comments, a list of individuals who have registered for this meeting, and a list of food safety metrics developed jointly by CDC, FSIS and FDA. This list not comprehensive; it is not final. It is provided as an example of some existing ideas on metrics.

To give you a little background on today's meeting, it is a follow-up of an initial one-day public meeting held on March 30th in Washington, D.C., attended by more than 400 people. At that meeting, FSIS, FDA and CDC discussed their collaborations on the methods and data challenges involved and the feasibility and effectiveness of food safety metrics.

The federal agencies have been collaborating to reduce foodborne illness as part of the present Food Safety Working Group. A key element of this federal government's effort is the adoption of appropriate metrics to measure our success in food safety.

These public meetings are a way of engaging the public, engaging food safety experts and all stakeholders in this important issue.

Our first public meeting in D.C. was largely to inform the public about current and potential measurements for assessing progress in food safety and how to improve those measurements. Presentations were made by FSIS, FDA and CDC as well as representatives

from academia, consumers and industry.

Today's meeting is a little different. We're going to allot the majority of the time to hear from you, to let you do the talking. We want to hear what you think about the metrics federal agencies are currently using or considering, what metrics you are using and those that you think might be appropriate.

This same format will be used in our meeting in Portland on October 20th.

We're going to begin our agenda today with brief presentations from the three federal agencies hosting this meeting, CDC, FDA and USDA, as a way to summarize the information presented in the first meeting and to set the stage for your input. We'll move quickly, following these presentations, into the public comments section of the agenda. After comments, we've allotted time for Q and As.

Now, let's get started. Our first speaker this morning is Dr. Patricia Griffin. She's Chief of the Enteric Diseases, Epidemiology Branch, for the Centers for Disease Control and Prevention, in Atlanta.

Patty.

DR. GRIFFIN: Thank you, Jeff, and thanks to all of you for your interest and for coming to this meeting.

So at grand rounds that we gave at CDC, Mike

Doyle said the foodborne disease surveillance system is to the food industry what radar is to automobile drivers. It's the threat of being caught that helps drive compliance of the best safety practices, and CDC's job is to do that surveillance of human illness.

So I'm going to talk about four of the systems that CDC uses for surveillance and to measure progress in food safety. PulseNet, OutbreakNet -- yes?

So if I screw up on the slides or you don't see slides or you can't hear me, please raise your hand, yell, say something. It's not that big a group. We can talk to each other. PulseNet, OutbreakNet, FoodNet and Foodborne Disease Outbreak Surveillance System.

So PulseNet and molecular subtyping, the Hubble Telescope of foodborne disease prevention. In 1995, the Hubble Space Telescope found large numbers of distant galaxies and star clusters never seen before and transformed the notion of deep space. Do you hear the music?

In 1996, surveillance for foodborne disease was similarly changed by the launch of the molecular fingerprinting network, PulseNet. It's a national network of public health and food regulatory agency laboratories. It's coordinated by CDC. The members are

state and local health departments and federal agencies.

So this graph shows PulseNet activities 1996 through 2009, and it shows the pulsed-field gel electrophoresis, PFGE, patterns submitted to the PulseNet databases. Each of these patterns is a pattern of one bacterium. So this shows the number submitted, and the basic message here is more and more were submitted each year, which means that surveillance was getting better.

So let me tell you the timeline for this. In 1996, it was first implemented in Minnesota, and the result was a 67% increase in the number of *E. Coli* 0157 outbreaks detected. In 2001, it had been implemented in all states, and it's now a routine part of surveillance for some pathogens, mainly *E. Coli* and *Salmonella*. It's been shown to be cost effective, because the cost of foodborne disease hospitalizations and deaths is high, and the cost in Colorado was covered by preventing just five *E. Coli* infections.

Each year, PulseNet identifies about 1,500 clusters at the local or state level, about 250 multistate clusters, and out of these clusters, the epidemiologists find 10 or 15 disbursed multistate outbreaks, an outbreak being defined as a cluster and in which we've shown the source is a common one for all

the people ill. Most of these outbreaks would not have been identified in the past.

So progress in the past year, in PulseNet, has been in developing and implementing new tools for subtyping, including molecular serotyping of *Salmonella* and MLVA, which is a type of subtyping for *E. Coli* 0157, and for some of the *Salmonella* serotypes, Typhimurium and Enteritidis.

We also have a pilot project on genotyping of Shigatoxin-producing *E. Coli*, such as 0157, and that project combines molecular serotyping, virulence characterization, and SNP subtyping. (That's single nucleotide polymorphism).

PulseNet is also developing new tools for visualizing and analyzing data, so that we can more easily detect clusters that may represent a common-source outbreak.

But PulseNet has some challenges. One big challenge is state capacity. Some states have limited resources for subtyping bacteria. So fewer of the bacteria that are isolated from ill people get subtyped, and often the subtyping is delayed. And the result is that detection of the outbreaks is compromised.

CDC also has limited resources for PulseNet and

for the laboratory work that's needed to improve the methods to detect clusters, to link information about PulseNet patterns with data on ill persons and outbreaks and with our data on antimicrobial resistance.

We have a big national network for testing strains from ill people for antimicrobial resistance.

I'm not going to be talking about that today, but it's really important to link that up with the outbreak data.

PulseNet also needs to continually be naming new patterns and tracking them over time. So this map shows the annual rate of uploads of patterns to PulseNet by state.

So which state has the most illness? The answer to the question is that's not the right question. The dark states don't have the most illness. The dark states have the health departments that are doing the best job of getting the strains in from the clinical labs that have isolated these *Salmonella* and *E. Coli* from sick people, getting the strains into the state health lab, then subtyping the strains by PFGE and submitting them to the national PulseNet database. So those dark states are the ones where you want to live, because they are doing the best

jobs of detecting outbreaks.

Now, let's see, how is Illinois doing? Hum.

All right, no further comments on that one.

So now this is the same slide as before, and we're down to our second topic: OutbreakNet. That's an informal network of public health officials who investigate multistate outbreaks of enteric disease.

It's coordinated by CDC, and it helps to facilitate rapid coordinated response, and the participants are state and local health departments, regulatory agencies, FDA and FSIS, who are here, and PulseNet.

So this graph shows human specimen isolates uploaded to PulseNet and clusters tracked from 1996, the beginning of PulseNet, through last year. So the bars show the human specimens uploaded to PulseNet, and it's increased every year until recent years, where there's been a plateauing. And the pink line shows the clusters tracked by CDC epidemiologists.

So there are more and more clusters tracked, which means that PulseNet has been doing a good job of naming the patterns, identifying the clusters and sending them to the epidemiologists to track them, to see if an investigation can show a common source.

So this whole activity has been getting busier and busier, and, in fact, this very busy slide has a very simple message. This is the average number of

clusters tracked by CDC epidemiologists by month and pathogens from February 2008 through April 2010.

But what I want to show you is just here (indicating.) And I'm showing it on my right side. In 2008, the epidemiologists at CDC were tracking 24 clusters every week. So at our weekly meeting, we'd be going over data for 24 clusters, really between 10 and 37, and trying to talk to the states, see if there were common patterns of age, see if interviews had been conducted by states and see if we had any hypotheses.

By 2009, this had increased to an average of 29, a range from 16 to 41, and it's continuing to be at this level or higher. So this is a busy activity, and it highlights a gap in multistate outbreak investigation methods.

There are limited resources at state and local health departments to conduct interviews, and I'm going to talk about two types of interviews that relate to each other.

One is for sporadic or non-outbreak illnesses. In many jurisdictions, persons with lab-confirmed illnesses like *E. Coli* and *Salmonella* are not routinely interviewed to collect information on exposures, and if they were interviewed, some would be shown to be part of outbreaks.

Because, for example, somebody from the Health

Department interviews two people, who they get reports of close to the same time, with *E. Coli* 0157 infection.

They ask them what restaurants they've eaten in.

They both name the same restaurant, and then suddenly they get a third person. That person names the same restaurant, in addition to others, but there's that in common. They may start looking into it and find a problem. If you don't interview, you don't find the problems.

And then the second, for cluster and outbreak illnesses, we need to have interviews to probe possible sources, but those are often delayed by other priorities. And re-interviews to collect product information are often delayed, and question questionnaires are often not standardized among states.

So information from questionnaires cannot be put into a standard database.So it's difficult to combine data from multiple states.

And information on exposures is usually not transmitted electronically to CDC. So you can imagine, during a multistate outbreak, we're getting lots of faxes. And I mean nobody deals with faxes anymore. The paper gets all messed up, and it's sort of -- it's still a fairly primitive methodology, and a lot of improvements are needed.

And contrast this with PulseNet in which lab

information on every isolate is standardized and is rapidly transmitted to the national database, and summary information is available to all participants.

So to address these problems, we began OutbreakNet sentinel sites in 2009, in cooperation with the Food Safety Inspection Service -- thank you very much, Dan -- and the Association of Public Health Labs, and our goal is to generate collaborative and innovative models in states or large population centers to conduct rapid, coordinated, centralized and standardized surveillance and assessment of foodborne diseases.

So, in the summer of last year, we awarded funds to three applicants, Wisconsin, Utah and New York City. And some of you who know FoodNet will notice that these are not FoodNet sites. So we're sort of trying to spread the abilities to conduct great outbreak investigations, because our FoodNet sites tend to be our stars. The average award was $90,000.

In the spring of this year, we sent an announcement for the next funding year, and we included "Metrics By Which Success Will Be Measured." The metrics include how they will decrease the time to identify outbreaks. For example, the median time to interview persons with *E. Coli*, *Salmonella* and *Listeria* infection, how they will improve response in reporting

(for example, the proportion of clusters investigated and the proportion of outbreaks reported electronically to CDC's Foodborne Disease Outbreak Surveillance System), and how they will improve collaboration, for example, the development of common questionnaires for initial interviews of ill persons.

So our plans are that we're funding up to four sites in the fall of this year. We will provide resources for improved surveillance and outbreak response, especially for our key pathogens, and we'll improve three areas that are critical for foodborne disease outbreak, detection, investigation and control; and those are lab surveillance, epidemiology interviews and investigations, and environmental health assessments. We'll develop an infrastructure to share and work on data in real time during multistate outbreak investigations, and we plan to replicate successful models across the country by presenting this at the OutbreakNet annual meeting and encouraging other jurisdictions to follow the same plans.

So our vision is for a national multistate foodborne investigation network that will more rapidly develop hypotheses and implement vehicles by routinely combining epidemiologic and PulseNet data and by including the collection of exposure data from ill and well persons, and to more rapidly trace products back

to their source of contamination, by improving the amount and speed of collection of product information like lot numbers, by more rapidly collating product information from multiple states, by improving the quality and speed of product data provided to the regulatory agencies, and by sharing information in real time with the regulatory agencies. So that's OutbreakNet.

And we'll go on to FoodNet now. So FoodNet is our Foodborne Diseases Active Surveillance System. It was established in 1996 and is a collaboration among CDC, 10 state health departments, FSIS and USDA and FDA, and FoodNet conducts active surveillance for lab-confirmed infections at more than 650 clinical labs for a number of bacteria, *Salmonella*, *Shigella, Campylobacter, E. Coli, Listeria, Yersinia* and *Vibrio*, and for the parasites *Cryptosporidium* and *Cyclospora*, and also for hemolytic uremic syndrome (HUS) among pediatric nephrologists with a review of hospital discharge data. And as many of you know, HUS is that severe complication of *E. Coli* infection.

So these are the FoodNet sites. The 10 FoodNet sites are shown in green. Some of them are entire states, and some of them are parts of states. And FoodNet sites represent 46 million persons or about 15%

of the U.S. population.

FoodNet has an annual report on the incidence of infection with pathogens transmitted commonly through food. It's been referred to as "the report card on food safety," and it's used by regulatory agencies, industry and public health personnel to monitor the progress toward national health objectives and to prioritize and evaluate interventions.

So FoodNet has shown trends in incidents, and in our most recent report, which was the data from 2009, we compared that with our 1996 to 1998 baseline.

That's when FoodNet started. And some of the significant declines compared to that baseline were that *E. Coli* 0157 declined 41%, the incidence in 2009 was similar to the incidence in 2004, and it's the only pathogen that's met the Healthy People 2010 Target. *Campylobacter* declined 30%, *Listeria* declined 26%, *Salmonella* declined 10%. And compared with the preceding three years, the significant changes were that *E. Coli* had declined 25%, and *Shigella* declined 27%.

So put in another form, in reference to the Healthy People Objectives, across the top you see the incidence of lab-confirmed infections per 100,000 persons.

And it's important to remember that, for any of these, if you multiply them out, you need to create a multiplier, usually of around 20 to 30, to get the actual number of illnesses, because many of you, if you got a diarrheal illness in the next day or so, just would be too busy to see your doctor and would just like tough it out. Maybe only if you were sick for a number of days would you go to see the doctor, and at that point, the doctor might not even get a culture or the organism might not be there. So there are a lot of those stories for everyone we find.

So these are the pathogens. And this shows the incidence in FoodNet in 2009. This shows our Healthy People Objective for 2010. And this column -- and I'm talking about – the pointer's on the right side. And the last column is progress towards the objective.

And you can see that, for *Campylobacter*, we're close; for *E. Coli* 0157, we're currently at the target; and for *Listeria* and *Salmonella*, we're not close; and the national process to determine Healthy People Objectives for 2020 is underway.

The regulatory agencies are tracking the incidence of priority pathogens, and here are some examples. FDA's closely tracking *Salmonella* serotype Enteritidis infections, and USDA is closely tracking

overall *Salmonella* and *Salmonella* serotype Enteritidis infections, and CDC is providing quarterly FoodNet data for their analyses.

So, for every quarter, CDC will be providing data to regulatory agencies on lab-confirmed illnesses in FoodNet sites. We'll provide the number reported, that quarter, of *Salmonella* and of *Salmonella* serotype Enteritidis infections and the predicted incidence for the full year and the percent change from the comparison period, and we do that using a negative binomial regression model that uses the most current data and also data from previous years.

The reporting lag for these quarterly reports is one quarter. So, for example, the Quarter 1 data from January through March will be available at the beginning of Quarter 3.

So CDC is working on new estimates of the burden of foodborne illness acquired in the United States to help in prioritizing interventions aimed at reducing illness and to use for other analyses; for example, assigning illnesses to food commodities, which we call attribution, and estimating healthcare cost.

And estimating the burden requires many data sources and models, and only a small fraction of illnesses are confirmed by laboratory testing and

reported. So it's the tip of the pyramid that gets reported to surveillance.

So some challenges in FoodNet are that state health departments have competing priorities and are dealing with changing diagnostic practices in more than 650 labs.

And, at CDC, population surveys are used to estimate the number of episodes of acute gastroenteritis each year. And our last population survey was done in 2006-2007, and we're using it to estimate the burden of illness. And, right now, there are no plans to do another population survey, because the funding for that has run out. So, at this point, we are at a longer interval between population surveys than we've ever been. Also, the cleaning of the data, analyzing it and creating models to accurately estimate the burden of illness, is very resource intensive. So we've done FoodNet, and now we're on to the last system I'll discuss, which is the Foodborne Disease Outbreak Reporting System.

So this graph shows foodborne disease outbreaks by year, from 1973 through 2008. And you can see that, going from the yellow side to the red side, we don't think that there suddenly was a lot more foodborne illness in the country, but we did enhance

surveillance.

And the line shows the outbreak-associated illnesses. In other words, take all those outbreaks and add up all the illnesses in those outbreaks, and that's what that line shows.

So this map shows the annual rate of foodborne disease outbreaks by state, 2003 through 2007. So which is the worst state to live in as far as your likelihood of getting sick? The answer is that's the wrong question.

The dark states are the ones with the most outbreaks reported. So those are the ones where it's great to live because you have a Health Department that's received resources from the states and has it together to identify the outbreaks, investigate them, figure out the source, and then report them nationally. Illinois is doing a little bit better on this one.

This diagram is our hierarchical scheme for categorizing foods into commodities. We go from all food on the right here (indicating) to aquatic land animals, plant animals, and then various major categories of foods, such as meat-poultry, produce, and then subcategories.

In the meat-poultry, you can see there's types of meat and then there's the poultry. And the produce,

we go to fruits, nuts,and then the various types of vegetables. And the yellow boxes are the 17 commodities that we're using to report foods that are responsible in outbreaks.

So we categorize foods into simple and complex foods. Simple foods contain a single commodity. For example, a steak is categorized in the beef commodity. It's one of those yellow boxes. Complex foods contain multiple commodities. So meat loaf has the ingredients ground beef, eggs, bread and tomato sauce. So meat loaf includes four of those yellow-box commodities, beef, eggs, grains, beans and vine-stalk vegetable.

So this graph shows the proportion of outbreaks with simple, complex and unknown food vehicles, and you can see that around 20% are due to simple vehicles, more are due to complex vehicles, although it's about even in recent years, and a lot are due to unknown vehicles.

Now, a lot of people look at this graph and say this (indicating) is failure. That's not true.We're really glad when states investigate outbreaks and still report them to us even though they're not sure what the food is. You can still learn a lot of information.

For example, if a state Health Department

investigates an outbreak at a restaurant, and the outbreak occurs among 10 or 15 people and they all had turkey, dressing, cranberry sauce and salad, if they all eat all those foods, you can never figure out what food caused the illness, but they can still get good information. They can still find the pathogen. They may know that they have *Salmonella* infection. They can learn about the type of restaurant, whether the restaurant had a food service manager that oversaw food safety. So we get a lot of good information about the pathogens that cause outbreaks and the settings for outbreaks and other information that I'm not going into from these outbreaks in which we're not sure what the vehicle is.

This pie chart shows illnesses and outbreaks caused by simple foods, and the ones that are causing outbreaks, you can see the biggest ones here are poultry, leafy vegetables, beef, dairy, fruits, nuts, vine-stalk vegetables. Certainly, there's been progress, and there are plans and challenges.

So analyses that attribute illnesses and outbreaks to simple food vehicles are published in the MMWR. In June 2009, we published 2006. In mid-August of this year, you'll see the data from 2007. And in early 2011, we'll publish the data from 2008. And

here's what our MMWR looks like.

Also, we've put online the Foodborne Outbreak Online Database -- it looks like this (indicating), and the web address is at the top there -- where you can play with it yourself and find out about outbreaks in your favorite state.

And also analyses using outbreaks with both simple and complex foods are planned. We have a draft of a model to attribute illnesses in complex foods to food commodities. And when we have the new burden estimates of overall illness due to each pathogen, we'll incorporate these into the model and submit it to peer review.

There are selective challenges. The states vary widely in their capacity for investigation and reporting. One of the metrics for OutbreakNet sentinel sites is the proportion of outbreaks in which a report form is submitted to CDC.

At CDC, cleaning, coding and analyzing reports of the implicated foods is difficult and time consuming. It's especially difficult for complex foods. And interpreting outbreak data can be challenging. Also, creating analysis models that meet the needs of regulatory agencies, it's very important.

For example, we need to have models that

incorporate features of food commodities. For example, the manner of preparation is important. Roast turkey is very different from turkey deli meat. And models that incorporate the likelihood of contamination of an ingredient are also important.

The database of outbreaks is open, and that's good because important reports that missed the reporting deadline can be added and new information can be provided and errors are corrected. But a data download today may contain different information than a similar earlier download.

So "Nutrition and obesity (including food safety)" is one of the CDC Director's six Priority Winnable Battles. So we're very excited that it's being targeted by CDC as an important area.

In conclusion, we use many systems for prevention and to assess progress, and I've talked about four of them. There's been much recent progress, including development of metrics, and much more is to be done.

Thank you for your attention this morning.

(Applause)

DR. FARRAR: Thank you, Patty.

I forgot to announce at the beginning that we are going to have time for questions for each of the federal speakers after our break.

If there are a couple of burning questions before the break -- but after we get through the next two, we might be persuaded to take a couple before the break. But I'd ask you to write your questions down, and when we come back from break, we'll have a little time for Q and A for all three of the speakers here.

Our next speaker is Dr. Kara Morgan. Dr. Morgan is the Director of Public Health Measurement and Analysis in the Office of Planning under the Office of the Commissioner for the U.S. Food and Drug Administration.

Dr. Morgan.

DR. MORGAN: Good morning, everyone.

I'm going to talk about what Patty just talked about in terms of how the CDC high-level foodborne illness information is being used and incorporated at FDA and also kind of the work we're doing, to continue to do, to develop metrics that are going to be helpful for our programs.

First, I wanted to mention two things. One is that, of course, FDA is more than just foods, and so I'm going to talk today about performance measurement about food safety. But there is other work going on at FDA about performance measure in medical products as well.

And I also wanted to mention that, recently, the foods program was reorganized at FDA. So now, when we talk about foods, we are including not only human food, but also animal food. So feed products are included in the presentation I'm going to give today.

So just to give you an sense of what I'm going to cover today, the public health outcome information that Patty just talked about is, of course, kind of the cornerstone of the story of food safety, and I'm going to talk about the relationship of that type of information to performance measures for FDA.

I'm going to talk about current FDA performance measures in the foods program that are publicly available and let you know where you can find more information on those, and then I'm going to talk about the next steps, which includes the reason for having these public meetings and how the information that we'll be getting from you all today and at the Portland meeting will be used to improve this process of connecting foodborne illness information, public outcome information, to the measurements of our programs at FDA.

So these are a few examples from the one-page handout that Jeff mentioned earlier. You have this one-pager in your packet that is a list of metrics that was

jointly developed by FSIS, CDC and FDA, and these are ones that are public health outcome levels and these are all ones that are generated by CDC using some of the methods and data that Patty just talked about.

So these are giving us the big picture, right? So incidence of priority foodborne illnesses, you know, how many people get sick from *Salmonella* in the U.S. every year, how many people are hospitalized because of *Listeria* every year. So these are the big-picture numbers that, as Patty talked about, are very complicated in terms of the way you go about getting the information together. But there are established methodologies for doing so, and FDA looks to CDC for that information.

The number of outbreaks and outbreak associated cases is another way to slice it. As Patty discussed, there are reasons that things are categorized as outbreaks or not that aren't really related to the fact as to whether they actually were an outbreak, but it's more about the way data come to us and what information is available. But it's another way for people who are interested in knowing what the status of the food safety system is.

And, finally, another example from this list is -- food allergies, of course, are very important to the food safety issue. So the number of severe illnesses

from food allergies is another example of public health outcome measures.

What's not included here yet, but should be, in terms of the work we do at FDA, are public health outcomes related to chemical exposures. So you can see that there's not one set of public health outcome measures that tells the whole story of food safety.

You need this whole set of measures to really get a sense of what is the public health impact from foodborne hazards.

So what these measures are good at is giving us that big picture, that sense of how things are going.

We can use these measures to do things like compare to other countries. There are challenges with that, in terms of the way that they collect their data, and their methodology, and there's work going on to try to align those methods so that it will be easier to do that comparison, but these are really useful for that kind of high-level snapshot.

At the same time -- Patty talked about the changes in surveillance, the changes in the ability of states to collect data and all those things that could be changing these numbers that aren't related to the underlying truth of whether people are getting sick from food, what type of food they're getting sick from and what pathogen is causing that.

