FOODBORNE ILLNESS SOURCE ATTRIBUTION PUBLIC MEETING

Tuesday, January 31, 2012

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Sponsored by:

Food Safety and Inspection Service (FSIS)

U.S. Food and Drug Administration (FDA)

Centers for Disease Control and Prevention (CDC)

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Capital Reporting Company

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WELCOME AND INTRODUCTIONS

8:30 - 9:00 a.m.

MR. GORTON: Ladies and gentlemen, good morning. My name is Kerry Gorton. I'm the facilities manager here for the U.S. Department of Agriculture and for this, the Thomas Jefferson Memorial Auditorium. If anyone has issues, problems, questions that your hosts here can't answer, please come to me yourselves or ask them to come find me. I know I can take care of it. Okay?

It is my honor now to introduce your host for today's program, Greg DiNapoli, from FSIS.

(Applause.)

MR. DiNAPOLI: Good morning, and welcome to USDA. As Kerry said, my name is Greg DiNapoli, from the Food Safety and Inspection Service. I'm with the Congressional and Public Affairs Office at FSIS.

There is one request that I had before the meeting, and one of the reporters came up to me and asked the presenters and those who may ask a question to please identify who you are and who you're with, so if you could please do that, that would be wonderful. I'd appreciate it.

As far as the cafeteria goes, everyone who has an ID, if you got an ID when you came in, you can come and go as

you please to the cafeteria. If you have any issues, please come, and hopefully the security escort will come and help us find you and help you out.

The closest -- okay, they weren't given IDs. We've got a problem. You can't go to the cafeteria. Sorry.

FEMALE SPEAKER: Their names are on a list.

MR. DiNAPOLI: Okay. It sounds like your name is on a list, so I think we should be fine? Okay. Either way, we'll take care of you. We're not going to let you go hungry.

The closest ladies' room and men's room are in Wing 5 and Wing 6. Again, if you need help, just let us know, and we'll try to locate you one.

We unfortunately do not have copies of the presentations. We really would have wanted to, but with such turnout, we decided to not hand out copies of the presentations. So we apologize for that. They are all online, they should be online as of this moment. I know we've got a couple reporters here that were again asking me for some of our presentations to be printed, but they should be online on our website FSIS.gov -- .USDA.gov, right. Sorry, USDA.

(Laughter.)

MR. DiNAPOLI: Again, we'll be allowing questions, I believe, after each segment, so after each of the presenters, we will have time for questions-and-answers. We forgive you at this moment if we try to cut that off because we are going to try to keep the program going, and with that, I'm going to keep going.

As far as comments, because there are a few people who decided not to give comments, there will be some time to make comments. At the public comment period, we will hopefully allow some time. If you do have a comment, please come to us. I believe Juanita Yates --

Juanita, are you in the room?

(No audible response.)

MR. DiNAPOLI: She's in the back. If you would like to make a public comment, see the lovely Juanita Yates in the back and she'll take care of you.

At this moment, I'm going to introduce Dr. Goldman, from FSIS.

Dr. Goldman is the Assistant Administrator for the Office of Public Health Science here at FSIS. He's a family practice and preventive medicine public health physician and a member of the Commissioned Corps of the U.S. Public Health Service, has been assigned to FSIS since 2002. For 10 years, he was in the Army Medical Corps in

family practice and preventive medicine. He then worked at the Virginia Department of Health before joining the Public Health Science here at FSIS. He's got a Bachelor of Arts from the University of Virginia, a Doctor of Medicine from the University of Virginia as well, and a Master of Public Health and Epidemiology from the University of Washington.

Please welcome Dr. Goldman.

(Applause.)

PURPOSE OF MEETING

DR. GOLDMAN: Thank you, Greg. And it's really a pleasure for me to welcome you to this very important meeting on Foodborne Illness Source Attribution. I am currently the Chair of the Interagency Food Safety Analytics Collaboration, or IFSAC, which is the topic of today's meeting, so you'll hear much more about IFSAC shortly, and I won't go into that at the moment.

This meeting is being jointly sponsored by FSIS, FDA, and CDC. We really appreciate your interest, your attention, and your feedback in this very important topic.

Some of you have been students of this issue for many years. FSIS first presented questions about source attribution to the National Advisory Committee for Meat and Poultry Inspection back in 2003. We then hosted a public meeting on this topic in 2007, and as part of the National

Academy of Sciences' review of our development of a risk-based inspection system, they also commented on food source attribution, and here we are in 2012.

We have collectively -- FDA, CDC, and FSIS -- talked a lot about this issue. Today, we are here to tell you what we are doing about food source attribution.

We are sincerely interested in your views, whether expressed by the panelists, who represent various stakeholder perspectives, through the public comment, both here in the room today as well as any written comments you may have after this meeting. We are particularly interested to know whether you think our strategy is appropriate. Regarding specific projects, which you'll hear about later in the program, are we on the right track? Are we communicating this very complex issue clearly? For those who have been following foodborne illness source attribution for some years, you realize this is a very complex issue, and we want to make sure that we are communicating this very clearly.

FSIS is keenly interested in attribution, and for the past 2 to 3 years has been using CDC outbreak data to estimate the proportion of salmonellosis, listeriosis, and illnesses caused by *E. coli* O157, caused by the foods we regulate. We have used these estimates to set agency

performance measures aimed at reducing foodborne illnesses in order to help us meet "Healthy People 2020" goals. We have used the estimates in risk assessment models to help predict the public health benefit of a proposed policy change.

We have also used specific outbreak data to change policies or to create or induce industry best practices. As a few examples, we had a series of outbreaks related to tenderized steaks and *E. coli* O157 in the past that has resulted in consideration of the need for label changes.

We had a few isolated outbreaks over several years related to stuffed raw poultry products and salmonellosis. This resulted in label changes on the cooking directions for those products and development of some industry best practices.

This past year, we had a ground turkey outbreak related to *Salmonella* Heidelberg. This has resulted in reexamination of performance standards for ground poultry products.

And very recently, and in the news last week, we had an outbreak related to ground beef purchased at a retail market, and that has resulted in our reconsideration of the need for policies around grinding logs in retail establishments.

We know, however, that outbreak data is limited. Most illnesses are not part of an outbreak, and the data that we get from CDC is not timely. There is a necessary lag for the data to be compiled and presented to us. Outbreaks might occur perhaps only with gross failures of a food safety system, whereas sporadic cases may occur despite well-designed and well-functioning food safety systems. This is one of the hypotheses out there. So we don't know whether outbreak cases are representative of all the illness cases related to foodborne exposures.

Given the limitations of outbreak data, FSIS is particularly interested in the work of this collaboration to incorporate other approaches to estimating foodborne illness source attribution.

Finally, since source attribution is focused on illness, the most important use of this information will be to identify practices or policies that can be modified to prevent illnesses. You will hear this theme throughout the day today.

Some other aspects of food source attribution include knowing where in the process food contamination has occurred so that both regulatory and public health agencies can focus their efforts appropriately. We are also concerned about the uncertainty in our estimates of food

source attribution. Slight changes year to year in attribution may not be meaningful, and finding the right frequency for recalculating those estimates is very important as well. For example, implementing a significant policy change may not have its full effect until 2 to 3 years after that change is implemented, especially if the implementation is phased.

We believe that the combined expertise and resources from all three agencies you'll hear from today will help us both to develop a common approach to foodborne illness source attribution as well as to conduct the analytic work more efficiently and quickly than if only one or two of the agencies were involved.

You will hear today about our strategy for moving this forward as well as details about specific projects that are already approved and underway. We want your input and, in particular, we want your specific technical comments about the approaches we are taking and whether there are other data sources or new methodologies we ought to be considering.

Thank you again for attending today's meeting and for your assistance in shaping a project of great interest and great importance to all of us here.

MR. DiNAPOLI: Thank you, Dr. Goldman.

At this point, I would like to introduce Dr. Jeff Farrar, the Associate Commissioner for Food Protection at FDA. Dr. Farrar was previously the Branch Chief of the Office of Food and Drug Branch in the California Department of Public Health, where he led a large and diverse state food, drug, and medical device regulatory program. He led numerous environmental investigations of foodborne outbreaks in California, including salmonellosis associated with eggs, sprouts, and cantaloupe, *E. coli* O157, illnesses from leafy greens, unpasteurized apple juice, and sprouts.

Dr. Farrar graduated from the University of Tennessee College of Veterinary Medicine and received his Master of Public Health degree from the University of Minnesota, and his Ph.D. in epidemiology from the University of California-Davis. Dr. Farrar also completed CDC's Epidemic Intelligence Service 2-year training program.

Please welcome Dr. Farrar.

(Applause.)

DR. FARRAR: Thank you, Greg. I want to add my thanks to that of Dr. Goldman's and convey from Deputy Commissioner Mike Taylor, my boss, his regrets that he could not attend the meeting in person, but to relay his appreciation to you for your attendance.

In looking at the number of attendees, we at FDA are

very pleased to see such an excellent turnout for this public meeting on this important topic. In a lot of ways, the attendance here today is really validating for those of us who consider ourselves a little bit of a dated geek to know that we're not alone in the world, so thank you for being here and validating us.

Indeed, we did, as we reflect, have excellent attendance at our three public meetings last year on metrics. Many folks were quite surprised that we had 300 people show up here in D.C. at a public meeting on metrics. So, there is a lot of interest in these topics, and we certainly appreciate you taking your time to travel here today. As David said, we absolutely want to hear your input, both general and specific, on our plan as we move forward.