So the question that we have at the regulatory agencies is, given that there's this high-level picture available, that there are these underlying uncertainties in the data, there are things shifting in terms of trying to improve methodologies, which, as some of her graphs showed, actually could look to the untrained eye like disease rates are going up, but, actually, you need -- and also I loved her stories about the States that look like they're worse than other states, but it's really a fact of the way those states are operating.And those types of information are really important to understand when you're trying to understand this high-level data.

But what we're trying to do in FDA, and I'm sure Dan will talk about it at FSIS, is to understand whether our programs are working. You know, we're trying to understand if we issue this guidance or if we do this training or if we do this outreach, is that helping with food safety? And you can see how these type of high-level numbers aren't giving us that level of detail to understand that.

So the question that we're struggling with is: how can we, as regulatory agencies, impact these public health outcomes? We all know that the food safety system is very complex. There's a certain role for

regulatory agencies. There's a role for industry. There's a role for all parts of the farm-to-fork chain in terms of what the growers are doing, what the folks in transportation are doing, what the folks in storage are doing. There's a role for people in retail and what kind of controls they're maintaining. There's a role for people in food service in how they're preparing and serving the food. There's a role for consumers in terms of how they have their refrigerator set and how long they leave food out at picnics.

And so all these factors are impacting that foodborne illness rate. So the question we have is: how can we develop measures that are a step before, kind of the rate of people getting sick from *Salmonella* every year, that can give us a sense for what is working in regulatory agencies to help impact that public health outcome that we all care about.

So here are a few definitions to give you a sense of performance measurements and what it is we're aiming for in terms of having useful mechanisms to feed back information to us, about our programs.

So performance measures are specific indicators used to evaluate how well a system is operating. And let me just mention, too, that these definitions, of course, aren't relevant just for food safety or just for regulatory agencies. These are much higher-level

definitions that companies use and that other agencies use. So the idea is how can we take these concepts and apply them to food safety.

Performance measures will let us objectively, in a data-driven way, measure the degree of success.

So there's certainly a role for things like expert elicitation about how well do you think this program is working, what do you think is working here and what's not working, but performance measurements will ideally give you objective data so that everyone can agree on whether things are going up or going down.

They show indicators of progress. If there's something you're trying to accomplish because you believe it will impact the public health outcomes, it will show you, you know, one year you're at 10%, on year at 20%, kind of let you show the measure of that progress.

And then, finally, these are factors which, ideally, would help you get to root causes. So that, when you're trying to apply corrective action, trying to improve the way you're doing a process that, if have you a set of eight measures and seven of them are going up and one of them is going down in the wrong direction, then that will tell you something about where you might want to invest more resources to improve that program.

Here, again, are some generic basic principles for good performance measures; not relevant just for the food safety system, but certainly applicable to us. We want measures that focus on results that matter. We want things that are going to be, ideally, quantitatively --through research -- related to public health outcomes.

But those type of results are in short supply. So we're working toward that, but the idea is we're investing in things that everyone kind of agrees are related to public health outcomes.

We want measures that provide clear evidence, as I mentioned earlier, about providing data and observable events, and we want measures that are practical and affordable.

One of the surveys Patty mentioned in her talk was the large study that was conducted to get a sense of sort of underlying rates for gastro illnesses, and she mentioned that, because of resources available, that's not going to be able to be repeated. Well, when you're developing measures, you want to make sure that you're able to choose studies that you'll be able to repeat because, otherwise, you'll end up having to use data that are outdated. And that happens all the time.

But the idea is that you would be able to develop measures that you would be able to sustain over

time, because the timeliness factor can, of course, have an important impact on the quality of the data.

So there's this critical role that regulatory agencies have, in terms of developing these performance measures. We're really looking for this data-driven assessment of performance so that we have this feedback for how our programs are working and can make adjustments along the way, and it also really gives us a sense of what is working and what's not working. Instead of just, well, we think we need to issue this or to do that, we would actually, ideally, have quantitative data that tells us, yes, when you did this particular activity, it had this effect on the public health outcome.

The performance measures give us a way to share our priorities within the Agency and also with our regulatory partners in the state and local areas and also, of course, with FSIS. There are a lot of overlapping roles in the food safety system, and having these performance measures helps everyone kind of understand what the goal is, what is it that you're aiming for. Instead of just everyone kind of shooting for ”public health,” you have something more concrete to agree on, in terms of what it is you're trying to accomplish.

And then, also, in terms of the these meetings, having these performance measures allows us to get concrete input from our stakeholders and allows us to communicate with our stakeholders, so everyone is clear on what the expectations are, in terms of what the agencies are working toward.

So that gets to some of the discussion about what we're looking for that we hopefully will gain from these public meetings. One is this recognition that the food safety system is so complex. And there are things that the regulatory agencies can do, but there's only so much the regulatory agencies can do.

So the question is, What should we be doing? And what we hope to hear from you about is: what are the other stakeholders in the Food Safety System doing; what information is industry collecting in a systematic way, or maybe not in a systematic way, just to start; what information are the states collecting; what information are the distributors collecting.

And there are all these people who are making decisions to try to improve food safety, but it's not coordinated or aligned, since we don't have a way to share that information. So we're hoping to hear those kind of things from you all.

We're also hoping to get your feedback on --

given the measures we have now, what you think is helpful, what you think is not so helpful and, ideally, some suggestions for other things that you think would be helpful in terms of our ability to monitor our performance.

So this slide talks about logic modeling. And I'm going to talk a little bit more about this later, but this is really the crux of what we're trying to do at FDA to understand how the things that we do impact public health outcome measures. And, again, this is all from performance measure literature. I think it's business school type of stuff.

So there are things that we do, which are the activities. There's training; we hire people; we do outreach; we conduct inspections. There are all these things that regulatory agencies do, and in order to do these things, we need input. So we need information, we need funding, we need people.

And then from those activities, we create outputs, which are inspections completed, samples taken, compliance actions taken; all those kind of things that are the result of what we do. And, truthfully, a lot of the things that we report now, the things I'm going to talk about in terms of our current performance measures, are those types of output kind of things, and those are important things because they're

showing how much of what things we're doing.

Now, those three things, as you see at the bottom, talks about we can use, measures to improve the efficiency and effectiveness of those things we do, but the reason that we do those things is because of the outcomes.

So our ultimate outcomes are the public health outcomes that we talked about earlier, the number of people getting sick, the number of people dying, the number of people with food allergy reactions. And the intermediate outcomes are the things that are steps before that.

So I'm going to give you some more concrete examples of this, but this is really the tool that we're using, this idea of using logic models to help lay out all the activities the FDA is doing, all the public health outcomes that we care about, and trying to connect those two things in, ideally, a quantitative way.

So let me just step back and talk about some of the current performance measures for food safety at FDA. And there are two types of these, and I'm going to give you a few examples of each one.

One is the set of GPRA goals, as they're affectionately called, Government Performance and Results Act goals, and these are associated with the

budget. So I put the information here on how you could find these measures. They are basically just in a pdf. It's not a database or anything. It's a pdf. And they're reported on annually. So there's -- you know, I can't remember how far they go back, but several years back, and you can find these on our website. There are about 20 of these that have a food safety component. There are many more, of course, that are associated with FDA.

And then the other type of public performance measures that we have now is a new program called FDA-TRACK, transparency, results, accountability, credibility and knowledge, and I also put the website there. And these are internally-generated performance measures reporting on things that the program offices in the centers have identified as important things that they are doing and contributing to.

And, currently, we have about 15 foods-related measures in FDA-TRACK, but that number will change. This is a relatively new program. It's under the leadership of Dr. Sharfstein, who used a similar type of tool when he was in a Baltimore public health agency. And he is looking to really build this up. And these are all publicly-available information, and so the idea is more transparency, in terms of measures. As I mentioned though, these are mostly output measures.

So here are a few examples of the GPRA measures. The number of high-risk food facilities that were inspected, the number of import field exams that were conducted, the ability to maintain accreditation for labs, and the number of state, local and tribal regulatory agencies that are enrolled in the draft voluntary retail food program regulatory standards.

So these, as you can see, are counts of things that we do. They're important. They're telling you the work that we're doing and giving you information about how things might change from year-to-year.

Let me show you a few FDA-TRACK examples. Percent of cases reviewed within a certain time frame; that's an important kind of efficiency / effectiveness measure. Number of firms under which environmental sampling was conducted and number of firms that had positive samples. So this is getting a little bit closer to the sense for how many illnesses might have been caused, but, again, these are kind of focused on counts of things that we did.

And so I talked before about why the public health outcome kind of disease rate measures aren't that useful to our program because they're not telling us about whether our programs are working, and now I'm going to tell you why these measures aren't really that useful to our program because, again, they're telling

us what we're doing, but they're not telling us how well we're doing it. They're not telling us how effective we're being. And we're not able to link this yet to the rate of illnesses, and so that's really the work that is yet to be done.

We do have some outcome measures that are associated with food safety at FDA, and as Patty mentioned, these are under the Healthy People goals. They are very similar to the ones I showed you earlier that are on your one-pager, but slightly different wording; number of infections caused by pathogens, number of outbreaks, and then we also have one about consumers following food safety practices, which is getting to this recognition that there are roles for people in the food safety system beyond what the regulatory agency can directly control.

But, of course, we can affect that by providing information about key safety practices to consumers by assessing whether they're understanding the information and so on. So there's still a role for the FDA there.

And then we also have this priority goal that Patty had mentioned about *Salmonella* Enteritidis, and I think Dr. Englejohn's going to talk more about that. But this was a special goal that was identified and is associated with the FDA's egg rule, which came out last

year to go into effect this year, which is designed specifically to reduce the rate of illness from *Salmonella* Enteritidis.

So I showed this graph to some folks at the FDA, and they said that it was way too complicated. So I tried to simplify it, and I'm going to show it in pieces to see if that works. And it is very complicated, and I apologize for that, but it's really important in terms of showing you what the work is that we're trying to do and how what you'll tell us today will fit in.

So, as I mentioned, there are all these things that FDA does, and when you talk to individual people at FDA, they can say they do one of these things. So it's really concrete. And then people's individual performance plans. So there are lots of “things” we do.

And then there are things we care about. Right at the end, there are things that we want to see changed. We want to reduce infections caused by key pathogens. There are other examples of public health outcomes that we talked about, but I'm going to use this to try to simplify.

So the question is, how do we know that we're doing the right things in the right amount and that we shouldn't be doing more of something else? And another way to slice it would be, how do we know we're doing

the right things in the right areas, on the right pathogens, on the right food quantities?

We're doing all that now. We're making decisions about how much to invest in different programs, which guidance to issue, which rules to issue, and we're doing it based on our understanding of how they could impact public outcomes. But we don't have this method to go back and tie it in a quantitative way to see if it had the impact that we wanted to see.

So, based on these activities that we have, we've produced these outputs. So I used a GPRA goal, the number of high-risk inspections, and I used an FDA-TRACK goal, the number of environmental samples taken.

So, of course, in order to do those things, we need to have people trained, hired, we need to know which facilities to go to, we need to know how to take the samples, we have to know how to analyze the samples. So all the things we are doing in terms of activities are allowing us to create these outcomes.

And I put a box around this (indicating) because this is the list of things that we can control.

This is the list of things that -- the activities at FDA -- we can generate more high-risk inspections, we can take more environmental samples. So these are the things that we can manage in terms of

making more or less of them happen.

But we still aren't all the way to public health outcomes. That's what we want to get to. So there are these intermediate outcomes, and this is really the key to what we're working on. One of the FDA-TRACK goals is more like an intermediate outcome, and that is the number of a firm's positive environmental samples. So, of course, we need to be able to take some samples. We believe that the firms are taking those samples themselves, but we don't have access to that information. So we can't report on that without actually taking that sample ourselves.

So we take the sample, and then we report on how many firms had positive samples, but the number of firms that have positive samples is outside of our control, all right? That's in industry's control. And we can issue guidance, we can provide training. There are things we can do to influence the likelihood of there not being positive samples, but the ultimate ability to not have positive samples is not something that FDA can change. So that's why it's outside the yellow box.

So these intermediate outcomes are getting us closer to understanding how the outputs that we're creating are related to the public health outcomes that we care about. So we're really trying to fill in this

type of logic model, you know, for every type of pathogen, probably broken down by food group commodity, by the different tools of things we could do to make more informed decisions about our activities, what kind of people we're hiring, what kind of training we're offering, what kind of outreach, what kind of guidance we're issuing, all those kind of things. So this is kind of where this work is going.

So, again, back to the objectives for today and in Portland. We want to understand what are the measures that are being used by other stakeholders in the food safety system. The degree to which we understand that and, ideally, even have access to that data, the better job we'll do in terms of characterizing those intermediate outcomes.

And, also, if there are studies that exist -- we're not aware of a large number of these studies -- but studies that show how taking performance measures within your organization have changed intermediate outcomes. Things like the prevalence of pathogens on products at the time you do this work, the degree to which you have those type of studies available, that would be incredibly valuable to us in terms of being able to understand this whole system.

And then also, of course, I've shown you some of the GPRA goals and FDA-TRACK goals. You can look

at those online later, but also ideas and thoughts that you all have in terms of the output goals we're using, the outcome measures that we're using, the ideas for intermediate outcomes, any feedback that you have in terms of those things that we're using now would also be very welcome in terms of the outcome of these public meetings.

So the next steps are that, in the short-term, we'll be working in depth on this *Salmonella* Enteritidis project, on which we're seeing some of the pilots, where FSIS and FDA are sharing these metrics on a quarterly basis to get a sense of how things are changing within our organizations and in terms of what we're seeing with the folks with compliance rates and things like that, in the laying houses and in the FSIS firms, for broiler chickens, which is where FDA gets them.

And this is a nice pilot, because *Salmonella* Enteritidis is something that we know that the bulk of the diseases are attributed to either eggs or chickens, so we can actually have a nice study to say, well, if things change in eggs, how is the illness rate changed?

When you get to other illnesses like *Salmonella*, there are so many potential foods that could be involved and there's so much more uncertainty,

that it's going to get much harder to model. So we're trying to do it with SE to see what we can really understand.

And then we're also working to identify the outputs and intermediate outcomes that will help us connect the things we're doing with the things we care about. In the longer term, we want to develop methods and identify the data, collect the data needed to be able to use these improved measures.

And then, of course, ultimately, if we have many quarters, many months, many years of data in terms of the things we're doing within our Agencies and the information that we have in our Agencies, and then we also have these disease rates from CDC data, we could start to model and understand how when we do more of this, we see less of this, or when we do more of this, we don't see a change, and try to really get a better sense, quantitatively, of what we're doing and how that can impact the public health outcomes.

That's all that I have. Thank you for your attention.

(Applause)

DR. FARRAR: Thank you, Kara.

Our next speaker is Dr. Dan Englejohn. Dan is the Acting Assistant Administrator in the Office of

Data Integration and Food Protection, the Food Safety Inspection Service in USDA.

Dan.

DR. ENGLEJOHN: Thank you and good morning, and I'm going to give you a perspective about how we are attempting to measure the success of our inspection program at FSIS, the Food Safety Inspection Service at the U.S. Department of Agriculture.

The outline that I'm going to follow in the presentation will give you an introduction to how we measure the performance, identify some of the types of strategies we have in place for which the Agency reports, either through the Department or through the Office of Management and Budget and now for which we're reporting also to CDC and OMB.

Much like the work that FDA is doing on their logic model, we have also identified what we call Operational Performance Measures, which are the things we have control of within the Agency. I'll give you a perspective on the farm-to-table framework for which CDC, FDA and FSIS are working toward with the Food Safety Working Group metrics, and then specifically give you a preview of the approach we want to take with *Salmonella* Enteritidis as a case study on how we could demonstrate progress on a particular pathogen-causing

illness in products that both Agencies regulate.

FSIS has developed a comprehensive set of performance measures and objectives and goals that we think can help measure the progress that we have related to foodborne illness attributed to the products that we regulate, which would be the meat, poultry and egg products.

The purpose for setting these goals and objectives is not only to measure our progress, but also to prioritize the Agency's activities and identify program areas for which we could, perhaps, begin shifting the focus that we might, in fact, have good control over and begin focusing differently on how we can better control or mitigate risk within the distribution chains that we actually regulate or have jurisdiction over, and then FSIS measures that are used to help track both our progress that we have direct control over, over our predictions for how they actually impact public health.

For those of you not familiar with FSIS, our mission is to protect the public health, the safety and the accurate labeling of meat, poultry and processed egg products.

It's important to note that although the Agency has focused for the last hundred years within the federally-inspected slaughter and processing facilities

for which we provide daily inspection activity, we do have jurisdiction which we share with FDA at retail and in distribution throughout commerce. And we have traditionally not focused specific activities other than surveillance-type activities at retail, but we are also looking at what can and should we be doing that might have a better impact on public health with regard to meat, poultry and egg products.

Like FDA, we do use the Healthy People 2010 as our goal-setting prioritization document, in which we're focused upon the pathogens that specifically are in the products that we regulate. That includes *Campylobacter*, *E. Coli* 0157:H7, *Salmonella*, and *Listeria*. We have our 1997 baseline, which Patty mentioned earlier, and then we have the progress that's been made up through 2009, the last that was reported through FoodNet. And, as was identified before, we've had success with *E. Coli* 0157 and actually are close to having success with *Campylobacter*, but with *Listeria* and *Salmonella*, we still have progress to be made.

Within that, then, at USDA, we do have a strategic plan, and it is just now finalized for moving forward for the years 2010 to 2015, and within the U.S. Department of Agriculture's strategic plan, FSIS has three measures that we report to the Department and ultimately to the Office of Management & Budget, to

demonstrate how we believe our program has an impact on public health. Those three measures include a particular focus on ensuring that the progress made within the broiler / slaughter industry is, in fact, improving from our baseline year in which we began tracking, in 2006, a specific focus on reducing exposure of the public to *Salmonella* in broiler chicken carcasses.

Our goal is to get, under the current standard that we've had in place, 90% of those establishments into Category 1, which would be half the acceptable number of *Salmonella* in a sample set, which is just over 50 days when we do our sample set, which could occur once every two years. Or, if poorer performance is indicated, then that sampling would occur more frequently.

We have an all-illness measure, which today captures the illnesses associated with *Salmonella, Listeria monocytogenes* and *E. Coli* 0157:H7, and we will be modifying this performance measure as we put in place a new performance standard that we have recently published as a draft for which we're seeking comment on, and that relates to *Campylobacter*. So, again, we'll be reporting on *Campylobacter* at the end of this calendar year.

And then, because we believe that food defense

plans have an indirect impact on food safety, we've also added a measure for which we are moving our industry to ensure that they have functional food defense plans for which they have knowledge about who is, in fact, having access to their property and to the transport vehicles, and so forth, that move meat, poultry and processed eggs around the country.So these three measures are what we report to the Department.

To give you a perspective about the *Salmonella* performance measure in Category 1, as I mentioned, the Agency has had a *Salmonella* performance standard in raw products that was put in place in 1996 through our pathogen reduction HACCP regulation. Our goal has been to move the industry, the raw nine classes of raw products, into half the current standard that we have in place, and then, as well, issue new baseline studies to set new performance standards and reset the category guidance we have.

But, presently, we're using the current standard for *Salmonella* in broilers as our primary indicator, and then from there, we determine whether or not the industry is making progress toward controlling *Salmonella* in raw products and, ultimately, reducing exposure of the public.

Our fiscal year 2010 quarterly 3 measure is that 82% of the broiler industry is meeting these

criteria at this time. We set the goal out to 2015 to get 97% of the broiler establishments into Category 1.

As I mentioned, we have a current standard on *Salmonella*, and we've proposed a new standard, which, in essence, has the current standard, and we'll be pushing the industry to also have, again, the percent positives in the *Salmonella* sets we collect over time.

So we'll adjust our Category 1 standard and monitor the progress toward meeting the old standard and the new standard over the course of the next few years, out to year 2015.

For the all-illness measure, I apologize for the busyness of this slide, but it does give you a perspective about how we do, at this time, calculate our all-illness measure. Our goals, again, are set on the Healthy People 2010 goals. I'll also talk about our high priority performance goal for *Salmonella* and the fact that we anchor this in CDC FoodNet illness estimates.

We measure our progress, in part, to our Pathogen Verification Testing Program in order to estimate the number of illnesses. When we don't have baseline studies to actually set prevalence, our verification testing program is not designed to actually determine prevalence. And we do use baseline

studies to accomplish that, but we have not regularly done baseline studies in the products that we regulate.

Our goal is to improve and to have ongoing baselines to actually have actual prevalence information.

Meanwhile, we do use the adjusted based-on-volume percent-positive rate for our pathogen testing program. We also align this with the case rate that's recorded by CDC.

For 2010, quarterly 3 then, in taking that case rate and transferring it into numbers of illnesses, and our Secretary of Agriculture is interested in reducing illness, and so we've converted this to illnesses, we're starting with the quarterly 3 measure at just over 640,000 illnesses for all pathogens. This would be *E. Coli, Salmonella* and *Listeria*. And our goal in 2015 is to reduce that to just under 549,000 illnesses.

How do we measure this progress? Well, for the all-illness measure then, for *E. Coli* and *Listeria*, again, using the Healthy People rate. For *Salmonella*, ultimately we've set a 4% decline from the baseline case, right, to the end of year 2011, and then we use this case rate as the fiscal year 2011 objective.

We multiply the case rates by the pathogen-specific simple attribution fraction calculated using the CDC NORS outbreak data to get a total number for

each of the pathogens, that is in the products FSIS regulates. And, again, beyond 2011, then the Agency has established for this time a 1% reduction each year out to fiscal year 2015.

This chart presents the information in real numbers, in terms of the illnesses that we predict are associated with *Salmonella, E. Coli* and *Listeria* and then a total for all the illnesses, and it gives you the projection that we have out to fiscal year 2015.

For the functional food defense plans, the Agency does not mandate that establishments have these plans at this time, although we have identified to our industry that it is our intention to mandate that all establishments have a functional food defense plan.

We use the word "functional" from the perspective that we think it's not sufficient to simply have a written program. We think that the establishments need to, first of all, have a written program and to continuously test it by running mock types of recalls or mock situations where there might have been a threat or an unannounced or inappropriate exposure of product that potentially could add a hazard to the food products that are regulated by that establishment.

So we had some criteria that we've identified

that qualify as a functional plan. We've told the industry that we are moving toward regulating this particular issue, but that the priority for the Agency in moving this regulation would be dependent upon the voluntary adoption of these programs by establishments.

We break out our establishments by large, small and very small. These are determined by the Small Business Association's definition, which is really related to the numbers of individuals working in the facility, not related to buying the product produced. And we do have information by volume.

But, for purposes of this exercise, we have looked at the establishments to see who currently has a functional plan and who doesn't. As you can see for the large plants, 97% of them do; the small, which could be 500 or fewer employees, but more than 11, have 72% of those establishments with a functional food defense plan; and then the very small at 49%. We have roughly 300 of the large plants, and the rest of the 6,000 or so establishments that we have are either small or very small.

We do issue an annual survey in order to measure our progress. We ask our inspectors, who are in each facility, to answer some questions as to whether or not there is a written plan, whether or not they have access to that plan and what the content of

that plan is with regard to some specific questions that we ask. We've informed the industry that we will begin this survey again in August of this year so that we'll have our report for this annual measure by the end of September.