The attribution that we're talking about today provides critical information for us at FDA in our need to set and prioritize our goals, to guide our policies and interventions, our research, and help determine our distribution of resources, and to monitor our progress in a true risk-based food safety system.

Focusing on the greatest risk in a food safety system has always been intuitive to those of us in the regulatory world, and, indeed, there are many risk-based efforts

underway. Within FDA, for instance, how we determine which facilities get inspected on a yearly basis we approach on a risk-based system, considering their compliance history, their recent inspection and lab results, the type of operation and so forth.

We do set new food safety requirements and develop guidance documents based on the practices in foods that we believe pose the greatest risk, using our best data and judgment at hand, but at the same time, we also recognize the need to take a risk-based approach to a completely new level, as reflected very specifically in the IOM report that probably most of you are very familiar with.

The work that IFSAC, our Interagency Food Safety Analytics Collaboration, is carrying out to develop this clear stepwise path forward to generate food source attribution data that is timely, accurate, and specific will help us achieve that vision.

Working together, CDC, FSIS, and FDA have developed a Strategic Plan for attribution, and we are here today to get your input and your important feedback on our plan. We all know that a variety of methods can and are being used to look at this issue, and our plan reflects the need to include a variety of methods to generate that data and ensure that no single method or agency or individual has an

undue influence on guiding the direction of that approach.

There is widespread understanding among those that have a degree of familiarity with these various data sources that we can't depend on any single data source. Outbreak data, as we know, is extremely valuable and extremely important, but has its limitations, as does data on sporadic cases, prevalence surveys, and all the other data sources that are currently available.

At the same time, we all agree that we cannot wait until we have a perfect data stream to develop attribution estimates. We must start now with the data sources that we have and the methods that are available to develop those estimates and improve them over time.

Food source attribution, as many of you know, is not an easy task by any stretch of the imagination. It's going to require an investment of time and resources, and we all know we have a lot of work ahead of us, but we fully intend to make our efforts as transparent as possible and to include our stakeholders as we move forward.

As we develop our work on attribution, we cannot stop our day-to-day activities. We must still continue to develop food safety policies and carry out our regulatory programs based on the best information we have available. Under the new Food Safety Modernization Act, FDA is

developing several foundational rules focused on preventive controls that will prevent illnesses from happening. Our work in that area will continue and is continuing, and we believe those preventive controls will complement the work on attribution, modeled on the HACCP principles, identifying the specific hazards and putting specific preventive measures in place to control those. These FSMA initiatives will complement the work on attribution we are here today to discuss and provide a framework for achieving safer food, our collective ultimate goal.

So, in closing, thank you, David, for the opportunity to make a few opening remarks, and we look forward to the discussions here today. Thank you very much.

(Applause.)

MR. DiNAPOLI: Thank you, Doctor.

I apologize if I'm looking down and not out at you because I'm so tall, I can't even read what's on the paper.

(Laughter.)

MR. DiNAPOLI: So, I apologize. I do want to mention that there are about 30 copies of each presentation, I believe, out at the registration table, so we did make some copies. As I said, everything is online for you all to access, but we do have about 30 copies, so at the break, if you all want to rush to the back and fight each other for a

presentation, you can do that.

The next speaker is Dr. Dana Cole. Dr. Cole is a large animal veterinarian and doctoral epidemiologist responsible for the direction of the Outbreak Surveillance and Analytics Team in the Enteric Diseases Epidemiology Branch at CDC. Dr. Cole oversees the data collection and quality assurance for the Foodborne Disease Outbreak Surveillance System, as well as the online tool for accessing outbreak data. She also leads work to conduct analytic studies of source attribution of foodborne diseases to specific food commodities and settings. Before coming to CDC -- or before going to CDC -- we're not in Atlanta -- but before going to CDC, Dana worked in the Georgia Division of Public Health in the University of Georgia College of Veterinary Medicine.

Dr. Cole.

(Applause.)

DATA AND METHODS FOR ATTRIBUTION

9:00 - 9:45 a.m.

DR. COLE: Good morning. Thank you. I have a tall order to get through a lot of data and methods here in a short time, so we'll get started.

Slide.

So, a brief outline of what I'm going to talk about

this morning. I'm going to go through our background and purpose of foodborne illness source attribution, where source attribution starts. We've had some excellent comments this morning, and I'm going to go into some more detail about our outbreak-based attribution, and then how we paint a clearer picture of foodborne illness source attribution, and then our goals for looking forward.

So, first, our background and purpose with our goals and some questions.

So, I would like to start off with this quote, "Art and science have their meeting point in method," and that's because, as a scientist and an artist, I know that method is at the core of how we deal with our input, such as if as an artist, your paints and your paintbrushes, and as a scientist, your data and your analytic methods.