Again, this is overall the presentation of our performance goals and objectives for how we would be looking at progress over time for the *Salmonella* Category 1 measure, the total illnesses from all FSIS's products and the establishments with food defense plans.

At USDA, as well as at FDA, we have what is called a High Priority Performance Goal. This specific focus that we have is on *Salmonella*. The Secretary of Agriculture has made very clear that we have to make dramatic reductions in the exposure from the products we regulate, to *Salmonella*, and so we've also been asked to specifically put in place a program that would drive down *Salmonella* exposure.

For us, we're looking at all illnesses from *Salmonella*. The goal through the end of 2011 would be to reduce the number of illnesses by 50,000. It also would translate to approximately $900 million in savings to healthcare. This would be based on an economic research number as well as the number that FDA used in their rulemaking on *Salmonella* Enteritidis, in

which we estimate that the each case of *Salmonella* is roughly $17,900. So that's how we get the healthcare cost reduction. And this would then have a specific goal of reducing the 15.4 cases per 100,000 down to 14.8 cases per 100,000.

As was mentioned in the FDA presentation on doing a better job of ensuring that we know what we're doing is in fact providing efficiency and effectiveness, we're calling these Operational Performance Measures at FSIS at this time. These are the things that we know we have direct control over.

And so the Agency is looking to ensure that, when we issue policies, we are actually, in fact, enforcing the policies that we issue.

As an example, it is an expectation that when we schedule a sample to be collected for verification testing, that that sample would be collected and analyzed. We have a very low compliance rate with that. There are a variety of reasons why samples don't necessarily get collected and sent to the laboratory or they get discarded.

And so we have specific measures in place to track the reasons for why the sample doesn't get analyzed or collected. We look to see whether or not the inspectors have the appropriate amount of time to collect the samples. But, in any case, these are things

that we control.

If we say that we're going to do a thorough food safety assessment of the HACCP system after we find an adulterant in a product, our policy is that we would conduct that analysis within 30 days.

Presently, we don't have as good a compliance rate with that as what we should, and so we've put in place a measure that would, in fact, track whether or not these food safety assessments are being performed in the time frame that we've identified.

So we have a series of these for which we are developing. Like FDA, our intention is to make these publicly available so that our stakeholders can see what it is we're holding ourselves accountable for, but, more importantly, so that our inspectors and frontline supervisors, who know what we think are measures of success, and whether or not they are in fact addressing those issues that we think are important. But the industry, as well, needs to know what we think is important so that they, in fact, know where we're going to be focusing on product improvements.

We do have the Food Safety Working Group, in which FDA, CDC, FSIS and other federal agencies are working towards improving and enhancing the food safety

system that we have in place, and there is a need to look from a farm-to-table approach.

In the packet that you have, as was mentioned earlier, are some examples of a collaborative effort at identifying metrics at a very high level that the Agencies can, in fact, be monitoring and tracking, and we will be using these and further developing them as FSIS measures the success of its program.

FDA and FSIS have entered into a very specific project in which we're going to begin tracking *Salmonella* Enteritidis. This would be in conjunction, as well, with CDC, who's actually providing the data to help us measure our success with regard to this issue.

But this also has a broader implication at USDA, in that it involves an additional Agency, which is the Animal-Plant Health Inspection Service, which has some responsibility with regard to protecting the animal food supply.

APHIS has had a tradition of looking at *Salmonella* Enteritidis, in the past, through its National Poultry Improvement Program, and we're looking to see how we can benefit from, perhaps, making changes in modifications to a focus with regard to broilers, which FSIS regulates. So we've identified a project which we are going to begin piloting and measuring some success with.

In this slide, it gives you a pictorial view of the farm-to-table approach in which there are actions that are controllable by FDA; for instance, on the farm now, with their new egg rule, which has gone into effect this summer, and then it progresses from those layers to the shell eggs. Those shell eggs, if contaminated or are directed for processed products, end up in an FSIS-regulated facility, and then FSIS has jurisdiction at that point. And then as they transfer into retail, FDA again assumes primary jurisdiction over the further processed products that have had added ingredients to them.

But we also know that broilers, within the products that FSIS regulates, is, in fact, the one commodity for which we've seen an increase in *Salmonella* Enteritidis in our verification testing program that we conduct for *Salmonella*, and specifically in broilers. And so we've identified that we believe that this is a controllable hazard on the farm and that we could, in fact, and should be looking at how we can force change in the industry through the program that we regulate, beginning at the slaughter facility. And so we've identified that we begin our jurisdiction at the slaughterhouse. There are activities that we can undergo there and then demonstrate that we are actually having a reduction of

exposure to the public of *Salmonella* Enteritidis.

For us, here are some examples of things that we're specifically monitoring. The Agency, more than 10 years ago, did a baseline study on pre-pasteurized liquid egg products that are being diverted to pasteurized egg products facilities.

And so we have an estimate of what *Salmonella* Enteritidis was roughly 10 years ago. It is our goal to complete a new baseline study on pre-pasteurized eggs this year. We know that there should be a difference, in that the FDA regulation on shell eggs does mandate that eggs get diverted that are *Salmonella* Enteritidis positive or that violate the temperature and time criteria in that regulation to the pasteurized egg product facility.

So, in conjunction with the FDA rule going into effect, we're going to conduct a new baseline study on pre-pasteurized eggs, to get some perspective on what is the frequency and level of contamination of *Salmonella* Enteritidis coming into the processed egg facilities.

We also will be looking at the *Salmonella* Enteritidis in our verification testing program that we have at slaughter facilities. This program is designed to look for *Salmonella* on a daily basis when we conduct a sample set. For instance, for broilers, it would be

just over 50 days consecutively we would collect samples.

Industry's required to provide to the Agency the prior producer or owner of the birds that are coming to slaughter facilities. It's the Agency's intention to develop a program similar to what we do with illegal drug residues, in that we track producers that present product, or animals in this case, to a slaughter facility, and then we target testing of those producers if, in fact, they've had a history of *Salmonella* Enteritidis, to see whether or not control has been underway.

In order to make this a program that is effective, there is a need to reach out to industry and to find a way to provide helpful information that likely would be constructive in reducing *Salmonella* Enteritidis exposure coming to slaughter facilities.

We know that the poultry industry has expressed an interest in looking into, perhaps, a national poultry improvement plan type of approach that was done with eggs, with great success, to see if, in fact, it can be conducted on broilers.

We also have a need to use our public health veterinarians in a way that they can be, perhaps, looking more broadly at the activities that they do, in terms of working with industry in providing information

about this particular pathogen, which we do believe is controllable on the farm.

So we will be monitoring the percent positive rate for *Salmonella* Enteritidis coming into our facilities. We just completed a baseline on broiler carcasses for which we have a new prevalence rate for *Salmonella* Enteritidis in broiler carcasses, and, this year, we're conducting a baseline study on poultry parts, which would give us further information about exposure to *Salmonella* Enteritidis on further processed products that are raw and that likely would be distributed to consumers.

So this particular project, working with FDA and CDC, has great significance for us, in that it would put in place a new focus as to how we could use the data that we collect in a way that can be more directly related to public health impact.

So our next steps, then, will be to continue to work in this collaborative effort of developing management controls and operational measures that we have direct control over, make them more efficient and effective, and continue to look at what we're doing to see whether or not our actions are effective in being protective of public health.

And with that, I thank you.

(Applause)

DR. FARRAR: Thank you, Dan.

We do have a little bit of time. We are a little bit ahead of schedule. So if you have a few questions, two or three questions before the break for the three federal agency presenters; we will entertain those now.

We also have some time after the break. So we encourage you to take some time now or after the break to ask some really difficult questions for this group.

When you ask questions, I would like you to remind you to identify yourself and your affiliation for purposes of the transcript, please.

MR. MANN: Thank you. Jim Mann, Handwashing for Life.

I like the idea of the whole report card on food safety, but I'm wondering, either Dr. Griffin or Dr. Morgan, where norovirus fits in. Are we ever going to have a really good report card without dealing with norovirus?

DR. GRIFFIN: All right, so norovirus. Norovirus is handled by a different group at CDC from my group. So there's probably more going on with norovirus than I can completely speak to, but I can say a bit of it.

Norovirus diagnostics have gotten really good in recent years. So we are getting a much better handle

on norovirus. Still, most norovirus illnesses are not diagnosed.

And to explain what norovirus is, the typical story would be that some of you go out to lunch in an hour, and a day or two later, you develop vomiting and some diarrhea and it lasts about two days.

So it's sort of, often, not enough to send to you a doctor. You often can figure out what meal it was, because the other people get sick as well. And the organism is not like most of the organisms that we've been talking about today, which are carried in the intestines of food animals. Norovirus is not.

Norovirus likes people, and that's all it likes.

It lives in our intestines, and then when we use the toilet and aren't good about washing our hands afterwards, then prepare food for other people or care for other people, sometimes those noroviruses get into their mouths and they can make them sick.

So it's often a problem with food handling in restaurants. It's also a big problem in nursing homes. It will come in maybe on the food, but then it can spread through the air onto surfaces and easily be transmitted directly from one person to another.

Probably most of the foodborne illnesses in this country are due to norovirus, and though it's usually a mild illness, in the elderly people, if you

are elderly and you're vomiting a lot, you can end up in the hospital and you can even die.

So the norovirus group is getting a better handle on norovirus. One of the things that's happening is that we are really encouraging, they are really encouraging states to report on all norovirus outbreaks, to that same outbreak reporting system that we've been talking about. So we're getting a much better handle on what proportion of the outbreaks are from person-to-person spread and which are really from foods and what are the type of retail establishments and the foods that are transmitting it.

The other thing that they're doing is that they're working with some managed care organizations to figure out better what proportion of people who come in for healthcare have norovirus illnesses, so that we can get better estimates of the amount of norovirus.

MS. VAUGHN GROOTERS: Hi. My name is Susan Vaughn Grooters. I'm with S.T.O.P., Safe Tables Our Priority.

Patty, I have another question for you. Sorry, maybe you're going to get tired. So my question is for you, Patty.

I have to wonder about the plateau that we are seeing with PulseNet for 2007 and 2009, and I'm just

sort of curious what CDC is doing to improve that utilization.

Are you looking at it by pathogens and seeing what pathogens can improve getting results by PulseNet? What are the barriers, and what DC doing, and how can we, as a consumer group, help you improve that utilization?

DR. GRIFFIN: Yes, I think the first challenge to FoodNet on my slide was states doing the PulseNet typing. So some of the states don't even get all of their *E. Coli* and *Salmonella* isolates into the state's public health laboratory. And one of the reasons they don't get them all in is because, if they all came in, there would just be too many isolates for them to even categorize, much less do the subtyping on.

That's been one of our problems in outbreak investigations, where we're trying to get a handle on whether there's an outbreak and why we're not getting illnesses from a certain area. Does that mean the product is not distributed there, or is it a problem in the system?

And sometimes it's been that that state laboratory is just not getting the subtyping done and they just don't have the resources to do it, and it's because the state hasn't devoted that amount of resources to the public health laboratories.

And, of course, CDC, through its federal funding and with the help of regulatory agencies, tries its best to supplement so that they can buy the equipment and hire the personnel to do this work, but you saw the map. There are some states that get it done, and there are some states where there are huge gaps. So that's a big issue.

There's also a gap at CDC because there are continually new patterns, and CDC has to name those patterns because you can't do anything with them until you have a name and you figure out which ones have the same name so that they might be linked. So that's also a clog in the system.

DR. FARRAR: Just to add, coming most recently from the State of California, the issue of continuing dwindling state and local resources are very real and I think a very chronic problem and, hopefully, together we can find some solutions to shore up that infrastructure. Because I don't think it's necessarily a short-term issue. I think it's definitely a long-term issue.

MS. NESTOR: Hi. I'm Felicia Nestor with the consumer group Food and Water Watch, and I actually have two questions. One is kind of a quickie for Dan.

If I saw the slide correctly, there was an

anticipated increase in the number of *E. Coli*-related illnesses between 2010 and 2011 or 2009-2010. One was under 17,000. The subsequent year was over 17,000.

And what's that based on, that anticipation?

DR. ENGLEJOHN: The reasoning is just how we're doing the calculations and the information we have on the baseline. So it's the baseline information that we're using in that change. That's really what it is.

MS. NESTOR: Okay.

And then the question I have for all of the Agencies is, if you look at the Federal Register Notices that have been published on the Trace-Back meetings and some other things, trace back to the source of contamination is more directly and extensively addressed when outbreak is mentioned and not when a simple contamination event is mentioned.

So my question is for all of the Agencies. Do you put equal priority on finding the source of contamination when your only evidence of it is a pathogen finding in product versus people already getting sick from the product?

DR. FARRAR: Can you clarify a little bit about what you mean "a simple contamination event"?

MS. NESTOR: For instance, FSIS has an *E. Coli*

testing program. They routinely take tests at grinders, and 40 times a year they findpositives at the ground beef at a grinder.

And I know that the FSIS has a bifurcated policy, where the response to that is not identical to the response to an outbreak.

So I'm just wondering if FDA and CDC also have that bifurcation, whether there's more urgency about addressing an outbreak versus -- for instance, if FDA found out about the contamination in the peanut butter not through an outbreak, but through some test, would the response have been the same and what does the CDC think about that?

DR. FARRAR: I'll give it a shot from the FDA perspective. Those, what you referred to as contamination events, are very important. We do take those very seriously.

One of the more recent ones that come to mind was the HVP contamination, the contaminating ingredient that went into hundreds, if not thousands of food products. Thousands of hours were spent on that particular incident examining how the -- trying to get to how the contamination occurred, where it occurred, tracing the ingredients back and so forth. So we do take those contamination events very seriously.

That said, in each of the Agencies, there are limited resources. You got a glimpse of the number of clusters that are being tracked at any one point in time at CDC. The number of outbreaks that are being actively investigated at any one point in time by the federal agencies varies as well.

So I think the answer is we do take them seriously; we do have to -- we are inevitably faced with how to allocate our resources most effectively and efficiently.

MS. NESTOR: So there might be a difference at FDA as well? You might respond differently to a finding of contamination in a product versus a known outbreak?

DR. FARRAR: Well, I think we look at each event individually and try to assess the magnitude, the complexity, what's the probability of investing additional resources beyond what we have getting us to a more definitive answer.

Ms. Nestor: Um-hum.

DR. FARRAR: So each one is handled pretty much on its own merits.

DR. ENGLEJOHN: This is Dan Englejohn. If I could speak for Patty, perhaps in the interest of CDC, but I would just say that we have had at FSIS, particularly on the 0157 issue, which is a formulated

product for which, generally speaking, there are multiple suppliers contributing to the finished product where we do have a disproportionate focus on verifying grinding operations versus the slaughter operations, we take 11,000 -- we actually analyzed just over 11,000 samples a year for ground beef, and we analyzed fewer than 2,000 samples at the beef slaughter facilities on the trim that's used actually to go into the grinding.

It takes more than an hour to collect the trim sample, but it would be the most valuable sample in order to prevent the contamination from going forward into the slaughter facility.

We have put forward a number of new initiatives to shift the focus back to the slaughters earlier in the operations so that we know exactly where that contamination most likely originated.

So it is a resource issue, as Jeff identified, and we are actually identifying ways to get back to the source supplier as opposed to grinder. So just to make sure that you were aware of that.

MS. NESTOR: And does the CDC have any position on this? Is this something that's discussed in CDC or you basically just deal with the outbreaks?

DR. GRIFFIN: Our jurisdiction is only in the case of human illness. We deal with human illnesses,

but I think, having listened to the others, I can say that my feeling is that all of the Agencies with the regulatory agencies and CDC have their eye on human illnesses. It's the major outcome of concern.

And so that means that a product, a contaminated product that is now being linked to human illnesses, if there's an outbreak now, is going to be tracked most carefully.

If that product has been associated in the past with human illness, then that's a repeat offender and we say, this is not just a one-time problem. You know, CDC's very interested in doing everything we can to get the product information from the patients so the regulatory agencies can figure out what this ongoing problem is.

When I look at what the regulatory agencies are doing, I think they're looking at those products that have tended to cause human illness; like you just heard Dan talking about ground beef and the components of ground beef, looking for the potential of human illness, and they put a lot of their resources there.

And so a lower priority would be just an isolated positive from a product. And depending upon the product, it might be fairly high priority, but depending on the resources, it's going to be a lower priority than those other categories I mentioned.

MS. NESTOR: Thank you.

DR. FARRAR: Just to add to that discussion, a reminder that, recently, and I can't remember the exact date that it was implemented, but a Reportable Food Registry recently was activated mandating requirement for food processors to report events that were likely to result in food contamination, and FDA dedicates considerable resources to looking into, evaluating those reported food contamination events.

And I think we're about a little past six months into that Reportable Food Registry. Probably a report will be coming out in the next couple of months, two, three months on our first six months of effort in that area.

Jack, did you want to say something?

MR. GUZEWICH: To get to Jeff's point, one thing that's changed for FDA is we're getting many more reports of food contamination than we used to because of several things that have happened.

The Farm and Food Registry is one. We're getting many more contaminations with that that taps our resources. Number two, the Agricultural Marketing Service of USDA has this microbiological data program that tests produce all the time. We're getting pathogen findings in that way, and that's more

things to follow up on there than we used to have in the past.

And Kara mentioned environmental sampling.We're doing more environmental sampling with the food plants than we ever did in the past. So we're finding pathogens more often in the environment in food plants.

And in all these cases, they need to be followed up and also tied into CDC. All those isolates, whether they be *Salmonella*, *E. Coli* or whatever they are, they are all matched against the CDC database, the PulseNet database, and we look for links to human elements there.

Surprisingly, not very often do we find them.

So if we find *Salmonella* in product X, we go right to the PulseNet database and put it in there and match it; occasionally, we'll find a case or two.

Oftentimes, we find no cases.

But there are several things that are happening that are increasing the number of contamination events in the food or potential contamination we find in the environment. So our workload has really expanded in the last couple of years.

DR. FARRAR: To take those events back to the farm of origin is incredibly resource intensive, again, in many instances. Taking a positive in, say, leafy

greens, for instance -- trying to find the farm of origin can result in traces to 12 or 15 farms that could have supplied product during that time period or for that particular lot code. So to actively investigate 12 or 15 farms that could have contributed to that one production code, as you can imagine, is just a pretty amazing effort.

MR. WALDROP: Chris Waldrop, Consumer Federation of America. I have two questions for Patty.

The first one is on the new burden of foodborne illness numbers that you mentioned that CDC is working on. I may have missed it, but I just want to be clear. It looked like there was going to be, certainly, more data added, additional methods used.

So that means that the new numbers will not be comparable to the old numbers. Is that correct, that you won't be able to make that direct comparison and say, “All of a sudden we've seen a decrease”; is that correct?

DR. GRIFFIN: That's correct. There will be new data sources and the methodology will differ, yes.

MR. WALDROP: Okay, thank you.

And then the second question, on your food categorization --

DR. GRIFFIN: Let me just say you won't be able to compare them for the purpose of measuring

trends. You can always say, “This is different,” but they're different in many, many ways.

MR. WALDROP: Thanks.

DR. GRIFFIN: For the purpose of trends, you can't.

MR. WALDROP: Terrific.

DR. GRIFFIN: But we have the FoodNet data for that.

MR. WALDROP: Great.

The second question was on the food categorization chart that you had up there that had meat and the poultry and the different types of fruits and vegetables.

Are other agencies as well as the state agencies using those same categories when they are trying to do this sort of work? Because it just seems, for consistency's sake, if everybody's on the same page and using the same definitions, that might make things a little bit easier.

If they're not, are there efforts underway to try to get everybody sort of using these same sort of definitions?

DR. GRIFFIN: What agencies are you talking about?

MR. WALDROP: State agencies.

Does FSIS use those same categorizations in

terms of beef, poultry or do they break it out even further?

DR. GRIFFIN: So those agencies can speak for themselves, but the states report outbreaks to us, and then we summarize the data for them.

I don't know that any of the states put out their own state-based reports with commodities. You know, they are aware of our process. They know how we do it. We go over it with them. We ask them to tell us, as much as possible, the ingredient that caused the outbreak. So I think we are very well coordinated with the states.

As far as the regulatory agencies, we worked with them in selecting how to do the commodities. We came up with one plan initially and showed it to regulatory agencies, and they said, “That doesn't work for us.” And then we came up with a different one.

There's no perfect hierarchical tree. There are issues with this one, and there are certainly many things that we need to do with within that tree. For example, I gave you the turkey example. Roast turkey and deli turkey are very, very different products from a regulatory perspective.

So there's a lot more that we need to do to work with the regulatory agencies to make sure that the foods in subcategories are categorized in ways that are

useful, and there should be ways that -- sometimes there are several subcategories, and across subcategories, you may combine several types of ready-to-eat foods, say, do analysis of ready-to-eat foods.

So there's still work to be done on that whole categorization, but my impression is that, at this point, we're on the same page. We have working groups that talk about attribution and are working on common methodologies.

MR. WALDROP: All right, thanks.

DR. FARRAR: I'm getting the signal here that we need to take a break. Can I ask you to hold your question until after the break? These are excellent questions and comments. We'll reconvene at 11:15.

Just a heads-up that lunch will be on your own. So, during the break, if you want to make plans for lunch, it might be a good thing to talk about. There are lots of restaurants in the building and nearby. So thank you. See you at 11:15.

I have an update. I said 11:15. If you come back at 11, that will give us some time for some additional Q & A. So, my mistake, 11:00.

(Recess taken from 10:49 to 11:16 a.m.)

DR. FARRAR: We'll resume where we left off. We'll have a few more minutes for questions for the three presenters this morning.

One question was handed in, and I'll start with that one. This question is to Dr. Griffin. It says, "Please discuss the development of second generation subtyping methods by PulseNet. When will the transition occur? What impact will it have on the program?"

DR. GRIFFIN: So, yeah, I'll speak for the CDC Laboratory, which is a different group from mine, but let me just preface it by saying that more subtyping is not always better. There are times that you can take STEC strains, and which is very clearly from a common source, and do much more subtyping, and you start to find differences that aren't important.

So that's one thing. You can subtype things to the point where it's not relevant. And the second thing is subtyping is always a balance between the cost of doing the subtyping and the method.

What's nice about pulsed-field gel electrophoresis is that most states, with some help from federal agencies, have been able to buy the equipment to do the subtyping, and it's not that hard to do. Everybody in each state can have a person who knows how to do it, and the patterns can be submitted. So having something that can be done is a really

important component, just as important as having something that's a good procedure.

And so, with that in mind, CDC is hard at work on developing various subtyping methods, and I mentioned some of them. And for some of the more common patterns, we really do need further subtyping by different methods. So we're doing that.

At this point, all of that subtyping is being done by sending the strains in to CDC, and I don't know what the plan is for whether some of those methods will always have to be done at CDC or in selected regional laboratories or whether some of them will get pushed out to states, but there's definitely a lot of work on further subtyping and that, we will hope, will help us to get at the bulk of our *Salmonella*, which is Typhimurium and Enteritidis. And many of those have big, major subtype patterns that need these further subtyping methods to distinguish.

MS. ROSENBAUM: Good morning. I'm Donna Rosenbaum, Executive Director of S.T.O.P., Safe Tables Our Priority, and that's a consumer and victims' assistance organization for those suffering from foodborne diseases.

And we're really glad to see the Healthy People Goal of 2010 especially for *E. Coli* 0157:H7, for which

our organization was founded around 18 years ago, in the aftermath of the large outbreak from Jack in the Box.We're really glad to see that that has come somewhat under control.

I have two questions and comments relative to that, both of them having to do with the non-0157s, really, and we've been seen and we've been following the non-0157s for quite a few years. We're going to be talking about that in our presentation this afternoon.

But I'm wondering, across the Agencies, what you think of, in terms of 0157 control versus non-0157 control, if we can say that, because we have the 0157 under control -- and my opinion is that we don't necessarily know that the same is true for the non-0157s, which seems to be emerging and the 19 or so outbreaks in different places than have been noticed before, due to a variety of factors.

But can you comment, please, on any information or your opinion on whether you think that the same is true for the non-0157s and what your Agencies are doing about it?

DR. FARRAR: Patty, you want to take a shot at that? And Dan will probably have some follow-up.

DR. GRIFFIN: Just a clarification.What do you mean whether we think the same is true?

MS. ROSENBAUM: That by controlling 0157, are

you, or not, necessarily controlling the non-0157, do you have any information that would indicate that that's true or not true?

And I have a second comment. Maybe I'll go into the second comment, which will probably make that clearer.

The non-0157s, from our research and from our database, when we encounter folks who are suffering from the non-0157s, it seems to be an older age frame of reference than necessarily you see with 0157. So I'm wondering if we're looking at the right metrics, if you have any idea whether the metrics that indicate that we have some semblance of control over 0157 would indicate anything similar for non-0157s?

DR. GRIFFIN: Okay, good. So the first issue with the non-0157 Shiga toxin-producing *E. Coli*s, and what we're talking about is *E. Coli* that produce Shiga toxin, but they're not 0157. And those *E. Coli* that produce Shiga toxin cause diarrhea, bloody diarrhea, and can cause hemolytic uremic syndrome. *E. Coli* is the most common of them and is responsible for around half of the Shiga toxin-producing illnesses in this country.

But the rest of them are caused by non-0157, and we use the term STEC as an abbreviation. For 0157, it's really -- we know it's carried in cattle and we

can often trace illnesses to cattle products, ground beef, raw milk. And we suspect that, when it's produced, there's been some contamination from the environment around cattle feces, that sort of thing.

We know that non-0157 are also carried in the feces of cattle. They're also carried in other animals. There's been -- it's a lot harder to find them in the stools, because the culture methods are not as easy. So that, if you have a non-0157 STEC illness and you go to your doctor and get a stool culture done, chances are the laboratory will say that no pathogen was found, because most laboratories don't look for them.

We've put out several guidances trying to improve the detection of these, and because some labs are starting to follow those guidances and we're starting to detect more of these illness, and that means we're finding more of the outbreaks.

But because we haven't, for a long time, been good at detecting them or finding the outbreaks, we know less about the transmission. We know that they can be in ground beef, but very few of our outbreaks have had any link to a meat product.

So I think of the non-0157s a little bit more like *Salmonella*s, sort of – the organism seems to get into a lot of different things and there seem to be

different modes of transmission. We're not hearing that strong ground beef story that we hear with 0157s.

So I think that some of the measures that decrease 0157 illnesses are likely to help with non-0157 illnesses. Having safer ground beef and safer leafy greens should help, but I think other things are needed. And, because of that, we are embarking on, in FoodNet, some studies of transmission of the non-0157 STEC and we're really, really encouraging the clinical labs to look for these organisms so that we can find the outbreaks and know more about the transmission.

MS. ROSENBAUM: Thank you.

DR. ENGLEJOHN: I think from the FSIS's response, that we would recognize and have said that if you don't measure something and look for it, then the chances are it's going to continue to go unnoticed or unaddressed.

And that would be the case within the -- the beef industry, generally, for which we regulate 0157:H7, is, in fact, the organism being looked for and controlled against, but not a broader category of pathogenic *E. Coli*.

And so to just simply answer the question, if a policy were modified to address a broader spectrum of pathogenic *E. Coli*, all of which would likely be in the product for the same reason, for contamination during

the slaughter process as being a primary mode, then it would also be more protective against 0157:H7. So that absolutely would be true.

And based on the petitions that we have received, there is a reason to believe that, at retail today, there is an identifiable prevalence of the organism there. It's not true prevalence, but the incidence of -- when looked for and found, was running roughly, I think, around 2%. So it would give you an indication that, until it's addressed as an issue to be controlled, it likely would remain in the food chain.

So addressing that would certainly make a more broad and protective program for 0157:H7, for which illnesses are being readily tracked in our program.

MS. ROSENBAUM: Thank you. I have a short -- and does the FDA have anything on that or no?

DR. MORGAN: No.

MS. ROSENBAUM: I have another short comment along those veins having to do with the 0157s and having to do with our data as well in the data we've studied of victims of foreign disease.

And that is just a comment on the FoodNet sites looking for hemolytic uremic cases and doing surveillance with the enterologists. And while that's a good thing, I just want to caution you to not

overgeneralize or try to look at trends in that, in terms of overall control of HUS in the population.

In our database, we have a tremendous number of middle age and teenage -- upper -- not even teenager. Teenagers would still be seeing pediatrics, but we have a number of adult patients with HUS that wouldn't get tracked by that method. And what we're seeing from the non-0157s, we're seeing that there is a huge proportion of non-0157s that affects an older age population. So that by tracing HUS in those populations, we certainly wouldn't be able to have good metrics on that kind of information as well.

So I don't know if there's a way to widen the net, in terms of how we're looking for HUS, but we think that would be helpful because we're hearing that -- in our opinion, there's a lot more in this outbreak than currently is being found. So that's just a comment.

DR. GRIFFIN: If I may respond to that. So it's an excellent point that HUS, that severe complication of *E. Coli* infection, can and does affect persons in all age groups. The highest incidence is in young children, but the highest death rate is in the elderly.

Persons of any age can get this disease. We publish our numbers on children because, in most

jurisdictions, people send their really sick children to a children's hospital, and so we can capture them, but adults go to -- I mean there are hospitals on every other block in some cities, and we're just not sure of getting great data.

So for measuring incidence, we use our data on the children under five years old, but we actually gather information on the older people. We try to capture that data on HUS in any age group, so that we learn about them and so that we try to look for the organism that's causing the illness.

And so we are looking at them, and non-0157 is a very uncommon cause of hemolytic uremic syndrome, but as of those of you who read the newspaper read about the 0145 outbreak this year, many people in that outbreak had HUS. So these organisms do cause HUS.

DR. FARRAR: We have time for one more question.

MS. DUNST: Good morning. I'm Lorene Dunst, and I'm with Jack Links Beef Jerky, and I just wanted to comment from an industry perspective.

You know, the USDA is in all of our facilities and they're a welcome ally, and everything they say they're going to do, from my experience, they do. You know, if there's a non-conformance, a non-compliance, they're there to work with you.

But they're a complete ally, and they're there day in and day out. And, you know, from an industry perspective, we really appreciate that.

Not only that, at times, I do use them as a weapon because I'll say, "Hey, what would the USDA say about that?" And they say, "Whoa, whoa. Okay, yeah, we'll listen to you."

I just wish there was a quality aspect like the USDA that I could use in my corner. So thank you.

DR. FARRAR: Since that was a comment, we're going to take one more question.

Thank you for your comment.

MR. GIANNINI: Thank you.

The House of Representatives passed a bill last July, 2749, that was going to mandate a tracing of food back to its source. It didn't define source, as far as I know, and the bill hasn't been passed yet through the Senate.

My question, I guess, to the group here is what is the definition within this context here of "source"? Some people think that it goes all the way back to the birth of the animal or maybe the feed lot or even the farm, but most of the discussion here seems to be really from the processor or from the slaughterhouse forward.

And a corollary question is, if, in fact, it does require the source to be back to the origins of the food, how is this going to be handled? And I was wondering why APHIS wasn't part of this meeting, because they are very much a part of it with the National Animal Identification System.

DR. FARRAR: Good question. Let me start, and Dan and Patty and others can chime in.

There are different definitions of "source." Probably each agency has a little different definition of "source."

MR. GIANNINI: That's my question.

DR. FARRAR: For instance, when we do trace-backs, take an example of leafy greens, our effort is not only to determine the farm of origin, the field of origin of that contaminated produce, if possible, but to take it one step further, obviously, and find out how the pathogen came into contact with that product.

That may involve factors that are not actually -- that emanate from that farm or field, maybe upstream from that farm or field or uphill.

So "source" is a pretty involved and somewhat complex term, and you're absolutely right that there should be appropriate definitions with that.

Dan, you want to comment on the FSIS perspective on source?

MR. ENGELJOHN: Sure. From the FSIS perspective -- and I think it's true also for FDA and APHIS, and I'll speak a bit about that as far as where we had jurisdiction.

So part of the issue becomes where does jurisdiction begin for the federal agency on regulating a particular product. FSIS does not regulate live animals, except if they are offered for slaughter. So once they come to slaughter, then that's the point where we would generally trace back to on a particular issue.

But if it's a ready-to-eat food product, then it's generally the place for which the ready-to-eat product was actually made, as opposed to prior sources for those sourcing materials. But we look at cause. If there was underprocessing versus wheat contamination, then that becomes a source issue as well.

So I think each situation is unique, in terms of identifying, but we presume that when live animals come to slaughter, they will have inherent pathogens in or on them and that the responsibility is to prevent or eliminate or minimize, to the maximum extent possible, those organisms getting on the products from which a person may become sick. So a raw product is looked at differently than ready-to-eat.

On the issue of APHIS, APHIS is involved, but

typically their jurisdiction, obviously, is on animals, but it's with regard to organisms or conditions that would cause the animals to get sick or to spread disease. So the fact that 0157 is in cattle isn't an issue that APHIS presently has its hooks on, because that organism, 0157:H7 doesn't make the cow sick. If it did, then that would be a situation that they would likely have a different or more appropriate focus upon.

Salmonella Enteritidis is an issue for which APHIS has an interest, and eggs, in particular, because it was something transferred from hens and it has an effect on the animal's health.

So each situation creates a different scenario, in terms of how you would define it.

MR. GIANNINI: Does anyone have any idea when the Congress, in their ultimate wisdom, is going to come up with a definition of source?

I've been to some conferences where the feeling is that they're going to want to go back to the origins of the animal and have traceability all the way to market, and that's just speculation because the Senate bill hasn't come through yet. And you guys are from Washington, so you have better idea than I do, from California.

DR. FARRAR: Well, just because we're from

Washington doesn't mean we know what Congress is going to do, and the absolute only answer we can give you there is that Congress is going to do what Congress does and I can't tell you what their intent or what their resolution of that particular issue will be.

I can only tell that we have publicly stated, on many occasions, that pending legislation, such as the 510 bill and other bills, would give FDA valuable new tools that we don't currently have in our arsenal.

So...

MR. GIANNINI: Thank you.

DR. FARRAR: All right, let's move ahead to the consumer presentations. Up first, Chris Waldrop, Consumer Federation of America. Chris, I believe you have a PowerPoint presentation, correct?

MR. WALDROP: I do.

Thank you very much. I'm filling in for Carol Tucker-Foreman, also of Consumer Federation of America. So there was a slight change in the agenda at the very end.

Again, my name is Chris Waldrop. I'm the Director of Food Policy at Consumer Federation of America. CFA, for those of you who don't know, is a national non-profit consumer advocacy organization. We were founded in 1968 to advance consumer interest through research, education

and advocacy. We are made up of about 280 pro-consumer groups all across the country and represent about 50 million Americans nationwide.

Now, very happy to be here. We appreciate the Agency's holding this meeting on this idea of measuring progress on food safety and developing metrics. We think it's important to really be able to develop a means of assessing and measuring whether or not we are having an impact and reducing foodborne illness, since that's the goal of everyone here.

But in order to do that, it's really important to have reliable, appropriate and sufficient data to be able to measure that progress. Dr. Morgan's presentation, I think, said reliable and credible data, but she was making the point, as well, that the data need to be there if you're going to be able to develop these measurements and then know whether or not you are measuring what you are intending to measure.

Without good data you, won't have that accurate measure of success or failure or you could have -- using inaccurate or insufficient data, you could then end up developing a system that doesn't address the real heart of the problem that we're trying to get at.

So as we look at this issue of data, I wanted to focus the Agency's attention on two Letter Reports that were published last year by the National Academy

of Sciences, Institute of Medicine. These two Letter Reports were commissioned by FSIS to review its risk-based inspection proposal at that time, and, while those reports were done in the context of risk-based inspection, the committees that looked at these reports, the NAS committees that looked at these issues, really identified some fundamental issues of data, the collection of it, the analysis of it, the use of it, that I think are very appropriate for this discussion.

So I'm not going to get into the details of the risk-based inspection issue, but I do want to draw everyone's attention to the sort of higher-level data issues that the committees raised.

So a couple of themes came out of these reports. One was FSIS -- we're going to pick on them for a minute, because they're the ones that commissioned the reports, but I think there is some relevant information here for FDA and CDC, as well.

But the themes that kind of rose out of these reports are that FSIS lacked sufficient data to be able to do what it was trying to do or lacked data that were collected for a specific purpose to be able to do what it wanted to do on food safety.

And then the committees went to a great length of time to actually suggest additional data that FDA

should collect or retrieve or gather from other places. So these reports both have a lot of information here about data that would be essential or useful for the FDA in designing not only its program, but also in performance measures.

I want to just give an example of that from the first report, the Process Control Indicator Report.

The NAS committee provided a whole host of information that they thought would be useful for the Agency to collect in terms of a number of different pathogens. So I'd just show you this one for *Salmonella*, but they also did a similar list for *E. Coli*, for *Listeria monocytogenes*, for ready-to-eat products. The committees did a lot of work in suggesting different data that Agencies should collect and that I think would be valuable in this process.

So, for example, faster quantitative testing methodologies, national baselines for *Salmonella*, collecting data on *Salmonella* serotypes by raw product throughout the entire farm-to-fork process, and then looking at prevalence and load of *Salmonella* in incoming raw materials. So, again, these are data that I think would be useful as the Agency is developing its performance measures and trying to determine what they should measure and how they should measure it. And,

again, there were other pathogens that were addressed, as well.

The second report that was done, which I'm going to spend a little more time on, is the attribution report. Obviously, attribution is very important. We've heard it discussed already here this morning.

It was discussed in much more detail at the earlier March meeting on metrics.

The NAS committee really focused in on the need for combination of approaches in developing attribution data, not just relying on outbreak data or expert elicitation or just a few sources. They really suggested that you need a combination of approaches.

They quoted the IOM study of the Scientific Criteria to Ensure Safe Food from 2003, which also suggested the combination strategy was the optimal science based-strategy there.

And then one of the key findings of last year's Letter Report to the Agency was, again, that data sources currently available for assessing attribution are insufficient to be used independently and that it provided some suggestions on how FSIS could use additional data and said that this could help in the development of better-informed attribution estimates.

I believe the March presentation by Dr. Tauxe from the CDC also suggested the combination approach

was appropriate. However, as I was going through the presentations at the March meeting, I noticed that a lot of them were predominantly focused on the use of outbreak data, and I just wanted to raise a few concerns that CFA has too much reliance on outbreak data when you're looking at attribution.

I know outbreak data are the easiest data to get -- or not to gather, but the easiest data to use.

It's available. But we're concerned that if you rely too much on outbreak data and don't try to develop plans to gather other data, that you're really going to be missing some key issues.

Outbreak data, obviously, don't address sporadic cases, which are the vast majority of foodborne illness cases that occur each year.

Campylobacter, for example, is almost never linked to foodborne illness outbreaks. It's almost always linked to sporadic cases, and *Campylobacter*, the CDC estimates, causes 2 million cases of illness a year.

Many outbreaks are also not identified because they're lacking information. There's just insufficient ability to connect an outbreak to a particular food. So, again, the outbreaks that we are able to identify are just a small portion of the larger outbreaks that are out there; also of the larger foodborne illnesses

that are out there.

And, in addition, and I believethis was raised at the last meeting, that outbreak data reflect disease occurring at the point of consumption and don't necessarily translate to where contamination may have occurred. So there's some disconnect there and a need to rectify that.

So our concern is, if there's too much reliance on outbreak data, that you end up over-, or possibly under, -estimating the risk of particular foods and designing programs that don't necessarily address the reality of the situation.

So, again, the committee recognized that FSIS is not using all the data available to it and made some suggestions; here they bring in the CDC and FDA and said that the Agencies should work together to develop a coordinated approach to really using data, to collecting data. They list a whole number of suggestions here. They also recommend that FSIS should work with FoodNet and PulseNet to look at the sporadic case data and begin to develop estimates of attribution for sporadic cases.

So, again, I'm raising these because this information was paid for by FSIS and taxpayers. It's great scientific input on FSIS's programs and the need

for additional data to be collected, and I wanted to highlight this because I think it would be useful for the Agencies, all three of them, to go back to these reports and really help them identify data that may be needed so that they can move forward in developing these performance measures.

As we're sort of thinking through this, I wanted to recommend that the Agencies really -- we've seen that the Agencies are working together on this pilot project on *Salmonella* Enteritidis, and I think it's great that the Agencies are working together more than they ever have in the past.

I want to keep pushing on that and suggest that the Agencies really work together very closely and develop a core data to integrate a data collection strategy, a strategic plan for data collection to help inform the performance measures and help perform the work they do on a regular basis, and this would include identifying specific data needs.

And I think as the Agencies go through these performance measures, are trying to figure out what they can measure and how they can know that they are making progress on food safety, there are going to be data gaps that arise, there are going to be additional data that they recognize that is needed. So

incorporate that into a strategic plan, identify those data needs, develop the plan, put it out for public review and comment, see what the public has to say about it. That may bring in additional ideas that may be useful.

Just as an example, one of the performance measures that is on this sheet that's in your package today, in the top, "The Prevalence of Selected Foodborne Hazards in Key Food Commodity Groups," that would be a performance measure that the Agencies are considering.

Now, if you look at FSIS, Dan said, and I thank him very much for making this very clear -- what he said is that the Agency's verification testing program is not designed to measure prevalence. Yet the Agency has tried to use verification testing data to say the prevalence of foodborne pathogens in particular food has decreased or will be decreasing.

Since they can't use those data, they don't have the data that do that, this would be a key gap where they could start looking at how do you measure prevalence and what's the data system you need to collect to be able do that and then go forward there and try to collect those data, and so you can accurately make those statements.

CFA has, in the past, and will continue to,

challenged the inappropriate use of data in developing performance measures and making Agency comments about the intended use of those data.

So this is a suggestion of a way that the Agencies could go forward and really sit down, develop a plan and collect data that are useful and are coordinated and integrated so that all the Agencies can work together to move forward.

And with that, I will thank you very much for your time and the opportunity to make comments.

(Applause)

DR. FARRAR: Thank you very much, Chris.

Next on our agenda is Katherine Fedder, Michigan Department of Agriculture.

MS. FEDDER: Thank you very much.

My name is Katherine Fedder, and I am the Director of the Michigan Department of Agriculture's Food and Dairy Division, and we're very pleased to be here today and to see this collaboration amongst our federal food safety regulatory partners, and we feel that this is a very critical issue in our effort to integrate the nation's federal, state and local food safety protection programs.

I read the transcript from the March 30th workshop and viewed the presentations, and it left me

with a very optimistic feeling about our opportunity to improve our Food Safety System by optimizing our collective resources, setting national goals and mobilizing those collective resources to achieve the goals.

I'd like to begin by making a few remarks about some of the challenges that currently face federal, state and local food safety programs. Jeff made mention about some of the challenges that do face state and local programs, and even though there's not much need to reinforce that, I do want to reinforce that, in Michigan, we are facing our 10th year of continuous reductions. And even though food safety is the top priority at the Michigan Department of Agriculture, we certainly haven't been immune from those budget reductions.

We're also very concerned, though, about our 45 local health departments and the fact that we rely on them so heavily to do the food service work in Michigan, and some of those organizations are even at risk of having to turn the program back over to the state, and we certainly don't want that to happen.

These budgetary issues mean that we are being scrutinized, much as our federal partners are, on how we spend our public dollars to protect the public health. Each year, the call has been louder for

government agencies to establish performance goals, outcome-based measures, transactional costs, risk- or priority-based budgeting plans or some other method to help decision makers allocate dwindling resources for the public good.

We recognize that the bottom-line objective for our program is to reduce the incidence of foodborne illness. As you know, current evidence indicates that much foodborne illness cases are cases of sporadic non-outbreak illness, and we just heard that. And states are collecting some of that non-outbreak data, and therefore, that might be one thing we want to look at to better integrate some of our data.

That sporadic outbreak, coupled with the fact that gastrointestinal illness can be the result of person-to-person, waterborne, foodborne or zoonotic transmission, makes it very difficult to attribute the variety of foodborne illness to the consumption of specific foods or food ingredients.

Resource limitations at the state and local level have made obtaining accurate state and local foodborne illness estimates even more difficult. Were it not for our cooperative working relationship with the CDC, we really wouldn't have the data that we needed to assess our program effectiveness. And even though we do have those data, we don't believe that they

are being used optimally or, as we've already heard, we have data gaps that preclude us from having the optimal data that we need in order to measure our program efficiencies.

In Michigan, we've utilized various measures, with varying degrees of success. For example, we have used output measures, such as licensed establishments, inspections, recalls, numbers of standardized trainers, samples, enforcement actions, and some of the other outputs you heard earlier today.

We have also incorporated risk and frequency by setting goals for the percentage of high-, medium-, and low-risk establishments inspected on time, with the obvious priority being on high-risk establishments.

We've established goals for the FDA ratings program in the Grade A Milk Program. We have set program improvement goals, such as progress toward meeting the Voluntary Retail Standards or the Manufacturing Standards or the performance of local health departments in meeting our state accreditation program standards.

We've also worked on linking into the national FDA Retail Performance Standard of reducing the risk factors for foodborne illness by 25% by 2511, and we've set up a similar model in the State of Michigan, in

order to capitalize on that national model.

Although these measures have served the purpose of giving us something to measure and report, they're still weak for a number of reasons. They don't give us a clear way to associate action with outcome.

Are these programmatic efforts leading directly to a reduction in foodborne illness? Are we directing our resources toward interventions that reduce illness? Could our resources be better directed? Do our priorities as a state link up with the national priorities in order to optimize our collective resources in meeting outcomes? Are we truly utilizing foodborne illness and outbreak data in research to approve regulatory programs?

It appears there's a lot of room for improvement in linking the collective knowledge of the epidemiology laboratory sciences, regulatory industry and academic sectors in order to improve our food safety program. This also means we'd need to have a common vision and goals in order to optimize all of those resources.

MDA, Michigan Department of Agriculture, has made an effort to participate in several important FDA initiatives. I already mentioned our participation in the Voluntary Retail and Manufacturing Standards. We

are also one of the six original Rapid Response Team states. We've been a long-time Food Safety Task Force partner as well as a long-time contractor for food processing inspections.

With the Rapid Response Team and Food Safety Task Force's opportunities, there was originally very little guidance from FDA on the outcomes or the expectations for these programs. So we designed our programs to capitalize on opportunities and meet the needs of our state.