So, our overarching goal is to prevent illness and death by gathering and analyzing information to create collective knowledge and stop food problems before they happen. So, with that as our overarching goal, we move forward with foodborne illness source attribution and its role in preventing food problems before they happen.

So, let's define foodborne illness source attribution. If you look it up in the American Heritage Dictionary, it's one of those words that, if you're like me, I hate it when

I look up a word and the word is defined by the word, and this is one of those. "The act of attributing, especially the act of establishing a particular person as a creator of a work of art." We keep coming back to art, I like this, but if you take away some of these American Heritage words and put in our own words, we get a bit closer to what I think our working definition is. "The act of attributing, specifically the act of establishing a particular food as a source of an infection." So, that works better for us for foodborne illness source attribution.

So, first our purpose. We want to inform food safety decision-making. So, we need to determine the most pressing food safety priorities, intervene to reduce illness at points in the food chain where intervention can have the greatest impact, target our prevention measures to meet our long-term goals, and measure progress toward our food safety goals. Ultimately, once we implement changes and guidance and regulation, we need to measure how we're doing, and foodborne illness source attribution is key to that.

So, as we move forward to attribute illnesses to food sources, we really need to use new tools to understand today's food safety challenges, and using these tools then, we paint a clearer picture of foodborne illness source

attribution.

So, let's start where foodborne illness source attribution starts. So, this is our sort of cycle of the public health cycle that we use to sort of outline our efforts in the process of leading us to food safety prevention. So, we start with surveillance. So, we have a variety of surveillance systems at CDC designed to collect information on what is causing illnesses in the population. And then, if we detect either a cluster of illness in the case of an outbreak, we may do an epidemiologic investigation or there are other types of epidemiologic investigations that I am going to talk about that, and that is an example of a case-control study. And then, using the information we collect during an epidemiologic investigation, then we gather the knowledge we can use to design prevention measures. And also, of course, during the process of collecting data during an epidemiologic investigation, we identify new research areas for applied research and rely on partners in the sciences to conduct applied research to help guide us in the best approach forward.

So, let's start, as I mentioned, where it starts, and that is at the time of an outbreak. So, a nice example of how outbreak investigations led to prevention measures is

the *E. coli* O157 outbreaks in the 1980s and early 1990s that were traced to ground beef. The information that was gathered during those outbreak investigations then guided interventions taken by our regulatory agencies, recommended minimum cooking temperature of hamburger was raised, and the Food Safety and Inspection Service implemented HACCP, or Hazard Analysis and Critical Control Points, and made *E. coli* O157 an adulterant.

So, right there, that's where foodborne illness source attribution starts: we detect illnesses, we conduct epidemiologic investigations to detect the source of those illnesses, and then what we learn from those investigations guides in the next prevention policies.

So, en masse, or overall, across outbreaks, outbreaks happen, unfortunately, with regularity. We collect that data through the Foodborne Disease Outbreak Surveillance System, and you've heard the previous speakers mention the outbreak data. So, the Foodborne Disease Outbreak Surveillance System then captures our outbreak data on the agents, the foods, and the settings that are responsible and contribute to foodborne illness. The system was started in 1967, but was really standardized into the system that we have today in 1973.

And outbreaks are critical and foundational to our

foodborne illness source attribution because it's one of the unique surveillance systems that we have that actually collects data at the time of the foodborne illnesses that links particular illnesses to a particular food source, and so, hundreds of these outbreaks are reported to the CDC each year by the local public health departments in the states.

So, this gives you a snapshot of how many outbreaks are typically reported to us annually. So, you can see, it goes back to 1973, when we -- go back a little bit -- 1973, when we really started collecting outbreak data in sort of the similar way that we do now, but then you see a big jump in 1998. This jump is credited because we introduced a new surveillance system, PulseNet, where laboratories collect microbial fingerprinting data on the pathogens that cause illness, allowing us to trace them and link them, link illnesses together through molecular fingerprints.

And we also moved to an electronic reporting system of the outbreak data, simplifying the process of reporting outbreaks to the CDC, and, thus, we increased the amount of information we were able to collect since 1998. We did see a bit of a drop in 2009 associated with some additional changes that we made in the electronic reporting system in that now a much broader array of outbreak data is reported

to us across multiple streams, and so this is foodborne illness data. And we also have some other reasons to think that in 2009 resources were stretched as H1N1 was circulating in the population, and other reasons.

Next slide.

So, what we do with this data then is there are over 1,800 individual foods that are reported to us in the outbreak data, and, of course, it's difficult to base policy on individual foods, so we go ahead and categorize these foods into 17 commodities, which are the red, or orangish, boxes here. So, we categorize the individual foods into a beef commodity or a game commodity, et cetera.

Next slide.