Until recently, each of these five activities seemed to function very independently from one another and were really not part of a commonly understood objective. We've seen, though in the past year, a much greater effort from FDA to link these various activities together as a part of a common vision. Now we need to have commonality in the metrics used to evaluate their effectiveness in meeting short- and long-term goals.

How do we link our resources to outcomes? The Michigan Department of Agriculture is currently involved in a project, along with the food safety research consortium, several regulatory organizations and several state and local governments, to look at a framework for assessing how food safety resources are used. The discussion of frameworks, whether pathogen

food pairs, the farm-to-table continuum or the prevention-intervention response cycle, is often tied into organizational structure.

As you know, there is tremendous variation between and within federal, state and local structures.

This creates a series of problems when you're trying to link expenditures without comes, not to mention the aggregation of data from 3,000 agencies.

Based on the comments I've made, I'd like to offer the following suggestions on behalf of MDA. We believe that National Food Safety Outcome Goals should be set by the federal agencies in collaboration with state and local public health regulatory organizations as well as other industry and consumer parties. These include both short-term and long-term goals with data that are contributed not only through current systems such as FoodNet and PulseNet -- we've talked about that this morning -- but with method enhancements that help us to better address the issue of attribution. But this will require careful planning, as it will certainly mean a change in the way many agencies are collecting data. Therefore, we need to have a long-range plan for implementation.

Once national goals are set, the same parties should work collectively to establish intermediate

outcomes for state and local agencies. Short-term goals and metrics should be part of every contract, cooperative agreement or grant between states and federal agencies, and there should be a clear understanding as to how the intermediate goals link to the national outcomes.

Many efforts that are currently underway to address metrics, such as performance indicators developed by Secor, the Voluntary Retail Standards and the Manufacturing Standards, should be incorporated into this process.

I would also recommend that some of the lessons that the Michigan Department of Agriculture learned from our accreditation of local health departments could directly benefit FDA's program in working with state agencies. And we discovered when we went through a Manufacturing Standards assessment recently that we had dealt with many of the same issues 12 years ago, when we first began our accreditation program, and so there really are some lessons learned that we could contribute to this effort.

Resource allocation and capacity building should be based on risk and focused on outcomes. While public funding should be used to reduce areas of higher risk, private sector partnerships should also be

utilized to maintain efficacy of lower risk controls and interventions. For example, increased use of third-party inspections by the private sector can help us to maximize the use of public resources by redirecting them to areas of higher need.

The linkage between resource allocations and outcomes should be clearly discussed and determined, so that systems and structures can be modified, if necessary, to collect the type of budgetary and metric data that will provide maximum opportunities for continuous program improvement. All levels of government have an increased need to be able to clearly articulate what value is derived from the expenditure of public funds.

If we had a national model that allowed us to speak with one voice, clearly identify the roles and responsibilities of varying levels of government, utilize private sector partnerships, show the relationship between our program effectiveness and foodborne illness, I believe we would be able to function as a more effective food protection system.

And I have one final thought. We've been hearing a lot about the development of a two-track food system. I don't know that we heard that today, but I've been hearing a lot about it. The larger system that

ships its products across state lines and around the world and upon which most of the country relies and the smaller local system that focuses on keeping small producers in business and bringing people to the source of their food, I believe that both of these systems are important to our citizens, and we, as food safety and public health professionals, should do what we can to support both of these systems.

Sometimes we're torn between bringing risk as close to zero as we can or recognizing the right to make informed choices about risk. In the end, we have only so many limited resources at our disposal to perform this very important job. I hope that we can focus those resources on the areas of greatest risk, greatest exposure and greatest benefit for the dollar expended. If we can find the right metrics, use our collective resources to meet national food safety goals and commit to an integrated approach to our Food Safety System, I think we'll have a very positive story to tell.

So I'd like to thank you again for giving me this opportunity to speak on behalf of a state agency, and I look forward to continued partnerships with our federal agencies and all of our other partners.

Thank you.

(Applause)

DR. FARRAR: Thank you very much, Katherine. Michigan has been particularly hard hit by the economy. So very appropriate comments. Good timing.

Our next speaker is Helen Binns with the American Academy of Pediatrics.

DR. BINNS: Good morning. I appreciate this opportunity to present very brief comments to the Food Safety Working Group regarding appropriate metrics to be used to assess for performance in food safety.

I'm Helen Binns. I'm a pediatrician, and I represent the American Academy of Pediatrics, which is a non-profit professional organization of more than 60,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical subspecialists dedicated to health, safety and well-being of infant children, adolescents and young adults.

I currently chair the American Academy of Pediatrics Council on Environmental Health, which shares responsibility for food safety issues with the Committee on Nutrition. I am Professor of Pediatrics and Preventive Medicine in the Feinberg School of Medicine at Northwestern University, where I direct our Nutritional Evaluation Clinics and our Lead Evaluation Clinics here in Chicago.

The AAP urges the Food Safety Working Group to

give special consideration to children's issues in developing metrics to measure the effectiveness of the nation's food safety systems. Children are disproportionately affected by foodborne illnesses. From data from the CDC's FoodNet, about half of the reported foodborne illnesses occur in children, with the majority of these cases occurring in children under 15 years. For several of the infectious agents, they're documented to strike children under the age of nine at greater rates than adults. These illnesses can have serious long-term health consequences and, in some cases, even death.

And we just did hear recently, we just talked about here, that striking the elderly is also a concern here, but, really, children are a key vulnerable group. Children have higher risk for foodborne illnesses due to a number of factors. They have an immature immune system in the young child and they may be unequipped to deal with a virulent infection. Since they're smaller than adults, a proportionally lower amount of pathogen can cause illness. Children are entirely dependent upon their caregivers to select the foods they eat and to prepare them safely.

Given that children suffer from foodborne illnesses at disproportionate rates and have these special vulnerabilities, any efforts to track the

effectiveness of our nation's Food Safety System should focus on whether a child's health has been improved.

With these issues in mind, the American Academy of Pediatrics recommends that metrics should include child-specific end points that are measured and tracked, efforts should be made to link food safety data with trends in antimicrobial resistance, for instance, tracking not only various pathogens, but also the occurrence of the resistant forms of the foodborne illness, and metrics should be designed with sensitivity to the fact that some databases have limited capacity to track among certain age groups or geographic areas. For instance, FoodNet only covers certain state or metropolitan areas. All children's age groups should be tracked for foodborne illness.

Metrics should also include behavioral issues, such as whether parents and other caregivers are educated in avoiding high-risk behaviors for children, such as consumption of raw milk or raw milk products, raw or partially cooked eggs or egg products, raw or undercooked meat or poultry, raw or undercooked shellfish, unpasteurized juices and raw sprouts, and whether parents and other caregivers are educated about proper storage, preparation and cooking of food and leftovers.

The AAP would be pleased to be of assistance to

the Food Safety Working Group, and we encourage you to tap our organization's expertise.

In conclusion, the AAP would like to urge the Food Safety Working Group to place a special focus on children's health in developing metrics for our nation's food safety efforts. We appreciate this opportunity to offer comments, and thank you for your commitment to food safety.

Thank you.

(Applause)

DR. FARRAR: Thank you very much, Helen.

Our next speaker is Sarah Ohlhorst with the Institute of Food Technologists.

MS. OHLHORST: Hello. I am Sarah Ohlhorst.

I'm a staff scientist with the Institute of Food Technologists, which exists to advance the science of food.

IFT's long-range vision is to ensure a safe and abundant food supply, contributing to healthier people everywhere. Founded in 1939, IFT is a non-profit, scientific society with individual members working in food science, food technology and related professions in industry, academia and government. IFT champions the use of science across the food chain, through knowledge sharing, education and advocacy, encouraging the exchange of information, providing educational

opportunities and furthering the advancement of the profession. We thank the Agencies here today for this opportunity to give comments on measuring progress on food safety.

Since the 2002 release of IFT's Expert Report on Emerging Microbiological Food Safety Issues, IFT has advocated for the use of food safety objectives, or FSOs, which place specific values on public health goals. FSOs, which can be applied throughout the food chain, specify the maximum level of hazard that would be appropriate to avoid foodborne illness at the time a food is consumed. FSOs would enable food manufacturers to design processes that provide the appropriate level of control and that could be monitored to verify effectiveness.

Microbiological testing of finished food products and fresh fruit and vegetables can be misleading due to statistical limitations based on the amount of product sampled, the percentage of product contaminated and the heterogeneity of contamination throughout a food.

FoodNet data provide critical information regarding foodborne illness trends. However, we know that foodborne illness is severely under-reported. IFT strongly encourages the Agencies to promote outreach to

the public and to physicians, to increase the reporting and detection of foodborne illness. Without knowing the true incidence of foodborne illness, it is extremely difficult to measure progress in preventing these illnesses.

IFT recognizes the immense effort required to generate the 1999 Meade *et. al.* study. The number that was found by the study, more than a decade ago, an estimated 76 million cases of foodborne illness per year, continues to be cited, but is based on outbreak data from as much as 30 years ago and surveillance data that are approaching 15 years old. For years, we have heard that an update to the Meade *et. al.* study is in the works, and we anxiously await its release.

We also encourage CDC to release reports more frequently, since more accurate figures of the estimated cases of foodborne illness each year can be vital to determining where to focus valuable prevention resources.

IFT also seeks clarification on the definition of priority pathogens and would like insight on how the Agencies weigh frequency of occurrence versus severity of impact.

We would like to know how the information obtained from metrics will be used to inform regulatory

action and federal funding. As an example, the recently released USDA NIFA AFRI funding priority in food safety is for Shiga toxin-producing *E. Coli*. However, FoodNet data from 2009 show that the incidence of *E. Coli* 0157:H7 met the Healthy People 2010 Goals, while rates of *Salmonella*, *Campylobacter* and *Listeria* exceeded the targets.

We are furthest from the *Salmonella* target, but funding for research on the organism will not be available until 2011, and at that time, it appears that it will be limited to *Salmonella* and poultry. IFT would appreciate increased transparency with regard to how the Agencies determine which pathogens should receive priority research funding, recognizing that *E. Coli* infections are more severe, while *Salmonella* is more frequent. Having appropriate metrics is clearly critical, but how these metrics will be used to inform future decision making is just as important.

In conclusion, having metrics provides the opportunity for meaningful data to be collected, shared amongst stakeholders and used to determine future actions. For example, these data may populate risk assessment in risk-ranking models. Models that rank risks and hazards will allow the agencies to make more informed decisions on how to allocate resources to

achieve a maximum public health benefit.

IFT commends the Agencies for working collaboratively to explore metrics, and we offer IFT's assistance as metrics are identified and implemented. Thank you once again for this opportunity.

(Applause)

DR. FARRAR: Thank you, Sarah.

And with that, that concludes our morning session. We'll adjourn now for lunch. Please be back in your seats ready to start at 1:30 p.m.

Thank you very much.

(Recess taken from 12:14 to 1:35 p.m.)

DR. ENGELJOHN: Well, welcome back, everyone. We're going to go ahead and get started on the afternoon session.

The first presenter with public comments is Jim Mann with Handwashing for Life.

MR. MANN: Well, everybody came back from lunch. That's a pretty heartening thing when you're talking about handwashing. You never know, they might just skip a piece of the session. I really appreciate your being here. And Chicago is such an interesting eating place; I hope you found a good safe place to eat.

And I thought I would start out with something really light this afternoon. I picked up on something that Patricia Griffin was talking about. I was really attracted to the negative binomial regression factor, and I was trying to apply that to handwashing, but, sadly to say, I didn't quite figure that out. So there will be nothing on the negative binomial regression factor in my session.

So one of the things that I would like to do today is offer you three measurements on handwashing.

There are very few out there. I think when we think about adding hand hygiene to the list of food safety metrics, it's a little challenging when you think there aren't any standards, not a lot of things going on there that you can put a number on. And the only thing that we know for sure is handwashing compliance is not what we'd like it to be. Is it surprising when you don't have a standard and nobody has anything but rather subjective limits?

So what I'd like to do -- they're simple things for the most part, but I'm going to give you three of them. First of all, one of the things that Handwashing for Life does -- and we were so excited when the Food Code and the FDA and everybody started working on the "person in charge."

Now, most of the work and things that I'm going

to be talking about are based in food service rather than food processing. The principles apply, but most of the work is in food service, where we have more hands and less machines.

It's not an environment that HACCP has been particularly comfortable in, and it holds back, because, I think partly because, of the measurements. What we found was the person-in-charge, great idea, great concept, seems to be working out pretty well, but in the area of handwashing, we didn't give them many tools to work with in terms of getting things done and getting sustainable gains.

So what we asked them to do is drive the behavior change, give them some tools to see if we could get serve-ready hands and touch-ready surfaces. What I mean by touch-ready surfaces… there are a lot of surfaces that… one of the problems that came up over the 10 years that we've been working at this is that people say, Oh, I just washed my hands, I turn around and they're soiled again. And so there are some surfaces that are worthy of extra attention to keep clean in order to keep hands clean.

So our mission is to overcome underwashing, to reduce the pain and suffering of foodborne illness caused by poor hand hygiene and surface hygiene practices that are related.

We're dealing with behavior change, and I guess, in some ways, this is our negative binomial regression factor, in that it's not simple. But the people who are hoping that handwashing and the performance changes are going to be simple, that's probably just never going to happen. We're talking about behavior, and so many times, like so many other parts of our life, knowledge doesn't drive compliance.

Knowledge doesn't change a lot of things. If there were, there would be nobody overweight, we wouldn't be drinking and smoking as much. So taking people from one step to the next is a very significant step.

So we go from unawareness to awareness. That's (indicating) sort of me and the binomial regression piece. I don't really understand it and I don't think I'm going to use it at all, but if it was important, I'd have to understand it. And then I'd have to be convinced that I was actually going to do something with it. So then I'm going to convert it to an action, a repeat action, and now we're into a new habit.

And we've got to get to that habit level. Mind you, at the same time, all the things that are going around the outside of that circle, the customer service, the organizational turmoil, all the things that keep us extremely busy every day.

So this is something that we take into the top

of the organizations, to let them know that we're looking for a behavior change here, and the only way we'll ever get anywhere is to start at the top and have them understand and be supportive of this. Otherwise, there's an awful lot of wasted money going on with training, etc.

The next piece of this is that we're really dealing, many times, with a culture change, at least a nudge of the culture in another direction.And it's a very common problem, that productivity has many measures and handwashing has none. So handwashing tends to lose in this battle between productivity and handwashing.

It would be nice to think of handwashing as a given, in many ways, but it's many times seen as something that's deterring from the base product. People in food service don't usually lose their jobs for not washing their hands. They will for food service, for customer service.

So this is something that we have to be aware of so, when we put the hands-on system together, we look at to change the culture, we go in at the top and bring this down. And you will see, in some of the things that I'm proposing here, to bring it down to the worker level, to get them involved in some of the

setting of the safe standards.

What I like about the handwashing, in terms of the culture change, anytime you're changing a culture, it's really nice to have some repetitive action that you can go out there and measure, at least partly measure, and handwashing is that repeated tangible act of commitment that coalesces that new culture, so everybody is doing it.

Now, one of the best ways to waste your money on a training is to go through all the training and then have the boss walk by or come into the area that you're working in without washing his or her hands. People learn and unlearn very, very quickly.

So the reason that we think that hand hygiene deserves a metric is that poor handwashing is the most frequently cited contributing factor in foodborne outbreaks. Now, many times, it's listed with other titles, like poor personal hygiene, not wearing the gloves, poor this, poor that, but basically it's hand hygiene, and it's the most frequent one.

Next, we know from the CDC, thank you, that handwashing is the single most important means of preventing infection. So we've got a big problem; we know the solution.

And then we have one of the foundation

principles for the meeting here today from Jerold Mande, the U.S. Deputy Under Secretary of Food Safety, "What doesn't get measured doesn't get done."

Any questions as to why handwashing is less than you'd like it to be?

(No response)

MR. MANN: Now, one of the things that people usually go to -- and if someone feels like singing along with Hank Williams, "Yeah, my bucket's got a hole it," please feel free. But what we put this up here for is people are thinking we might have trouble funding and getting people behind this. When you look at how much money is tossed into this training, it pales against no standards; what we say is we need to fill these holes before you train. We need some numbers. We need some standards. We need some goals. We need the measurement. Otherwise, we're just going to continue to waste our money with the holes in the bucket.

The process -- I'm not going to go through this in great detail, but the simple logic of the hands-on system is that we assess the risk. Now, that risk is going to be different at the central headquarters, so to speak, or the owner of the business from the worker. But there's a risk associated with everything, so we try to set that risk as the first step in improving the handwashing.

The next thing is safe levels, optimize the system, train and motivate. Now, the train and motivate is the fourth step. Everybody runs to training right away without covering those other bases, and it doesn't work very well. You get small, short, temporary gains. So we need to get that up in order for monitoring to take place, and the feedback on that is the motivation for sustainability. Once everybody knows we're winning or losing, it's an important feature to build in.

Now, the other thing in food service that's been missing here is we get very concerned about the ill worker coming in the back door, and we've got a lot of policies on ill employees and everything that we have to do.

Now, we're also aware that there are symptomatic situations with norovirus, with hepatitis, with others of the diseases. And so what are we going to do with the front of the house? We can't very well keep the ill customer out, and we saw it with H1N1. We are learning that constantly with people coming in the front door. I noticed when we came in the front door here, somebody had a hand sanitizer out there so, in between all the handshakes, we can get rid of some of the bugs, anyway.

So some of the what we are going to do with the bugs that are coming in the front door, we’re not

suggesting -- we haven't come up with a way to have a standard there, but from an operator point of view, it's just as painful in the courtroom if that bug came in your front door as through your back door. So it's something to keep in touch.

And, really, that simple drawing we have there is to say front door/back door, but there's also the restrooms. The restrooms are where the bugs that we're mostly concerned about, where norovirus is a particular problem; that is one of the big transfer zones that we have to be really especially careful of.

We have to get more familiar with speaking with the operators about the risk. There's not a lot of risk terminology at the operator level, but it's important that they actually choose. So we've come up with just a simple document like this (indicating) to let them know what a Log 1 is and what a Log 2 is and start talking about, when it comes time to choosing a handwash, a lot of time the Model Food Code will talk about basically that first bar, and that is to say that, if it's a really heavy soil versus lighter soil, that we'll get somewhere in that 2 to 3 range. That's what the Model Food Code considers an acceptable handwashing, Log 2 to 3 reduction.

But sometimes that's not good enough. People

are putting on hand sanitizers after. You can add a nail brush. And all of these things have to do with the risk. It has to do with the business itself, if you're a hospital versus a corner restaurant, but it also has to do with the risk that the operator can tolerate.

And here's some low ways. It's also a way for us to let them know that the risk is never going to be zero, but that's not enough of a reason to not do anything. Handwashing is one of the cheapest ways to lower risk.

I've always wondered if somebody did a really good job, could we go to that insurance company and get a 5 or 10% or something off the bill. It seems like it should. We actually want to work on that.

So, Scott, what I wanted to do on this one is talk a little bit about what we call "Day 1 Handwashing," where we show a very short, graphic video, remembering that hardly anybody speaks English in the back of the house and speak many, many languages when we're working in places like Las Vegas. So we produced a very short piece, and then we follow that up with a form here. So bear with me, and you promise not to fall asleep. I asked them to turn the lights down.

(Day 1 Handwashing video played
from 1:47 to 1:49 p.m.)

MR. MANN: So we've now had some awareness.

We're up one step. Now, that video alone will give you some improvement in handwashing, but it's not sustainable.

So the next thing we do is take that very same worker that just looked at this, sit him down, put a tracer on your hands, like GlitterBug -- you've probably all seen that demonstration with the black light. You put it on your hands, wash it off. Well, instead of just washing it off, give them a score, score them as to how well they wash their hands. Now all of a sudden they realize you mean business, this is important.

Next, keep a log. "Day 1 Handwashing," you just did the simple training. I'm sure your inspectors would appreciate having a log of "Day 1 Handwashing" that you've got good handwashers right from the get-go, particularly in food service.

Next, safe level. How often should an employee wash? We asked that question of the manager, we asked that question of the worker. We put this in front of them and say, Well, do you think you should wash when you arrive? Yes, I've been changing diapers, or whatever. And you follow that through and you come up with that number, you do the math, and then you add one simple thing to your

handsoap dispenser, a counter. Now, we can keep track and produce graphs.

This graph is an actual study that we did over 11 months with four casual dining facilities. It started out that they were concerned about the handwashing. The lower numbers there, the four stores all were around a half a handwash per hour, which I don't find uncommon. But when they see the number, get excited, again, a reason to measure.

Pumped it up, things were going along pretty well there. All those tails where it really got interesting, we started a contest by doing nothing more than reporting to headquarters the four stores. Nobody wanted to be the low man on the totem pole, and things went crazy just before we ended the study. And I'm not sure what number. I think they ended up choosing a standard of one handwash per hour. A lot you can do when you have the information.

The last thing in wrapping up here is the surfaces that are going to contaminate the hands easily. We found the adenosine triphosphate (ATP) -- I know there's someone possibly from 3M in the audience here. I would like to know where she is. But, anyway, we found this technology to be extremely helpful in training.

And what it helps you do is define a level of

cleanliness, but by defining it in 25 seconds by running a swab over a surface that's just been cleaned, you can actually get a lot of mileage out of knowing when you're done. It's a very motivating factor, a very simple thing to do.

And there are a lot of discussions, because ATP doesn't tell what you bug; it's not high science in a lot of ways, but it's very, very good at letting you know whether the surface is clean or not. So we can keep some graphs of that in the kitchen, service areas, restrooms.

So we've got a Handwash Quality or a Day 1 Training Log, we've got our Frequency Safe Level Log, and we've got our High-Touch Surface Cleanliness Log.

Thank you.

(Applause)

DR. ENGELJOHN: Thank you, Mr. Mann.

Next we have Felicia Nestor with Food and Water Watch.

MS. NESTOR: Good afternoon, everyone.My name is Felicia Nestor. I'm a Senior Policy Analyst with the consumer group Food and Water Watch, and what I'm going to be talking about today on behalf of Food and Water Watch are some recommendations we have for actions that FSIS can take that we believe may reasonably -- that we

can reasonably assume will immediately prevent foodborne illness tragedies from *E. Coli*, and this is, I think, in real contrast to so much of the data gathering that we've been talking about today, where there's a lot of uncertainty or a long-range payoff. What I'm going to be talking about has a good degree of certainty to it, and the payoff would be immediate.

The actions that I'll be talking about are trace-back actions that the Agency should take when its routine testing program finds a positive in ground beef at a grinder. I'll also recommend associated food safety metrics, so that the agency can monitor the recommended actions and update the policy and optimize it as time goes on.

As Dan was saying earlier, FSIS currently analyzes about 11,000 samples of beef annually for *E. Coli* and 0157:H7. Most of those samples are taken at grinding facilities, and many of those facilities do not use the full production lot when they grind the beef. Each year, the Agency finds approximately 40 positives in those 11,000 samples.

So to the theme of this conference, "What doesn't get measured doesn't get done," I would say the trace-back at FSIS in food could almost be the poster boy for this management tendency. You would think that

trace-back would be an automatic activity at FSIS, since Trace-Back and HACCP both involve identifying a problem, tracing back to the source, taking a corrective action, and then preventing problems in the future.

We also thought that trace-back was occurring routinely at FSIS, because the Agency said so frequently and repeatedly. In '96, they said it was an essential part of the HACCP system, they made several statements that they routinely trace back to the source, and when they published a guidance for beef grinders who were coming up with their HACCP systems, they mentioned the importance of trace-back 10 times in the 14-page guidance document. So we really thought the Agency was doing some solid trace-back.

However, without the measurable objectives, a truly public health-based system was not put into place. Not all forms of trace-back, or what people call trace-back, are equal, and we think that what the Agency does in response to contamination already found in the market through their testing program, we think that's less than what's necessary to protect the public.

We believe that when *E. Coli* is found in ground beef at a grinding facility, a public health-based

system would require two essential features. First, the Agency should identify the source slaughterhouse.

This would be necessary whether you have multiple suppliers or one supplier. If you have multiple suppliers, you'd have to do a confirmatory test to determine which of the suppliers introduced the contamination. If you only have one supplier, the Agency still has to do the test to demonstrate that the contamination was not sitting in the grinder when the grinder introduced the raw supplies.

The second thing that would be part of this trace-back system would be the identification of the full contaminated lot. As I said, very often a grinder doesn't use the full lot and some of the subdivisions of that lot may be at other grinders. So unless FSIS identifies where all of the rest of that product went, they can't act to take it off the market.

In 2009, Food and Water Watch and several members of the Safe Food Coalition sat down with FSIS, and we learned that neither of those two, what we believed to be essential features, are part of the Agency's goals when it finds a positive at a grinder.

FSIS will take these additional microbial samples if there's an outbreak in order to identify the supplier and then have the authority to identify more

product, but not if it finds contamination through its testing program.

Now, if we look at the data from FSIS's *E. Coli* testing program -- the chart here is not based on a measurement FSIS is already doing. I just pulled this from their testing data. From '98 to 2009, there were approximately 300 positives that the Agency found. In three-quarters of those cases, the Agency found the positive at a grinder, not at a slaughterhouse, meaning that almost certainly the contamination came from a previous plant. And the final number is, in that time, although the Agency was saying it was doing trace-back, it only actually traced back to the source slaughterhouse somewhere around 11 or 12 times.

So that's the past, but we're very encouraged by what's been happening in the last year.We're very encouraged that the White House Food Safety Group recommends sensible measures designed to prevent problems before they occur. We're also encouraged by the fact that, in 2009 and 2010, the Agency held two meetings at which tracing back to a source slaughterhouse was discussed somewhat extensively.

And, finally, we're encouraged by the fact that, at the March 30th meeting and then also in your packs today, a proposed metric under consideration is that the percentage of contamination events for which

trace-back successfully identifies the source of contamination along the food supply chain. So that's not limited to outbreaks. That's any contamination event.

So I'll explain why trace-back is really the only sensible measure when FSIS finds a positive at a grinder. Now, this slide was used by Dr. Griffin, I think, to refer to the decrease in data as you go up the pyramid for reporting of the illnesses.

What I have it here is as an example of -- the top of the iceberg is where FSIS takes the tests. It's the grinders. The bottom of the iceberg is the large slaughterhouses that produce about 80% of the raw supplies that go into the ground beef.

As you can see on the slide, less than 5% of FSIS's *E. Coli* tests are taken at these large slaughterhouses. As we saw from the previous column chart, 75% of the positives were found at grinders that were not slaughterhouses. So they're at the tip of the iceberg, and FSIS is not getting to the bulk of contaminating product.

Now, it would be one thing if FSIS were testing proportional to volume, but it's not. Up to 70% of the tests have been taken at the smallest grinders that make approximately 1% of the ground beef. So if FSIS

tests at those facilities and prevents only that product from going into the market, that's really a very small percent of what's potentially contaminated, because each of those grinders may be only using a portion of the lot.

And if the grinders are using only a portion of the lot, we have to assume that the rest of the portions of the lot are at other unsuspecting grinders or in consumers' refrigerators.

Trace-back is not only sensible, but it also can prevent foodborne illness tragedies. Dan actually provided more recent estimates. So let's change that to 17,000. But if the Agency is estimating that there are 17,000 annual illnesses associated with its products, we would not call that success even though it may meet the Healthy People 2010 goals.

E. Coli's a very virulent pathogen, and every effort should be made to remove this deadly pathogen from the market. We're very happy about the increased epidemiological investigations, but, again, that happens after people get sick. And waiting for people to get sick is waiting too long. We have the uncertainties of trying to follow up a source after an outbreak is determined.

This slide got a little messed up here, but what this shows is that I went to the Agency's recall

website. The Agency learns about contaminated product on the market when it tests at a grinder approximately five days after thatproduct is produced. So there's a good possibility that most of that product is still at the grinder that's tested or at the other grinders. It hasn't had a chance to circulate in the market.

From the Agency's recall website, the median number of days is 45 after production that an outbreak will alert the Agency that there's contaminated product on the market. So 40 days later, you can imagine more of the product has already been eaten.

So, based on this, I would really like to urge the Agency -- we were talking today about resource allocation and whether it makes sense to do a trace-back investigation based only on an *E. Coli* positive. Based on what I've said, the Agency doesn't have the data to demonstrate that it makes more sense to try to trace back 45 days after the contamination than to trace back when its testing program has demonstrated conclusively that contaminated product left the slaughterhouse and received the USDA seal of approval and is now at other processing facilities around the country.

Before the Agency assumes how it should allocate its resources, I would urge them to select the necessary data to determine whether that's the best use

of the resources. Again, if we look at the Agency's recall website, we see that, between 2003 and 2009, there were 28 recalls of beef products triggered by the epidemiological investigations. Only eight of those were traced back to the source slaughterhouse.

So it seems to us that, at this point, this is an idea whose time has come. Many consumer groups in the Safe Food Coalition, in 2009, wrote a letter to Secretary Vilsack, saying, "We believe it is critical for the Agency to prevent human illness by tracing adulterated products back to the source and removing all affected product from commerce."

After that, we met with the Agency, and that's when we learned that the Agency does not do the same trace-back after an outbreak. And so we -- I don't know if I can move this up. Well, there's more on there, but, again, we urged Secretary Vilsack to do a complete trace-back based on a positive result.

So now I'll talk about the metrics that we're proposing. First of all, the very good news. This will not require more funds. The Agency can do it with the funds that it has and the testing resources that it has.

Currently, the Agency is taking approximately a thousand, 1,100 follow-up samples when it finds contamination at a grinder. The thing is they take the

follow-up samples of future production. It could be a week, two weeks, a month after the original product was produced. So it will do nothing to locate the rest of the contaminated product.

So we would propose that the Agency conduct a pilot project to use some of those resources to instead take trace-back samples of unopened product wherever that unopened product can be found.

The second metric on there we're proposing is the "Average number of samples needed to detect and identify *E. Coli*." We don't know whether, if the Agency takes an open product at the grinder, whether they'll immediately find a positive. They may need to take five samples to get another positive, they might have to take 10, they might have to take 15, but we think the Agency should do a little experimentation to find out whether it is productive to do sampling of unopened product.

We think the Agency should keep track of the percent of investigations in which it conclusively identifies the source, which is the Agency's own metric that it's considering.

We also would like the Agency to keep track of the percentage of the original contaminated lot that had already been released into the market -- that's to

consumers -- when FSIS learned about the contamination and on the date that FSIS identifies the source slaughterhouse. So this will indicate whether FSIS can identify the source slaughterhouse quickly enough to make it efficient to do the testing of the unopened product.

We'd also like them to keep track of the percentage of product that was subject to the recall that was covered. This is very difficult, because often in a recall, people return product that was actually not part of the original production lot.

And there are two other things we would recommend that they have metrics for. One is the number of times that the tested grinder did not receive the full production lot. It may be that most of the time when FSIS tests, these are grinders that are large enough that they are getting the full production line. We think that that's probably not the case. We think that, perhaps, in the majority of cases, FSIS will find that the grinder has not received the full production lot, which means that the rest of it is at other grinding facilities.

And the second thing that we would ask the Agency to measure and report on -- it's been described here that the Agency and CDC correlate the patterns

from the *E. Coli* testing program and the illness patterns. We would like the Agency to report on how often a PFGE or other identifying pattern from their testing program matches up with a pattern found with a human illness, either before or after.

So I talked about that the Agency has the resources to do this.I also think that if you review the FDA Basic Principles for Good Measures, you'll find that those metrics also are in accordance with the standards that they focus on, results that matter, and that they provide clear evidence based upon observable events.

Thank you.

(Applause)

DR. ENGELJOHN: Thank you, Felicia.

Next we have Barbara Kowalcyk with the Center for Foodborne Illness Research and Prevention.

MS. KOWALCYK: Good afternoon. My name is Barbara Kowalcyk, and I'm the Director of Food Safety at the Center for Foodborne Illness Research and Prevention, and we are a non-profit consumer group that was founded in 2006 to help America find innovative science-based solutions for the food challenges of the 21st century by preventing foodborne illness through research, education, advocacy and service.

As a statistician, I'm always excited to talk

about data, and I appreciate the opportunity to be here today to talk about performance metrics and how we can use those to measure our progress on food safety.

Last month, the Institute of Medicine and National Research Council of the National Academies issued their report enhancing food safety, the role of the Food and Drug Administration. It was a culmination of 18 months of hard work by a committee that I was honored to be part of.

The committee made several recommendations, including the adoption of a risk-based approach, creating information and research infrastructures, integrating federal, state and local food safety programs, enhancing the efficiency and efficacy of inspections, improving risk communications, modernizing food safety legislation and, finally, moving toward an efficient and integrated food safety system. While the report specifically addressed food safety issues at FDA, the committee's recommendations are readily applicable to the entire food safety system.

At the heart of the committee's recommendations was the adoption of a risk-based approach to food safety. Basically, we need to move from our current reactive system to a proactive one that uses robust data to assess the risks, weigh those risks and then

allocate resources appropriately and continuously improve and update the system, all while providing the greatest public health impact.

While most agree with this concept, the “how” has not always been clear. Therefore, the committee also recommend this conceptual brain work for risk-based food safety management that I've outlined here.

Basically, you begin with strategic planning, during which you identify the public health objectives and establish performance metrics. Then you rank your risks based on public health outcomes, conduct targeted information gathering and, if necessary, re-rank the risks.

Once you've prioritized the risks, you can identify your intervention options and analysis methods, including your performance measures, and then you gather information and choose the intervention strategies you want to implement.

Finally, you collect, analyze, interpret, and evaluate your data to see if, based on the performance metrics, the public health objectives are being met.

As you can see, performance metrics are a critical piece of this conceptual framework. Of course, it is absolutely critical that the food safety performance metrics be tied to public health

objectives.

As Chris alluded to earlier, this is not a new concept. In 2003, the Institute of Medicine and National Research Council report "Scientific Criteria to Ensure Safe Food" stated that, "Science-based food safety criteria must be clearly linked to the public health problems they are designed to address."

As already discussed today, there are two types of metrics that could be applied, direct metrics and indirect metrics, and these can be broken down further into intermediate goals and long-term goals.

We've already heard today about the need for an integrated approach with a common vision and common goals. In fact, one of the major recommendations of the report was for FDA, in collaboration with partners, to identify food safety performance metrics that have a clearly defined link to public health outcomes through the strategic planning process.

In a sense, this meeting follows that recommendation, for which FDA, CDC and USDA should be commended. However, in another sense, this meeting seems incomplete, as the states do not seem to be a full and active partner in this discussion, even though they share a large part of the responsibility for food safety.

I would like to see some of the states at this

table and would recommend that the federal agencies reach out to the states to set performance metrics for state food safety programs.

The report also discussed in depth the need for attribution data, which forms the cornerstone of a risk-based approach to food safety and is the most logical metric for determining whether public health objectives are being met. Attribution data will improve our understanding of the causes and impact of foodborne illness, including the long-term burden. And once we understand the burden, costs and causes of foodborne disease, we can begin to establish those priorities and determine potential prevention and control interventions.

Once we have done that, we must define our targets, such as food safety objectives, and measure the effectiveness of our efforts in reaching those targets. Attribution data ultimately establish the link between the performance of food safety interventions and foodborne disease.

Now, as many of you know, there are several different approaches that can be used in foodborne illness attribution. Each one of them has challenges and limitations, which, in the interest of time, I'm not going to discuss today. Really, the important point here is that the choice of attribution method will

depend on the question being asked and the data and resources available.

Also, as mentioned earlier today, most agree, as stated in the 2009 NAS Report to FSIS on Attribution, "Developing foodborne illness attribution estimates will require a comprehensive program that combines different methods and integrates many different types of end sources of data."

Now, I know this is not going to be an easy task. It will require the systematic collection, synthesis and analysis of data that relates food to foodborne disease. To achieve that, we will need to develop a comprehensive integrated data collection system that tracks human disease, animal disease, plant disease, food contamination, industry practices, behavioral patterns and environmental exposures. Such a data collection system can provide the metrics needed to measure progress on food safety.

Now, developing such a system will take time, and we will need to measure our progress along the way.

In 2008, the European Food Safety Authority identified several attribution data needs that need to be addressed before such a system can be fully realized.

Each one of these bullets can probably serve as

a basis for an intermediate performance metric of how are we progressing toward a comprehensive attribution system. Some of these have already been mentioned today, but there are a few new ones. Have we developed an integrated collection of isolates? How many isolates are in that collection? Have we developed discriminatory and definitive epidemiologic marker methods? What is the sensitivity and specificity of these methods? Have they improved? Have we developed standards for food safety for food categories? What is the prevalence of pathogens in and on retail products?

In 2009, the Institute of Medicine and National Research Council Letter Report on Attribution to FSIS also identified some of the same food attribution data needs. We need to have a common definition for microbial foodborne disease attribution, we need a coordinated approach to improve quality and consistency of data, and we need a process that allows for regular updating of attribution estimates, and we need, again, a standardized coding scheme.

Therefore, I urge the Agencies to develop metrics that measure our progress in addressing the challenges to developing accurate and reliable attribution data. One of the critical challenges that we face and must be addressed is data quality and

precision. As a statistician, the absence of metrics based on the confidence and power of the data collected to measure its ability to meet its intended goals is a glaring omission.

Now, one of the things that the Agencies requested in the Federal Register Notice was feedback on the perceptions in value of performance metrics currently being used by the federal agencies.

I'm going to focus my comments on the all-illness metrics that FSIS typically uses to measure its progress. As indicated in this slide, which was presented by Carol Maczka during the March 30th Metrics Meeting in Washington, D.C, and as discussed earlier by Dan, FSIS frequently measures its progress by meeting its food safety goals and objectives by using its verification testing data to estimate the number of illnesses attributed to FSIS-regulated products.

While I think it's a good idea to try to tie metrics to public health objectives, there are two problems with FSIS's approach. First, they only use outbreak data to estimate the number of illnesses attributable to FSIS-regulated products.

As I mentioned earlier, there are drawbacks and limitations associated with each method. Outbreak data, in particular, may not be representative of sporadic cases, which constitute the vast majority of foodborne

illness cases. Further, outbreak data may be biased toward certain foods and are often influenced by large events. It would be much better for FSIS to rely on a combination of methods instead of a single attribution method.

The second problem is that FSIS assumes that the verification testing data estimates the prevalence of pathogens in meat and poultry products, which it currently does not.

FSIS's verification testing program is a strictly regulatory program that was designed to determine if a particular establishment was meeting a particular performance standard at a particular point in time. As far back as 2003, FSIS has stated that the data collected from this program was not statistically designed to estimate prevalence and should not be used to make year-to-year comparisons. Further, several reports have identified problems in the way samples are collected, which could bias the results.

Now, more recently, FSIS has made changes to the verification testing program, to try and improve the representativeness of its samples. FSIS has proposed significantly increasing the number of samples they collect. However, I should note that, without measures of uncertainty, such as power and confidence,

it is difficult to assess the accuracy and reliability of these data.

FSIS has also changed their sampling procedures, and I applaud these efforts. But they are not enough and they make year-to-year comparisons even more inappropriate. Yet, despite these limitations, FSIS and others have repeatedly tried to use the verification testing data as an estimate for prevalence of pathogens in meat and poultry products.

Now, I do understand that FSIS is trying to make use of the best available data that it has, and I have been accused of being a purist and wanting to wait for perfect data, which, by the way, I will tell you only exist in textbooks. Many will argue that we don't have time to wait and we have to make do with what we have. But as was stated at the last metrics meeting, you get what you measure.

I also shared this cartoon at the last metrics meeting and decided to include it again, because I think it makes a strong point. In it, Dilbert's boss says, "Do you have those budget numbers from last month?" Dilbert says, "They're totally inaccurate."

"I know, but those are the only numbers we have." Actually, we have infinite inaccurate numbers to choose from." "Let's keep those in our back pocket in case we need them." I'll encrypt

them so no one else can use them, either."

Making do with the data we have is a reactive approach, not a proactive approach. Making do with the data we have will not give us an accurate measure of our progress in food safety and preventing foodborne disease. Making do with the data we have is not what we mean when we say we need a risk-based food safety management system.

In reality, the data we could collect are endless, but data are at the heart of a risk-based preventive Food Safety System. What we really need is strategic data collection, which is discussed at length in Chapter 5 of the recent NAS report.

Strategic data collection means that we collect data that is designed to meet the goals and ultimate uses of the data. We collect the types of data needed to achieve goals. We address proactively data issues, such as the heterogeneous distribution of pathogens.

We strategically plan to employ appropriate data collection methods and standards.

Strategic data collection means that we ensure the accurate, reliable, secure, timely data are collected in an unbiased and representative manner.

Strategic data collection ensures an appropriate level of confidence and power, which will ultimately ensure a generalized ability and

interpretability. And strategic data collection is transparent and acknowledges limitations.

Ultimately, strategic data collection will provide us with the necessary data to accurately and reliably measure our progress toward improving food safety and preventing foodborne disease. This is critical, because the metrics we use to measure the progress of food safety will drive public policies that will have a profound impact on American families in the future.

I strongly urge the Agency to consider developing intermediate performance metrics that will measure our progress in moving toward a strategic data collection system.

Thank you.

(Applause)

DR. ENGELJOHN: Thank you, Barbara.

Our next presenter would be David Thompson, Pearl Valley Egg, Inc. I don't see a movement there.

All right, we'll move on to Andrew Milkowski, University of Wisconsin. I'm sorry, am I right, do you have a presentation?

MR. MILKOWSKI: Yes. DR. ENGELJOHN: Okay.

MR. MILKOWSKI: Good afternoon, everyone.

Thank you, Dan.

I'd like to introduce myself. I'm Andrew

Milkowski, and I am an Adjunct Professor at the University of Wisconsin, and I'm here today as a scientific advisor to the American Meat Institute, which is based in Washington, D.C.

AMI is the nation's oldest and largest meat packing/processing industry trade association, and together AMI members slaughter and process more than 90% of the nation's beef, pork, lamb, veal and a majority of the turkey produced in the United States.

AMI appreciates the opportunity to provide comment on how to improve food safety and our thoughts on the efforts needed to further reduce the risk of foodborne illness in the United States.

Over the last 20 years, the meat and poultry industry has been successful in making a tremendous improvement in reducing the pathogen risk profile of their products. AMI members view food safety as their top priority and have instituted a non-competitive policy with respect to openly sharing their best practices and knowledge as well as supporting food safety research.

The AMI Foundation, which is a non-profit research, education and information foundation established and funded by AMI, offers numerous educational and short courses, where leading experts

among AMI company share their expertise in day-to-day food safety knowledge, to train other meat and poultry employees in environmental monitoring, sanitation and equipment design. This is a real-world education programming that has been essential as a component in commercial food safety programs, as the attendees to these sessions take their knowledge back to their facilities in the U.S. and to companies abroad. And also, since 1999, AMI, through their foundation, has issued research grants for more than $7 million to develop new food safety technologies that can be directly applied and implemented by the meat and poultry industry.

And in the spirit of further progress and improvement in food safety, we'd like to offer these following thoughts.

First, we'd like to speak toward measurement of foodborne illness. We think the only way to truly measure food safety progress is by accurately measuring human health outcome via illnesses, hospitalizations and deaths attributed to foodborne sources. And, in that regard, I think we're agreeing with many people here about attribution.

The 2010 Healthy People Goal that called for a 50% reduction in the illness from key foodborne

pathogens based on 1997 baseline was just a fantastic starting point, and the reason is that these were clear and very focused goals. And we hope that the 2020 goals will be equally clear and as practical as a means to convert all of the other types of food safety objectives into a target that really helps the human population.

But what we see right now are discrepancies between reported foodborne illness statistics that have to be resolved, if we're going to improve food safety in the U.S., and I'd like to give you a few examples.

The 1999 CDC Meade report estimated 76 million cases of illness, 325,000 hospitalizations and 5,000 deaths per year attributed to consumption of food products. These estimates were derived using numerous adjustments for under-reporting, and those adjustments are very possibly no longer valid given the changes in public health reporting over the past two decades, and a number of food safety improvements employed by the industry.

We closely monitor CDC's both monthly and annual reports and can note the following in the statistics that we face today. From FoodNet, which covers about 15% of the U.S. population, in 2009, there were a total of 17,468 laboratory-confirmed cases of

infection.

Subsequent to that, in June of this year, CDC issued their analysis of U.S. illnesses for 2008, which is based on reporting across the entire country, in all the states. And if you were to look through those data and sum up those same notifiable diseases, you would get a total of approximately 100,000 illnesses for these same pathogens, which is consistent with the FoodNet sampling.

But this is clearly a large discrepancy from the 1999 Meade estimate of 325,000, and that needs to be resolved. And we are anxiously, as others are, waiting for an update to the Meade report.

The current CDC data also have a lot of gaps in food attribution data. CDC publishes its annual FoodNet data by pathogen, but it's really an educated guess regarding what food causes the illnesses. For example, FSIS measures via imperfect, but the best that we have, prevalence data for ready-to-eat meat and poultry products for *Listeria*. We've seen a decline from 2.5% prevalence in 1998 to 0.37 prevalence in 2009. That's an 85% reduction. However, if you look at the CDC data addressing listeriosis, we find that the decline in listeriosis has only been 26%.

We also see inconsistency in that there have not been any largely listeriosis outbreaks from

commercial ready-to-eat meat and poultry products since 2003, but we are still looking at a 75% attribution of listeriosis to FSIS-regulated products. We see this as an inconsistency that needs to be resolved.

Additionally, while FDA and FSIS seem to favor pathogen reduction on food products as a measure of progress, the data really show some poor correlation between performance standards and human illness. So if you look at *Salmonella*, the meat and poultry industry has reduced *Salmonella* by 64% in chickens, 74% in pork, 75% in ground beef since performance standards were set.Yet salmonellosis is virtually unchanged.

So they have not been achieving the intended public health outcome, because either the illness is confounded by other foods or we're targeting the wrong cause and wasting resources.

So with respect to a number of the metrics that had been mentioned in the call for this meeting, we'd like to offer a few of the following thoughts.

The meat and poultry industry has a variety of metrics in place throughout their operations to address food safety. For suppliers, it involves, largely, auditing. New suppliers often must be audited with respect to food safety programs at each of the supplier's food production facilities that supply goods to a company. They must pass with an “acceptable”

rating before they can qualify.