So, how do we do this? Well, we need to determine whether the food that caused illness is what we call a simple food or a complex food. So, simple foods are those that the individual ingredient in the food that was contaminated is known or all the ingredients in that food actually fit into one of our commodities.

So, I have some examples here. You could have a green salad, for example, that was responsible for the foodborne illness outbreak, but it was known that that salad contained contaminated spinach. So, in that case, this would be a simple food, the spinach would be a simple food.

A complex food, on the other hand, is a food with many ingredients, it's not known, it's not possible to figure out the exact contaminated ingredient in this outbreak, such as lasagna. So lasagna, as you can see, has many different ingredients, and if we don't know which one was the source of contamination, then, of course, each ingredient would fall into a different commodity in our tree, so that's why we call it a complex food.

Next slide.

So using this data, we can come up with a distribution, a peak at the commodities that are associated with foodborne illness, and, so, this pie chart just demonstrates across 1,500 outbreaks the commodity distribution that was associated with simple foods that were reported as causing those foodborne illnesses, and that gives us a peak at areas of commodities anyway that are associated with foodborne illnesses.

We report this data, it's collected and analyzed annually, and we report this online at our CDC website.

Next slide.

And we also provide the data, the outbreak data, in what we call the Foodborne Outbreak Online Database, where we provide information on individual outbreaks and the foods and the settings associated with them for other

scientists and the public to download.

So, this is our foundation where foodborne illness source attribution starts. Let's paint a clearer picture. So, I'm going to walk through three steps that we've identified to foodborne illness source attribution, talk a little bit about the limitations of outbreak data and then talk about a pallet of other data sources that we can use for foodborne illness source attribution.

So, step 1. First we need to estimate the total number of illnesses, foodborne illnesses, occurring in the United States. Then we need to attribute illnesses to food. And then we need to determine the top priority pathogen-commodity pairs that we need to target. So, I'm going to walk through that a little bit here.

So, first estimate the total number of illnesses.

Next slide.

So, just last year, in 2011, the CDC released new estimates of the number of foodborne illnesses occurring annually in the United States, and this was somewhat landmarked in that it hadn't been done since 1999. So, these new estimates then were released in 2011, and this is the kind of information that these estimates can provide for us. For example, of the 31 known pathogens, it was estimated that nearly 48 million illnesses resulted in

128,000 hospitalizations and 3,000 deaths. So, we have an idea of the burden of foodborne illnesses in the United States.

And even more importantly, perhaps, for targeting specific interventions and knowing what pathogens are driving some of these numbers, we looked at seven pathogens among these 31 that caused 90 percent of the illnesses. And, so, right away we have information that allows us to guide our priorities in that if we target these seven pathogens alone, we have the opportunity potentially to prevent 90 percent of illnesses and hospitalizations and deaths. Five pathogens, if you reduce that down to just the top five pathogens, that counted for 88 percent of hospitalizations caused by known pathogens.

So, now the next step, attributing illnesses to foods. So, I don't expect you to read this. This is one of our tables available online that we produce once a year, but the point is that with the outbreak data that I mentioned that we summarize annually -- this is from 2008, you can see in the first column is the pathogens, all the pathogens and all the etiologies associated with outbreaks. This includes both our pathogens, it includes chemicals and toxins, it includes viruses, all associated with foodborne outbreaks. And then each column after the first column

represents one of our food commodities.

So, we produce columns of information showing the number of outbreaks and the foodborne illnesses associated again with those simple foods. So, when a single contaminated ingredient or a group of ingredients belonging to a single commodity was responsible for the outbreak, we categorize that in this table, and we produce this table then for each year of our data.

So, then now it's time to determine the top priority pathogens, link our pathogens now, our estimated number of illnesses, with our top commodities. And so, this is a blowup of that previous table just showing our top pathogens that I outlined from our estimates of illnesses, and you can see from the circles that, if you look, drill down in the outbreak data, you can start to look at the top pathogen-commodity pairs. For example, *Salmonella*, in 2008, was associated with fruits and nuts and vine-stalk, caused a lot of illnesses in 2008, and *Clostridium perfringens* then was one of our top pathogens associated with pork, and again that's based on foodborne illnesses reported in 2008. So, you can start to see how this data comes together so that we can target the pathogen in food commodity pair for guiding intervention.

So, using the data from outbreaks caused by simple

foods -- again, these are just the single ingredients -- to attribute illnesses to commodities can paint a picture of the pathogen-food commodity pairs that contribute to foodborne disease, but we want to create a clearer picture. So, let's talk a little bit about the limitations of the outbreak data.

So, as was mentioned before, outbreaks account for a small proportion of the total number of foodborne illnesses. So, the big blue pie, or the big blue pie chart, is the total number of foodborne illnesses caused by 10 common foodborne pathogens, let's say, and so the little gray sliver is that number that's associated with foodborne outbreaks. So, you can see that by using outbreak data, we're using a small proportion of the total number of foodborne illnesses to identify the pathogen-commodity pairs that we're interested in.

And, then, if you go farther, that little teeny slice on the end is the multi-state outbreaks, the proportion of illnesses associated with multi-state outbreaks. Again, these are the multi-state outbreaks that you hear about in the headlines and get traced back to the farm, implicated farm, and that sort of thing, and are really the best of the best as far as our outbreak investigations go, but that, again, is a relatively small proportion compared to

the number of outbreaks that are investigated and reported every year at the local level and drive a lot of our data.

So, another limitation, as I mentioned, the definition between simple and complex foods is that more than half of the foods reported are complex. If you can imagine, how often do you eat a simple food item or a food ingredient? It's rare that we just eat spinach, for example, without something else, or just have a hamburger without the lettuce and the mayo. So, more than half of the foods often are complex. Also, many outbreaks don't actually implicate a single food. These outbreaks, as I mentioned, are investigated at the local level.

And an outbreak is defined simply as two or more people who were exposed to a common food causing that illness. So, if you're investigating an outbreak of two or three people, for example, that shared a common meal, it can be very difficult to find what the actual single ingredient or food was because they all ate the same foods, for example.

There are also oftentimes delays in reporting the outbreaks to the public health department, so that can result in complications with the investigation and actually determining the contaminated food.

And then, finally, *Toxoplasma gondii* is a good example

of foodborne illness that is responsible for a high number of estimated illnesses annually, but we don't see outbreaks of *Toxoplasma* in our outbreak data. So, if you want to learn more about *Toxoplasma* for intervention and such, outbreak data doesn't serve as a good source of data to link that pathogen with its commodity. So we need other tools.

So, let's talk about the pallet of data sources. So, I'm going back to my art metaphor because I'm familiar with this, and in this case, all the data sources are colors of my pallet, and our brushes are our methods. The art and science of the source attribution brings in a pallet of data sources and then a variety of analytic methods, the brushes, to paint a clearer picture.

So, I'm going to start with a method called complex food attribution, where we bring in information, we pull in data on food ingredients, and use that with our surveillance data to expand our attribution estimates from outbreak data.

So, first an example of how powerful it would be when we pull in complex food data. If you look in the 1980s, when *Salmonella* enteritidis was increasing in the Northeast -- and this chart shows the dramatic increase in outbreaks associated with *Salmonella* enteritidis in the Northeast

compared to outbreaks occurring in the rest of the country was relatively flat, increasing slightly, but not nearly to the degree that it was increasing in the Northeast. And if you think back to the 1980s, we were still trying to investigate the main source of these outbreaks in *Salmonella* enteritidis.

If you looked at only the simple food outbreaks, for example, then 7 of the 35, or 20 percent, of the outbreaks specifically were traced to contaminated eggs, but if you looked at egg-containing foods -- so those complex foods -- suddenly 77 percent of these outbreaks were associated with eggs, and this was a much stronger conclusion or a much stronger association for linking *Salmonella* enteritidis to eggs. So, you can see the power of being able to pull in additional outbreak data from these complex foods and how that can help us determine a pathogen-commodity pair.

So, CDC has developed a method for pulling in the food ingredient information from foods that are contained in the Outbreak Database to sort of assign probabilities that that ingredient was a contaminated ingredient so that we can use that information to actually estimate the number of illnesses associated with a commodity that is also commonly contained in complex foods. And this is just a snapshot of what that looks like, in that the green is the number of

illnesses we could estimate if we just used simple food ingredient attribution. The blue square represents the increase, the power that we get when we use simple and complex food attribution based upon this probabilistic model, if you will, of what the contaminated ingredient was likely to be. And then the red is the worst case scenario, very unrealistic, but if you assume that every ingredient in that complex food was contaminated at the time of the outbreak, then that would give you the estimate of how many illnesses were caused by that commodity at the red. So, it gives us an opportunity to see sort of the lower end, the most likely estimate of the pathogen-commodity estimation, and then the high end or that is unrealistic in that we don't think that all the ingredients are associated with contamination.

So, that's one method where we can bring in the food ingredients to help inform our outbreak data and give us more power.

Another method is case-control studies. Again, think of that pie chart where the outbreak data was a small subset of the total number of foodborne illnesses reported each year. So, case-control studies allow us to investigate those sporadic illnesses, those illnesses that are not associated with outbreaks.

Next slide.

So, why do we need to use case-control studies? Again, sources of illness are rarely known outside of the outbreak setting. Ill people are routinely not interviewed as a result of their illness. Their illness is diagnosed, sent to a laboratory, and the laboratory then submits reports, that to the CDC as the basis of our surveillance, but unless part of a specific study, like an outbreak investigation or a case-control study, people who are ill are not routinely interviewed to determine what made them sick. And think about even if you were interviewed. If you were ill and you went to the doctor and received your diagnosis and then a public health representative called you in a couple weeks to interview you about your illness, how many of you think that you would probably know what it was that made you sick 2 weeks ago if you had *Salmonella*? So, it's very difficult in this case to determine because even the ill person can't tell you what made them sick at the time.