And the auditing systems employed are highly variable. Some are commercial services. Some involve internally generated auditing programs. And audit compliance is typically tracked by processors to monitor improvements or decline in the vendors that they have, and business decisions are made appropriately.

Most meat and poultry supplier specifications do have microbial quality parameters and includen in many cases -- in most cases -- a request for a certificate of analysis. Some processors require a copy of an actual laboratory analysis, and these get incorporated into the audit programs, with reauditing done at frequencies based on auditing scores and the business relationship between the parties as well as the historical sampling results.

For other metrics, the meat and poultry industry has a very wide and very diverse set of metrics in place to assess the food safety of the finished products that they produce, and it's addressed via a systematic approach, and it includes a number of programs, such as what would be called prerequisite programs, standard sanitary operating procedures, environmental monitoring in HACCP plants. All of these programs have data associated with them, indicating

either completion of preventative tasks, detection of potential or active food safety issues.

Since finished product analysis for very low frequency or rare pathogen contamination is not necessarily a statistically sound method to control risk, most measurements are done upstream of the finished product.

The American Meat Institute Foundation's Advanced *Listeria* Intervention and Control Workshop describes a number of the multiple environmental controls that are used for an effective *Listeria* prevention program, and it has a very useful formula that is used, and it goes as follows. "*Listeria* control equals controlled traffic patterns, dry, uncracked and cleanable floors, effective GMPs -- good manufacturing procedures -- sanitary design of equipment and facility plus effective sanitation procedures."

And AMI believes that this formula has been an incredibly successful tool in helping to prevent *Listeria* outbreaks.

Beyond that, environmental monitoring of food contact surfaces and adjacent non-food contact areas is heavily used for *Listeria* controls. Of note, most of these programs look for *Listeria* species, a wider and more conservative approach than looking only for *Listeria monocytogenes*. The data are collected,

they're routinely tracked, and there are various responses to environmental positives, which include a detailed root cause analysis, troubleshooting, enhanced cleaning and sanitation of equipment and extensive sampling until a consistent pattern of negative findings is reestablished.

Overall, the meat industry has a mentality of seek, find and destroy pathogens in the environment of meat and poultry processing plants.

Depending upon the pathogen of concern, the meat and poultry industry have various metrics to evaluate the effectiveness of their food safety systems. For *Listeria*, which is a post-processing contaminant, the primary methods used are charting and trend analysis of data. Thermal process data are tracked to verify that sufficient lethality was achieved during processing and that chilling of the meat and poultry products was adequate, and that works well to address natural contamination.

For *Salmonella* and Shiga toxin-producing *E. Coli* strains, the metrics involved use methods to limit the prevalence of the pathogens at production using validated interventions during harvesting at the slaughter plant or further processing and tracking, and verifying that all the procedures are operating under operation control.

Although this isn't a hundred- percent guarantee of pathogen-free beef, it's an industry standard to test raw beef components or raw ground beef for *E. Coli* 0157:H7. And meat and poultry facilities also use the FSIS microbial testing data as it's collected in there.

The most useful meat and poultry metric for *Listeria* has been the decline in the needed seek, find and destroy type responses to environmental positives, and this mentality has driven in the prevalence of *Listeria* down by 85%, as I mentioned before. And this, combined with interventions to inhibit growth or post-package pasteurization, has really helped reduce the listeriosis risk in products that we produce.

The meat and poultry industry has not found raw, uncooked, finished product testing to be particularly helpful as a pathogen intervention measure, due to the statistical limitations in this sampling. Finished product testing can be useful as a verification that control systems are working, if that uncertainty is considered.

Generic *E. Coli* is an indicator of overall quality, sometimes used for program effectiveness in plants. Analysis for *Salmonella* is used for tracking long-term performance, and because *E. Coli* is

considered an adulterant, programs that assay for this organism will properly divert or destroy the product so that it does not enter commerce.

So our industry has focused its efforts to reduce pathogen risk by embracing the hurdle concept of microbiological control. These hurdles, along with effective HACCP systems that require corrective actions and reassessment activities, are a key to ensuring food safety objectives and meeting them. As much progress as has been made, we realize that, still, a lot more needs to be done.

And we want to really make it clear that meat is a microbiologically perishable product and that there's a critical role for food preparers to play in ensuring food safety.Safe food handling instructions appear on all raw meat and poultry products, and continued education needs to be maintained as a means to measure and improve consumer handling and preparation practices.

So I thank you for your time and consideration, and we certainly will be providing some additional information in writing.

Thank you.

(Applause)

DR. FARRAR: Thank you very much. I think we

ad a cancellation in our schedule, so we're going to move the next speaker up before our break, Barbara Blakistone, National Fisheries Institute.

Just one quick announcement while Barbara was getting up here. There were several requests, comments about the availability of slides from some of the presenters. The best solution right now is for me to put you in touch with Juanita, in the back, in the red jacket. Raise your hand, Juanita.

If you want a particular set of slides, there are some issues associated with posting the slides.

They have to be compliant with certain rules and regulations, and they're not always compliant. So if you want a specific set of slides, see Juanita, and she'll help you out.

DR. BLACKSTONE: I'm Dr. Barbara Blackstone, Director of Scientific Affairs for the National Fisheries Institute. Good afternoon, and thank you for the opportunity to provide these remarks on the seafood industry's use of metrics for enhancing food safety in the United States.

For more than 60 years, NFI has been the nation's leading advocacy organization for the seafood industry. Its member companies represent every element of the industry, ranging from harvesters, processors and importers to distribution, retail and food service

operations. NFI's members work hard to ensure the use of practices that promote the sustainability, quality and, most importantly, the safety of their products.

Seafood is one of the more regulated foods under FDA's regulatory purview. The regulation procedures for the safe and sanitary processing and importing of fish and fishery products, also known as Seafood HACCP, was finalized in 1995 and went into effect for all processors of seafood products in December of 1997.

The Seafood HACCP regulation applies equally to all seafood products, both domestic and imported, that are sold in interstate commerce in the United States.

It is a general misconception that seafood products harvested and/or processed outside of the United States are not required to meet the same regulatory requirements as domestically-produced products. This is not true.

But before looking further at Seafood HACCP, we should step back and look briefly at the data reported by CDC on foodborne diseases associated with seafood. I shall highlight one recent assessment that has been most useful to the seafood industry.

In 2007, the National Advisory Committee on Microbiological Criteria for Foods, "the Advisory Committee," completed a study commissioned by the

departments of Agriculture, Health and Human Services, Commerce, and Defense to evaluate cooking parameters for safe seafood for consumers. The Advisory Committee evaluated six years of CDC data, from 1998 through 2004, and found that 11.2% of the foodborne outbreaks and 5.2% of the foodborne illnesses were due to seafood consumption.

The Advisory Committee further concluded that, "72% of the seafood-associated outbreaks and 38% of the cases from these outbreaks were associated with only three causes: ciguatoxin from isolated tropical reef fish, scombrotoxin -- that is, histamine toxicity resulting from mishandling and temperature abuse of a few species -- and pathogens in mollusk and shellfish."

Some interesting observations can be made by looking at this comprehensive review and some others that I have not mentioned.

Observation 1. There are several etiological agents that are uniquely seafood which may then result in more conclusive reporting by health agencies. These are natural toxins such as ciguatoxin and scombrotoxin, bacterial pathogens, *Vibrio* species and *Clostridium botulinum* Type E, and certain parasites.

Observation 2. Seafood-associated outbreaks, in particular the finfish-related outbreaks, tend to

have fewer associated illnesses. Large multistate seafood-related outbreaks are not as common as recently seen with other food commodities.

Observation 3. Outbreak data generally do not allow for the determination of the source of the seafood, commercially sold, recreationally caught, domestic, imported, how and when prepared, raw versus cooked.

Observation 4. Seafood products can be as susceptible as any other food commodity to handling-related causes of foodborne disease; that is proper temperature control, cross contamination, contamination by an infected food handler. Not an excuse, but instead a reflection that certain commodities go across the food commodity table and cannot and should not be painted as a specific food issue.

Although not commonly viewed in terms of metrics, HACCP as a food safety management system utilizes the evaluation of food safety hazards to establish methods for controlling such hazards. Natural toxins, including ciguatoxin and scombrotoxins; microbiological contamination; and parasites are specifically identified in the Seafood HACCP regulation for processors to consider when conducting a hazard analysis.

Other non-foodborne-disease-causing food safety hazards, such as pesticides, animal drug residues, unapproved food additives, allergens and foreign objects are also specified to be controlled through the Seafood HACCP regulation.

Years of experience with seafood safety allowed the seafood experts within FDA to provide guidance to the industry that, upon review, reveals itself as a metrics approach to identifying and controlling food safety hazards associated with seafood.

A comprehensive guidance document, The Fish and Fisheries Products Hazards and Control Guidance, outlines what FDA considers to be hazards associated with each individual species of seafood. Page after page of tables provide information to the industry and regulatory communities of the hazards that may be reasonably likely to occur with each individual species. Certainly not a one-hazard fits-all approach and only possible by studying historical foodborne disease outbreak data.

Hazards addressed in the guide again narrow the etiological agents associated with seafood-related foodborne disease outbreaks, specifically pathogens, parasites, natural toxins, scombrotoxin. FDA's Domestic Seafood Compliance Program applies to the

inspection of the more-than 13,000 seafood processors and importers and makes use of these historical foodborne disease data.

Focusing on the high-risk-potential products allows the Agency to focus compliance and foster improved industry control for the seafood products that may be susceptible to such foodborne disease agents as *Clostridium botulinum*, scombrotoxin, *Staphylococcus aureus* enterotoxin or parasites. As a side note, the FDA maintains a separate compliance program for mollusk and shellfish.

We feel it's essential for anyone assessing or communicating about seafood safety to recognize that not all seafood species are high-risk foods. Real measures of progress on reducing the rate of foodborne disease will not be achieved by broad-brush control inspections of all seafood products, but, instead, the continued targeted approach, focusing the most resources on the specific species products that may pose the highest risk to consumers for causing foodborne diseases.

The tools provided and regulatory strategies developed to support the Seafood HACCP regulation mark a great step in requiring the industry to take responsibility for ensuring the safety of seafood

products.

We do have a few suggestions on the use of foodborne disease data that will further help to improve the food safety record of seafood products.

(1) timely communication with industry of outbreaks, in particular, unique outbreaks, will allow the entire industry to further understand the cause, to provide information for improving HACCP controls; (2) improved descriptions of the food vehicle -- raw versus cooked, canned versus fresh, commercial versus recreational -- will assist the industry and food safety educators in determining control methods for decreasing the rate of illness from seafood.

I thank you for the opportunity to offer these brief comments on food safety performance metrics.

Thank you.

(Applause)

DR. FARRAR: Thank you very much.

Now I think we're ready for a well-deserved break. Great comments. We look forward to several more after the break.So we will return at 3:15. Help yourself to the refreshments outside, and we'll look for you at 3:15. Thank you.

(Recess taken from 2:54 to 3:22 p.m.)

DR. FARRAR: Our next speaker is Greg Gunthorp from Gunthorp Farms.

MR. GUNTHORP: Good afternoon. I'm Greg Gunthorp from Gunthorp Farms. I'm a small farmer from LaGrange, Indiana. My family raises pigs, chickens, ducks, turkeys, all on pasture on our 65-acre farm. My family has raised pigs in the same manner for at least four generations.

Our main market is white-tablecloth restaurants, primarily in the Chicago market. Actually, most of them are right here in this area, right between the Sears Tower and the Hancock Building. Our biggest customer is just around the corner, Rick Bayless over here at Frontera Grill.

Because we are in Indiana and we sell a large portion of our product in Illinois, we're regulated by the United States Department of Food Safety Inspection Service. We have an on-farm slaughter and processing operation we own and operate; it's called Brush and Prairie Packing. It's a very small operation.

We are one of the only small farmers in the country to have a full USDA-inspected slaughter plant right on our farm. We are one of the, if not the, smallest federally inspected slaughter plant in the

country. We are one of only about 30 federally-inspected very small poultry slaughter plants left in the United States.

In the past, we were part owners of a federally-inspected slaughter plant in another USDA district, prior to the one we built on our farm, and our one that is on our farm now was operated under state inspection for about two years prior to going USDA inspected.

I'm very active in the sustainable agriculture movement in the United States and the local food movement. I served on Secretary of Agriculture Dan Glickman's Small Farm Commission in the early '90s and was a Small Farm Advisor to President Clinton. I'm a Slow Food member. I'm also a Board member of the American Pastured Poultry Association.

The only reason I came to this meeting today is that I would like to share my thoughts on the need for USDA, especially, and also the FDA, to take into account the issues dealing with very small producers and processors. I've got some suggestions that would improve food safety to consumers and at the same time provide a more fair and equitable system to very small plant owners.

I know we are going to hear a lot today about

statistics and measurements. I hope my information brings a little bit of reality into how this actually is playing out in the field.

We have to be really careful in this country that any of the metrics and the regulations around those aren't putting unnecessary burdens on very small processors and small farmers.

I'm actually somewhat hopeful that metrics and risk-based inspection approach could be very beneficial to small producers and processors that are already doing an excellent job. I could honestly see how, with the correct metrics and applying those, that the small producers and small processors that are doing what they're supposed to could see less regulatory burden under this approach.

I had a couple of thoughts, and I think I'd be remiss if I didn't come up here and talk about food safety; if I didn't at least discuss HACCP-based inspection system from a very small plant owner's perspective, and the second item that I want to talk about is risk-based inspection and some of the testing as well as some of the manpower changes in the metrics and the risk calculations that are involved in that.

First, as I mentioned, I'd like to talk for just a little bit about HACCP. I think that, especially small farmers in, industry -- or not industry, consumer

advocacy groups and all that, I think we've known for quite a while that HACCP essentially has shifted all of the burden of responsibility in producing safe product over to the processing plant.

You know, we could sit here and argue why that was. I've got my suggestion or my ideas on that, but I'm really not going to get into that today. But I think that we do need to take a strong look of how HACCP has become implemented in the slaughter and processing operations in this country, because I know, in my plant, it's largely a paperwork shuffle, and more emphasis ends up being put on the paperwork by the inspection staff than the actual product that's being produced. And that is not right at all.

And, hopefully, taking a more risk-based approach and with the correct metrics, we can utilize this process to change some of that to move inspection and the plant personnel's time back to ensuring that product is produced properly rather than paperwork being produced properly because, you know, people don't eat paper. At least I don't think they do, anyway.

And I wanted to make a couple of comments.You know, lots of times, very small plant owners get the rap that they complain about the HACCP and they complain about the paperwork because they don't understand it

and they don't understand the science behind it. And I've only got, I think, 15 minutes to talk, so we're not going to get into that too well, because I could stand up here and I could spout all the regulations, and I could also spout all of my CCPs on my HACCP plan, and I could tell you the temperatures that various bacterias grow at, the pHs, etc.

So I understand the sciences behind it. I understand all the regulations, whether it's the 300s, the 381s, the 416s, the 417s, the 500s. I could spout all the regulations, too. We could talk about those all day long. So it's not a matter of that I don't understand it. I just think that the process is slightly flawed.

And I think that in this process of moving more to metrics and risk-based inspection, I think we need to take that into account and we need to try to correct some of that.

I was going to give a personal example of my plant and the staffing at our plant. We're actually staffed from a -- there's another local chicken integrator about eight miles away, does about twice as many chickens in a day as what we do in a year. Our processing is actually staffed by the veterinarian from that plant, and then we get a line inspector from that

plant just for the daily operations.

We end up with a veterinarian staffing our plant on average between three and four hours per day for processing, about half of which of that is administrative overtime for the USDA. Unfortunately, not overtime for us, at least. But I'm certain that under a risk-based inspection system, USDA would look at that and say, “Wow, there are 10 acre ready-to-eat facilities that get a quarter of the inspection that Greg's place does, there are beef grinding facilities that do hundreds of thousands of pounds a day that get a quarter of the inspection that Greg does, and he's hardly turning out any product here. So that's why I say I'm hopeful that this is going to increase the efficiency of the utilization of the time and the resources of USDA.

One other point I'd like to make is that I think we need to talk a little bit about the statistical analysis that USDA -- and I'm not sure about the FDA because we're not regulated by them at all. But USDA -- earlier we'd seen a slide that 70% of the tests in ground beef are done on what represents 1% of the product.

I know from personal example in our plant, the antibiotic residue testing at Brush and Prairie

Packing, Establishment 32042, that we're thousands of times the national average on rabbits and we're better than 20,000 times the national average on chickens.

We're no-antibiotic producers. We've never had any kind of violation and never will on antibiotics.

But I think that as we move to this, I'm hoping that we've got sound scientific and sound statistical data to back up where we are doing our testing and where we are applying our resources because, like I said, we have very, very few very small federally-inspected slaughter plants in this country, and we, as American people, don't need to be putting more regulatory hurdles on the few of them that are left. And local food movement is going like crazy in this country. Demands for product coming directly from farms to chefs and to individuals is extremely high. We should be seeing more very small slaughter plants, not less.

So I think that was about all I had. I really appreciate FDA and the USDA and the Center for Disease Control for allowing me the opportunity to speak today. So thank you, guys.

(Applause)

DR. FARRAR: Excellent. Thank you very much, Greg. I know how hard it is to break away from your business and come and give this presentation. So we

appreciate your time very much.

Next on our agenda is Donna Rosenbaum and Susan Vaughn Grooters from Safe Tables Our Priority.

MS. ROSENBAUM: Good afternoon. I'm Donna Rosenbaum, the Executive Director of S.T.O.P., Safe Tables Our Priority, and we're going to go tag-team today and go through our material, both of us, myself and Susan Vaughn Grooters, who has a master's in public health. She's behind me. And she'll come in, and I'll go out, and we'll trade places, depending on what we're covering.

And the topic of our talk today, it is a little repetitive, but I think that's the nature of this meeting, "What doesn't get measured... doesn't get done." And we very much appreciate the opportunity to be here today and talk to the regulatory agencies and all of you about some of the topics that are of interest to our organization and the people we represent.

S.T.O.P.'s mission. S.T.O.P., Safe Tables Our Priority, is a national non-profit public organization dedicated to preventing illness and death from foodborne pathogens. In 2010, S.T.O.P. will achieve its mission by advocating changes in public policy, educating and doing outreach, providing victim's

assistance and formalizing the Victims of Foodborne Illness Registry in order to study the consequences of food disease.

We're the last group to present today, and so, to capture your attention, we're going to get a little bit up-close and personal with some of the people we represent. We want you to meet some of the real people. So we're going to present you data, but we're going to show you the people that the metrics that we're talking about today affect as well.

Okay, so we're missing some of the pieces of the puzzle when it comes to talking about metrics and how to interpret metrics to get a better public health result. We have a lot of material to cover. We're going to skim the top of these topics so that we can cover all of it, and if anybody has any additional questions, please contact us after the meeting. I'll be staying after the meeting for a short while today or we have our contact information we'll be putting up on a slide as well. We'll be more than happy to explain why we came to these conclusions if we don't cover it as thoroughly as it seems to need.

Some of the topics we're going to be covering right now are recalls, *Campylobacter*, states and attribution, *Listeria* and the non-0157s. We're going to try to take what we've learned in the 18 years that

we've been working with victims and the public and use our own research and our own database to point out some places that need further work, metrics.

So a corollary to our topic here is that what you cannot measure accurately can also lead to missteps, and I'm going to start out with this issue of voluntary recalls.

And since our organization's inception 18 years ago, we've been a very strong proponent and advocate for mandatory recall for government agencies, and we realized that we're not anywhere close to that, and that we're possibly taking some baby steps with some new legislation. And we have a variety of reasons, which I won't go into now, why we think that's strongly needed.

In lieu of that, however, we're going to ask the regulatory agencies and the regulated industry to think very carefully, please, about the semantics of how you think about recalls. And the terminology that you use really determines how the public and the industry, in a great respect, respond to the information you're trying to gather and provide that information to you.

And one of the things that has really come to my attention in 18 years of talking to thousands of victims and thousands of consumers is how misleading

the term "voluntary recall" is. Because what does voluntary indicate? Voluntary indicates it's not important and perhaps unnecessary. So when the Agencies call something "a voluntary recall," guess what happens? Consumers don't report things. They don't call in about things. They see it's voluntary. Small grocery stores, retailers and people all over the country who don't really understand the nature of what a recall should be see voluntary, and they think, “I don't have to pull it from my shelves, it's unnecessary, maybe it's slightly recommended, but it's not a necessary step.”

So I would ask, right now, that everybody think about that very carefully, and if we can come up with in-lieu-of legislation that mandates -- we call it authority for government -- if we can come up with different terminology for what this is versus a voluntary recall, we would be a lot closer to trying to gather those numbers and statistics we need to accurately determine what's going.

And I'm going to give you a couple of really concrete examples of that. So here's a slide that shows what goes up in a recall notice. It's a firm press recall on FDA's website. And here's what we think is kind of missing, the amount of product that is removed from commerce, associated illnesses, illness

data are not included, retail consignee locations are not included, point source geographic locations are not included, and there are no updates to the original press release.

And I can tell you from personal experience in talking to consumers -- we get calls on our Help Line and information coming in through our office through our website -- consumers are very confused, because, when they see these recall notices go up, and especially when they go up in reference to just a finding of a positive in a sample somewhere -- and it's good to do the recall, but there's no illness information or it says "no illnesses reported," you may get subsequent illnesses reported, but nobody goes back and changes this information. So if two months later, after a recall for a *Listeria*-laden product on the market, a consumer thinks they have a *Listeria* illness and goes on the website and looks and sees "no illnesses reported," sometimes they don't seek medical attention, they don't report it to FDA, and it doesn't go counted because they're thinking, "Oh, well, I must be crazy, I can't be related to that, there's nobody getting sick from it, so it must not be that."

So be very careful about how you use that term and how this information is parlayed to the public because it needs to be updated regularly.

Okay, this is a new FDA release, a released form, and I'm hoping that it's in -- this has come about in reference to us having a series of meetings, very in-depth meetings with FDA over the phone when we do get consumer complaints into our office. And they have responded, and we're very, very grateful that they've come up with this updated mode of relaying information to the public, because it is the company recall notice that has to go up. But this is FDA's way of interpreting that to the public. So it is a much easier-to-understand format. It does give illness data, distribution data are included, it is FDA initiated, and it's different than a firm's press release.

However, there are just a couple suggestions that we have to make it even better, and that is, number one, consumers may not be able to easily differentiate between the two, between what they're seeing. So there needs to be some way of doing that.

In addition, it's found on a different section of the website. It's under "News and Events" instead of under a safety section. So it might be very, very difficult for consumers to find this in the first place. But it is a very big improvement over what we've seen in the past. So we thank FDA for that.

Okay, and on the USDA side, this is recalls and what data are included, the amount of product in

commerce subject to recall, the amount of product brought back from commerce, updates on volume of recall and retail consignee locations, which, again, is very, very helpful.

But what's not included is associated illness data, geographic location or point source contamination. And so, again, some room for improvement there, and these are things that we think are really important to feed into the system.