So, case-control studies are very useful to us because they interview the persons that were sick and compare their exposures to persons who were not sick, and then those exposures that are more common among the cases are probably more likely leading to the illnesses than their healthy

counterparts.

So, we've used case-control studies to provide what we call population attributable fractions. So, if we look at an example of our *Campylobacter* studies, we've done case-control studies of *Campylobacter* infections. For example, we learned that approximately 12 percent of the cases reported international travel, which was much higher than the healthy controls. We also found that chicken consumed in a restaurant had an attributable fraction of approximately 24 percent of the cases. So, approximately 24 percent of the cases may have been associated with consuming chicken in a restaurant, or another meat, at 21 percent. And then consuming undercooked or pink chicken was associated with an attributable fraction of approximately 3 percent of the cases. So, again, this gives us some information about the associations between illnesses and exposure sources in that population of persons, the sporadic illnesses not directly associated with outbreaks.

And then I'm going to talk about another model, the Hald model, which brings in product testing data, consumption data, and surveillance data to create a picture of foodborne illness source attribution. So, this model was initially designed by Danish scientists, and we've

worked to adapt it in this country. And I'm not going to go into a lot of detail about it because you're going to hear about it in more detail from one of our later speakers, but basically what this model does, it allows us again to try to estimate what were the probable food sources of foodborne illness using human illness data that we collect at CDC, data regarding food consumption -- so, what are persons exposing themselves to in the population? -- so, an estimate of food consumption, and pathogen isolation data from food products -- so, food testing data.

So, by linking all this -- we tried this -- again, it was designed initially by Danish scientists, so the model that they designed was unique to their surveillance systems. So, we worked with FSIS and CDC worked together to try to see how we could fit it to our data that we collect in the United States and used Food Safety and Inspection Service verification testing data at the point of processing, data that we collected at CDC on laboratory-confirmed illnesses, and then the USDA Economic Research Service data on market availability of food commodities.

So, again, you're going to hear more about that model later on, but the nice thing about that model, again, one, it estimates sources of illness for again the majority of foodborne illnesses not associated with outbreaks, and it

links contamination data as measured in food products at processing to consumption, the probability of getting exposed to that contaminated food product, to the number of illnesses.

So, using a variety of data inputs and sources and a variety of analytic methods, we can then fill in some gaps or help inform the basic information that outbreak attribution provides us. The Outbreak Surveillance data, as I mentioned and others have mentioned, provides a nice framework for associating illnesses to specific food commodities, but by bringing in additional data sources and additional methods, we can paint a much clearer picture of foodborne illness source attribution.

So, looking forward. So, one of the things that we recognized early on as we were working together among the agencies on this food safety analytic collaboration is the concept of uncertainty, and that was mentioned already today. We have a variety of sources of uncertainty. For example, I've walked through a variety of data methods, data sources, and each of those has its own level of uncertainty. So, for example, if you have a difference between a case-control study of 24 percent estimated attributable fraction, and you have outbreak data that says it's around 30 percent, are those different? How do you

explain that? What are the sources of uncertainty associated with different estimates that may be different using different methods and different data sources?

We also, as you heard earlier, have the source of uncertainty associated with annual variation. We're not going to get, as I mentioned, with Outbreak Surveillance, we publish our estimates annually, and if you look at the year-to-year variation between, say, the number of illnesses associated with a particular pathogen-commodity pair from one year to the next, it can vary quite a bit. So what does that mean? How do we work with that uncertainty? How do we analyze that uncertainty?

And, then, how to interpret change is another communication challenge. We recognize that we are always working to improve our data. We are working to bring new data sources in as part of our toolbox or part of our pallet of data sources, and we're trying to always apply new state-of-the-art methods to analyze that data and produce the best current foodborne illness source attribution estimates. So, as we're working toward this improvement process, then the numbers that we calculate perhaps are going to change somewhat as we do this. And also, then, where is the need to determine real change or what is actually changing with foodborne illness source

attribution? Again with the idea, are our systems working? Are our interventions working? How do we measure the impact of our interventions?

So, that's a challenge with communication, to always be trying to strive for improved data, improved methods, and improved best current estimates, but also measure real change over time, and determining and communicating the difference between what we think is real change and what is changing methodology.

And then, finally, as we go forward and we improve our estimates and produce best current estimates, then how do we communicate what it means to consumers for a food to be risky? How do we provide these estimates, for example, that show that commodity A is associated with a high number of foodborne illnesses and not generate fear of that commodity, but, rather, generate actually information that can be used to promote safe food handling, for example, and knowledge that can improve the way that food is used or prepared in the kitchen and other settings for improved food safety?