And we're going to move on and go on to our next topic, which is *Campylobacter*. And I'm going to turn it over to Susan in a moment, but I just want to start out by saying, again, what doesn't get measured doesn't get done. And we know that *Campylobacter* is a very, very serious disease. This is one of our members who suffered greatly because of *Campylobacter* disease, and it causes Guillain-Barre syndrome in many cases, which is extremely difficult to go through for victims. And we are today going to be asking for *Campylobacter* to be determined to be a nationally-notifiable disease, and we think that with a disease that's this awful, a disease that's affecting close to 2 million people a year, we need to get a better handle on what's going on with *Campylobacter*.

We realize that there are some problems with

Campylobacter that make it not as easy to understand and to detect and to find, but with 2 million people getting sick and the disease process it causes, we really need to be doing a better job.

I'm going to turn it over to Susan.

MS. VAUGHN GROOTERS: Hi.

So when we're thinking about *Campylobacter* and we're thinking about how we measure our progress on foodborne illness prevention, it really is about prevention, it's hard to do when a lot of those data are missing, that metric's missing. We have *Campylobacter* data from 2009 FoodNet data, but we don't have it from national data.

So if you look here, I want you to sort of gaze at some of these states. I've underlined the FoodNet data from the most recent report. It leads for incident rates in California, in Colorado, in Connecticut, in Minnesota, in New York and in Oregon. What trends are we missing nationally by the fact that it's not a nationally-notifiable disease?

I've heard that we need to petition the CSTE to get it to be a nationally notifiable disease, but this is a no-brainer. If we're seeing these geographic differences just in these states, how come we're not looking for geographical differences in all states. So

I think it's time this becomes a nationally notifiable disease, so we understand what trends are missing on a broader basis.

So when we think about state data and we think about what's missing on a national basis -- I've heard Patty Griffin say today a couple different things about some of the state capacity issues and some of the state capacity problems we have. S.T.O.P. did a survey of states, and we were looking at foodborne illness data that they collected in 2007, and some of the things that we found that were problematic across states had to do with data integration, they had to do with timing, they had to do with loss to follow-up rates.

We had to ask for these data, and I was really glad that Patty sort of mentioned that some of those things are now being looked at through funding for OutbreakNet state data -- OutbreakNet, Patty, I think, is that you're doing the funding now. So that states are now encouraged to look for some of these things like the loss-to-follow-up rates, the timing and some of the things we were looking at, because it's important to know how you're measuring progress through some of these very, I think, easy-to-measure things.

So when we're thinking about state capacity and we're thinking about what states are doing and what states aren't doing, I just want to give you some

information on a slide here from a presentation that I gave down in the Food Safety Educators Conference. And I'm going to spend a little more time on it here than I did there.

So we know that PulseNet -- we saw the plateau today that Patty put on her slide that was occurring from 2007 to 2009. I just want you to see how little is actually being pulsed when you're looking at it by pathogen. So we know these cases exist, but we're not pulsing a lot of them.

Especially, I want to point your attention to the non-0157 STECs. So if you look at that difference, we're not using the technology to its full potential, and we're missing not only illnesses, but we're also missing outbreaks. So I just think it's important to know that the technology exists and we're not using it to its potential, so we're missing those measurements.

And this is another important one that we talked a little bit about today, sporadic cases. We're missing data on sporadic cases because we have these on outbreaks or we're missing a lot of data on sporadic cases. But what we found on our surveys is that states weren't following up on sporadic cases at all.

So you might have one case in one state, a very small State like Vermont -- we have a member from Vermont whose son was sick in a Peanut Corporation of

America outbreak. And she was told by her health department, “You know, you should be really washing your hands, you should be careful that your son doesn't touch turtles, you should be paying attention to these safe food handling practices.” It wasn't until about a month later that somebody got in touch with her and said, Oh, by the way, you're part of this national ingredient-driven outbreak.

And so the fact that there was no follow up of her sporadic case means that we may be missing important information from sporadic cases that were not first identified as possibly linked to future and broader and bigger national outbreaks.

I next want to talk about listeriosis and some of the data that are missing there. When we talk about measuring progress on food safety and what that means, we want to think about how well we're preventing illness.

So how do we do this? We ID high-risk groups. Two of the high-risk groups we're aware of are pregnancy and over 65. Yet the way the data are broken down, when we look at incidents rates to meet Healthy People 2010 Goals, the data are not broken down by these high-risk groups. So we're not looking at data in these risk groups. So we're looking at arbitrary cutoff

points that may not relate to risk as well as they could.

So somebody like Stephanie and Michael, who are members of our organization, where would they fall within these arbitrary risk groups? Would they fall in No. 4? Would they all between the 2 and 49? It's hard to determine how we're improving when we're not looking for data that are comparable from one risk group in one year to one risk group in the next year.

There are other categories that we might want to consider, those being pregnancy- related and those over age 65. If you look here, we know that those incident rates do -- so it's important to look at them differently than the way we're doing it now.

So if you look here, there'd be ways of realigning these groups. Maybe for Healthy People 2010, we'd break out the data so we're looking at pregnancy-related and we're looking at over-65, as opposed to these arbitrary cutoff points that may not truly affect risk.

And then I'm going to turn it over to Donna.

MS. ROSENBAUM: Thank you.

Okay, I'm going to talk about the many non-0157 STEC strains, and this is an issue that our organization has been following for a very long time. I

think that probably for at least 15 of the 18 years that we've been in existence, we've been aware that non-0157s are a very big threat out there. And while we're encouraged to see some of the movement in terms of better laboratory testing for humans, we're very discouraged to see the lack of testing for attribution in food products and the lack of determination that these organisms are adulterants in the food supply, just like a 0157. And you're going to be meeting some of these people just very shortly.

Many non-0157 STEC strains cause disease. Studies in Michigan, Connecticut, New York and Idaho found a variety of non-0157 STEC when non-culture methods were used. I'm quoting, and there's a source at the bottom here, "Of the 373 STEC serotypes isolated from cattle feces or hides, 65 were detected in HUS patients, and 62 are known to cause other human illnesses."

So that's very disturbing to us, and we've met the people who some of these affect. There are six strains of non-0157 STEC that S.T.O.P. has petitioned should be declared as adulterants, and they are those.

And we do take this recommendation -- I believe this was made by the CDC a number of years ago, and yet, here we are years later without any really

determination. We have, like I said, moved in certain quarters with better testing in humans, but we really have had a lot of resistance in finding these in food products.

And you can see, on the ranking on the side of the slide, there, where some of these strains fall and what they've been found in.

But, again, what comes first, the chicken or the egg here? What doesn't get measured doesn't get done. And the argument has been, “Well, show me an outbreak.” Well, you can't find an outbreak if you're not looking for them in the first place. So it's very frustrating for us.

Meet Anna. This beautiful little girl died in 2002. She died from *E. Coli* 0121:H19, and I just want to add a note here on her story. This is a very interesting story, a public health story.

Anna's family lived on the border of two states. They shopped and bought groceries and went to restaurants in two different states. They lived in one state, were hospitalized in another state, the children's facility. So there was a little bit of in-fighting over what state was actually going to investigate this.

At the time of her death, she went from a well

18-month-old to dead in five days. And at the time this happened, her father got in touch with us, and I actually supported the family throughout this whole ordeal they went through. It took us two and a half years to find out what she died from, and it was a very arduous process. And this was in 2002, not back in the 1980s, and, unfortunately, the public health system really did let them down.

And they had two other children in the house at the time. They were told that this was hemolytic uremic syndrome. And then they tested for 0157 and found that it was negative and told them, “Oh, it couldn't be that; you know, we tested very thoroughly, we know we got it right at the front, so it's not that.”

The father did some research and ultimately did one of the smartest things he could have done. He took the dirty diaper pail full of her bloody diarrhea and put it in the deep freeze. And if he hadn't done that, they never would have gotten closure or found out what killed their beautiful child. Because, ultimately, we were able to find an outside lab. None of the state labs would handle this, because it was found not to be 0157.

Nobody really wanted to touch it. And, ultimately, we assisted them in finding an outside lab that at least did the Shiga toxin test. They found

Shiga toxin and then we convinced one of those states to go back and look. The process literally took two and a half years. They did go back and type it and found 0121.

And so, for some of these families, not everybody finds, this and not everybody has access to that. So this is what it takes to go through for some of them, with some of these horrible disease processes.

And meet Kayla. Kayla was 14 years old when she died in Iowa from *E. Coli* 0111, and this was in 2007. And her death and illness came within a week of the first meeting held at USDA on the non-0157 issue, where we came and gave a presentation. And it's really, really unfortunate, again, in 2007, that there were more people in her small town with bloody diarrhea, and when this child died, public health failed again. There was not an investigation done, there was no attribution, they were never told what -- it took a long time to find out that it was *E. Coli* 0111, and then there was really no follow-up. So this is in 2007, again, a more recent case.

Okay, and the --

AUDIENCE MEMBER: Do you know what the food was that caused it?

MS. ROSENBAUM: I'm sorry?

AUDIENCE MEMBER: Do you know the food cause?

MS. ROSENBAUM: No, we do not know the food cause. Uh-uh, we don't know what food caused it. It's unfortunate. And that's, unfortunately, this is what happens -- these are just two examples, and it's unfortunately what happens to most of the people who get sick from the non-0157s, when they do find out that it even is a non-0157, which is increasing that they find out, but they still have no way to find out exactly what food it was.

Okay, so the incident rate of the non-0157 is greater in three sites than the 0157 STEC is, so we can see that here by those that are kind of circled or squared. You can see that in Georgia and Maryland and New Mexico that the incident rates are higher.

So national trends in non-0157's disease burden, what are they? We really don't know. And here is one of the things that we would like to see changed. Just like the information with listeriosis doesn't really provide us with enough information to gauge the risk, it's a similar situation here. With putting all Shiga toxin-producing *E. Coli* into one group in the MMWR, it's impossible to identify national trends in non-0157 infections, because we don't really know what to do to what.

And I fully understand that those in the

Agencies, at CDC, might be able to break down those data further, but I would like to request that be made public, because I think it would be very helpful and would, I think, help convince all the constituencies that this really needs further looking into.

And we're going to end very shortly here. Okay, meet Andrew and meet Emily, and these are our most recent victims from the 0145. They survived, luckily. They were very sick as college students, not falling in the usual age group of young children.

And I want to read you something that's not included in my slides, because it's hot off the press, and I just found this yesterday, and this is from the website and blog called The Packer, and this is called "*E. Coli* Concerns Mount. Produce Finds Itself in Cross Hairs." And I think it points out something very important, so I'm going to read this to you.

"In 2006, *E. Coli* 0157:H7-tainted spinach from California was blamed for the deaths of three people and illnesses in 200 others." And many of those people work with our organization.

"Earlier this year, shredded Romaine lettuce contaminated with *E. Coli* 0145, a lesser known strain, sickened at least people 26 people in five states. Three of those people suffered kidney failure, though no deaths were reported. It's not clear whether

contamination from 0145 and less common strains is on the rise or if recent cases reflect improved or more frequent testing."

And they go on to say that, "Earthbound Farms science advisors strongly recommend screening for the six non-0157s *E. Coli* strains. In the aftermath of their calamitous *E. coli* outbreak in 2006, they have taken upon themselves..." and it reports in this article that they do 120,000 microbial tests a year. So our kudos to them, because we think that's fantastic. That's what we believe is called for and is very admirable.

But what they have found in this, they have found that tests conducted by Earthbound Farms suggest that non-0157 strains are becoming more of a problem.

"Of the 120,000 microbial tests last year, about 1 in 1,000 showed a presence of pathogens, and the vast majority were non-0157 strains."

So it's definitely a problem whose time has come, and we really do need to address this. So thank you for looking at our statistics, our database, our people with us. We hope that some of this sinks in. We know we've just touched the surface of a lot of it.

We are America's voice for safe food, and these

are some of the people we represent. And, again, we ask that *Campylobacter* become a nationally-notifiable disease; that we think really carefully about calling something "a voluntary recall"; that the non-0157s must be declared as adulterants; that people are getting sick and dying from STECs from non-0157 *E. Coli*, and we need to get information very quickly. The writing's been on the wall for over 10 years, maybe 15 years.

We need information very quickly on attribution, so we can control this in the food supply.

Listeria needs to be routinely monitored for amongst pregnant women, and, especially when pregnancies terminate, we feel a lot of information is being missed, because we don't look at the data correctly. And what doesn't get measured doesn't get done. Also, on the flip side, what does get measured needs to be acted upon in a timely manner.

So we appreciate the opportunity to be here and to express our views, but what we're asking the regulatory agencies is that we don't want to be 10 years down the road with the next emerging threat and having to say, Well, now we need to have some metrics, when what we really should be doing is very quickly identifying those emerging threats and pathogens that we need metrics for and actively going out and seeking

them with a time stamp on them. So if we identify something as a threat, let's give it a year, 18 months, two years. Say, in two years, we're going to be making a decision on what we're going to do about this and go for it. Because some of these things are dragging on for a long time and it affects some of the people you're seeing here on the screen.

Many of these people -- the type is small.You can't see it. About half of the people are up on that wall, and these are just some of the people that are in our brochure and we have some with us if you'd like a copy of it. But many people who are up on that screen are deceased, and among those who survived, many have long-term consequences. And it is our firm belief that most, if not all, of these could have been prevented, if we'd only known what to do.

So time is of the essence. We can't wait. We need to use what we have, and there has to be a good balance between getting metrics and making decisions. And, obviously, that's up to the regulators to decide, but as a consumer group who supports these people and hears their stories on a very minute basis, on a daily basis, please, we ask you to speed up the process whenever possible.

We are tremendously happy that the Food Safety Working Group has come together, because, for the first

time you have agency heads sitting down to work together to solve these problems. And, really, that's what it's going to take, because a lot of these issues are not single-agency issues. They are collaborative issues and have to come forth from all of the agencies that oversee food safety.

So we are hopeful that the metrics can be used quickly and accurately to move public health in a direction such that we don't have to meet a lot more of these people in the future.

So thank you. And to contact S.T.O.P., I'm going to leave this up at the end here. And, again, we will be staying shortly after this. And thank you for your attention and for the opportunity to tell you what we've learned. Thank you.

(Applause)

DR. FARRAR: Thank you very much. We have allotted a few minutes after the presentations for a question-and-answer session, a discussion. So if you have questions, please step up to the microphone, give us your name and your affiliation and who the question is directed to, and we'll do our best to stimulate a little discussion.

I see Nancy heading toward the mike.

MS. DONNELLY: Hello. I'm Nancy Donnelly,

President of S.T.O.P., Safe Tables Our Priority, and thank you very much for having this meeting today. I think it's really interesting. We've heard a variety of perspectives, and I think it's been very enlightening, at least for me.

My question is actually for Patty Griffin. Patty, I see on this sheet, which is great, by the way, where the food safety metrics that you've developed, that under the multistate outbreaks, one of the things that you're looking at, a metric that you've identified is "the average number of days it takes to conduct multi, comprehensive standardized interviews with persons with priority pathogens regarding food and other exposures."

Do you now -- because I know that when multistate outbreaks occur, that it's kind of -- I know it can get very confusing who's in charge, who's doing what.

Are you currently evaluating differences as far as what worked and what didn't and using that as you go to the next one?

And if you're not, I think it might be something that's pretty good, that there be a way of measuring the effectiveness in the cases of multistate outbreaks.

DR. GRIFFIN: Let me try to -- tell me if I'm addressing your question correctly. I think you're asking whether we're evaluating what works and what doesn't in multistate outbreaks.

I personally think that every multistate outbreak investigation should have a review at the end, by the participants who were involved conducted, to look at what went well, what didn't go well, and what lessons we have learned from that.

It's happening a lot more often now than it used to. It's not happening in every investigation, and the reason is the same as the reason has always been, that the number of people around to do the work has not been a match for the escalating number of outbreaks, and, sometimes, when you try to conduct a review like that, the people are too busy -- the same people are too busy dealing with the next outbreak who have the information about the previous outbreak.

So that's an issue. I think it's been recognized, and there are a lot more attempts to do that and to look at what worked.

One of the things that a group is looking at right now is how we develop what turns out to be the right hypothesis about what's causing an outbreak, and that's an interesting process, and people have different theories about how to go about hypothesis-

generating. And so a group is looking back at our multistate outbreaks, at how the winning hypothesis was generated.

I hope that answers your question.

MS. DONNELLY: It does. The crux of my question was is there some sort of an evaluation process at the end of it, and then once you've determined what worked, what didn't, is there then I guess is there a feedback with the states or, even as you're going to the next multistate one, that you say, Hey, we found this to be helpful.

DR. GRIFFIN: Right. I think it's been recognized that that's needed. That has not been fully implemented. I think it's one of the reasons that we created the OutbreakNet sentinel sites, because if you wanted -- if you say, “One of the problems is that we're not all asking the same questions,” and then pooling the data can be really difficult if you've asked slightly different questions.

You know, to do an accurate epidemiological analysis that a regulatory agency feels confident in acting on, to ask a company to do a major recall, you want to be really sure that your data are good.

But CDC is not in charge of the epidemiology in the whole country. We coordinate with the states. And so to try to get things to be done in a coordinated

uniform way, it's sometimes necessary to get people together to agree. And one of the reasons we have the OutbreakNet sentinel sites is to start building up a core of sentinel sites that have some extra funding from CDC. And so they are encouraged to work with us to develop uniform ways of doing it and then to follow the metrics to see that they do that, and we'll get more and more states that will come on board on that, once the value of that is recognized in that what they lose in state autonomy isn't as great as what they gain in the ability to indicate food products rapidly.

MS. DONNELLY: Great. Thank you very much.

MS. KOWALCYK: Barbara Kowalcyk, Center For Foodborne Illness Research and Prevention, and I just wanted to follow up on what I discussed in my presentation and something that was addressed in the recent NAS report.

And that is that we currently collect lots of different types of data. And have the Agencies been working together to examine the utility of those data, what data are meeting our needs and what data aren't and what data could be improved?

So, for example, I discussed a lot -- I talked a lot about the FSIS verification testing program, which is a valuable testing program, but needs to be improved.

So are the Agencies, as they work together, looking at where the data gaps are, what types of data you currently have, what types of data you need, and what types of data that you could improve upon right now?

DR. FARRAR: Let me just start by saying I think the impetus for the series of metric meetings are exactly about that. That is a large part of the reason for those; we realize we did need to come together, identify what data we are collecting and what the gaps are and then collectively prioritize those and try to find the resources to move forward.

So the short answer is I don't think there's been a well-coordinated strategic effort in the past to do that. We have recognized the need, and this is the first step in that direction.

MS. KOWALCYK: Okay, thank you.

DR. GRIFFIN: You want me to say something about that also?

MS. KOWALCYK: Sure.

DR. GRIFFIN: Yeah, CDC is always dealing with questions from regulatory agencies and from consumer groups, in which they want information that they reasonably think we should have, but we don't have.

So those are data gaps.

So, for instance, in our outbreak data, FDA or

FSIS might want to know how, in a milk outbreak, whether the milk was raw or pasteurized; in a turkey outbreak, whether it was deli turkey or roast turkey. And sometimes that's not completed on the forms, and so no matter how much people want the data and it's reasonable to get the data, they're not in the dataset that we have.

The information that we get from states on outbreaks is very, very extensive, but we want a whole lot more. And to get more is more work for them, and a lot of them, as you've heard in my presentation, probably don't even fill out all the forms on all the outbreaks they investigate.

So, sometimes, what we can do is work with a few states that have supplemental forms on particular products of interest, so that we can get that added information. Some states always figure out a way to get us all the information we could possibly want. But, again, that's one of the reasons for the OutbreakNet sentinel sites. One of the things that we're encouraging them to do is really report all of that information that you need on the forms, so that we can do the sorts of analyses that we all need to do.

MS. KOWALCYK: Well, I mean that's great, and that addresses part of my question. But as I alluded to

with that cartoon and as is discussed in the NAS report, we collect lots of data that are “siloed” and are not shared very well for a variety of reasons. And in the recent NAS report, they outline how data sharing could be improved and how some of the obstacles really don't -- some of the perceived obstacles really aren't as big an obstacle as people think.

So I guess I think it would be interesting to have a conversation about the data that are collected in these various silos and how we can better leverage them to improve the data that we have.

And we obviously have data gaps, but I think that's really going to what you were saying, in the sense that how do we get over – you know, the states have data that could improve the CDC's data, and I'm sure FSIS and FDA have data that could improve other people's data, and how do we move beyond this, and then, instead of having data that have limited utility, we're actually leveraging each other's data better?

And I feel like that would be, really, an important conversation, and it would be a long conversation.

So I guess it's more a comment than a question.

So thank you.

DR. FARRAR: Thank you.

Jack.

MR. GUZEWICH: Jack Guzewich, FDA. Just a comment with respect to some of these questions the consumer groups were raising about the states and locals in epidemiology.

The Conference of State Epidemiologists does surveys of their members on a lot of the issues surrounding epidemiology, and they've recently conducted a survey about the epidemiology capacity and capabilities that the states have around foodborne disease.

They presented those data at their annual meeting out in Portland, Oregon, about a month ago, in a PowerPoint presentation, and it's going to be written up in a report and will soon be available. So I would suggest that you watch the www.cste.org web page, because the report will be up there, and I think you will be impressed, or depressed, in the state of affairs for epidemiology capacity in the states. It really is -- it's going down, folks, it's going down and not going up.And that's what Patty deals with. It's not that the people don't care. The people aren't there.

DR. FARRAR: And just to echo, that same trend, although not quite as well studied, exists clearly on the environmental health side at the local

and state level.

I don't see anyone else at the microphone. Any last questions, comments before we go to closing remarks and let everyone get on their way?

(No response)

DR. FARRAR: I just want to thank you all for your time and your participation. We all recognize that metrics are extremely important. They were recognized recently in an IOM report, and also are recognized by the President's Food Safety Working Group, as critical to measuring our success in food safety.

In speaking with many of the panel members at lunch here, we were all very impressed with the presentations. We were impressed with how informed the presentations were, how specific many of the suggestions were, and how constructive they were in providing suggestions for moving forward. Those are very helpful comments, and we appreciate those.

Our intent, after the Portland meeting, is for the three Agencies to meet, review the comments and suggestions, and work together to identify and prioritize our goals and our needs around metrics, and work together to find the resources to implement those, and we could certainly use any and all help in that area.

There were a lot of themes identified today.

Just to touch on a couple that kept popping up time and time again, we clearly heard that non-0157 STECs are an important and somewhat overlooked area that, perhaps, needs additional attention and effort. We heard that. We heard the call to look very closely at *Campylobacter* as a reportable disease. We heard that some progress has been made in the area of providing information to consumers in recall notices, but more progress is needed.

Many of you were able to identify some specific data gaps, and at the top of the list, over and over again, were the attribution data, clearly a pivotal foundation point to move forward on.

You also identified that we need to consider intermediate measures, in addition to the public health outcomes, because our data collection and our surveillance efforts are often not that finely tuned to go straight to public health outcomes, measurable public health outcomes, at every opportunity. So we may need to look at some intermediate and, perhaps, some process measurements along the way.

We clearly heard the message, and we share your suggestions that development of these metrics must include all of whom you represent in this audience,

that our government has a key role, as do state and locals, industry and consumers.

So with that, I want to thank you, once again, for your time and your attendance and your incredible suggestions, and, hopefully, we'll see many of you in Portland. Don't forget that you can submit suggestions through the information provided in your packet to the website.

Thank you very much.

(Applause and adjournment at 4:17 p.m.)