So, looking forward, as I said, the common theme is that attribution estimates are always changing or always improving our data. We're always looking for new data sources to incorporate with our methods, and our analytic

methods continue to evolve. So, our goal in the Interagency Food Safety Analytics Collaboration is to continue to improve these estimates by using the best available data methods and that which will enable us to use the most current accurate and state-of-the-art information for making decisions.

And, with that, I will close with one last shameless plug for my art. And I don't know if we have time for questions.

(Applause.)

MR. DiNAPOLI: I believe both of those mics are live, so if you have a question, please feel free to come up to the mic.

(Pause.)

DR. COLE: The art metaphor worked. All right, no questions.

MS. SMITH DeWAAL: (Off-mic comment.)

DR. COLE: Okay, good.

MS. SMITH DeWAAL: Hi, Dana. Caroline Smith DeWaal, with CSPI. Can you give us an explanation of the decrease in reporting, the rather dramatic decrease in reporting, in 2009?

DR. COLE: I can't give you an explanation that I am confident is the right one. I think what we have actually

is, as I mentioned, a variety of influences that impacted our numbers, and we're still investigating, we're still looking into that, and working with the states, talking to the states and the public health agencies that reported that data.

But as I mentioned in my talk, one of the things that changed in 2009 was the actual electronic reporting system. We moved from the electronic Foodborne Outbreak Reporting System to what's now known as the National Outbreak Reporting System. And as I mentioned, when we did that, we moved from an electronic system where only foodborne outbreaks were reported to now we have a centralized system where outbreaks associated with any transmission pathway can be reported through the same electronic interface. And while that doesn't seem like it should really change the numbers -- a foodborne outbreak is a foodborne outbreak -- we think that it actually did cause a little shift in the way outbreaks are reported.

For example, norovirus is highly infectious and is often difficult. It is one of those outbreak-associated pathogens that is really difficult to implicate a specific food. So, we think that now because the same electronic system is capturing the data on norovirus outbreaks associated with person-to-person transmission, that, now,

if it's unknown, that big piece of the pie -- remember I said that there are a lot of unknown foods – now, if the food is unknown, for example, but the persons are at a common setting, it may have been a wedding party, and it's not known exactly, and it probably was a combination of transmission pathways, some people might have gotten ill, for example, person-to-person, and others, there may have been food contaminated at that setting, and so it may have been a combination, well, now those outbreaks are being reported potentially to the other part of the system as person-to-person. So, that's one hypothesis that we have, is that we're collecting data across multiple sort of inputs.

It's also now possible to input an outbreak as unknown transmission pathway, so some of those that may before have been classified as foodborne because they occurred at a restaurant, if they don't implicate a food, they might put "unknown," and the only way that we're really going to be able to pull that out is to actually investigate those and read the report and find out if, in fact, this was something that may have been reported as foodborne in the past, but now with the new system, it's being reported as unknown because they couldn't pin down a food in particular, where before it would have been reported as

foodborne, but unknown food.

The other thing that happened in 2009, in particular, was the outbreak of H1N1, and so the impact that that had on local resources, which, by the way, only have a certain number of resources, of course, to investigate outbreaks and illnesses due to any transmission pathway may have impacted them such that they struggle to investigate as many outbreaks as they may have because they were working really hard on the H1N1 outbreak and the associated tracebacks and prevention measures associated with that. So that's another hypothesis.

But, again, we're working with the local public health departments to try to get from them what they think happened and why those numbers are dropped and so we can provide that information.

MS. FELDSTEIN: Hi, Faye Feldstein, of Deloitte Consulting. I'm intrigued by the fat paintbrush in your pallet in terms of the distribution of ingredients within a complex food. And over the past few years, we've seen a lot more incidents related to perhaps food or food ingredients that we may not have seen before. So I wondered about the data sources you were using to really tease apart the ingredients in the complex foods.

DR. COLE: So, the initial method that was used was

simply using good old Google to Google recipes and take a variety, take the top three to top five recipes and identify the common ingredients across all those recipes, and then the ingredients then were assigned to commodities. We're looking at potentially other sources of information that would be standardized and other methodologies associated with that because we're really interested in making sure that we have the most current sort of recipes, if you will, or ingredients that are probably actually being used by consumers in their recipes, if that's the word, yeah.

DR. BOOREN: Hi. Betsy Booren, the American Meat Institute. A follow-up to that question is that, is there consideration in expanding the commodity groups? Because many of these are ingredients, and you're placing them into those simple commodity groups. It's not really giving a truthful estimation of what's caused the illness, or what food. And so, are you considering expanding those commodities perhaps to include spices or different ingredient categories that truly captures that data?

DR. COLE: Perfect question. The answer is yes, and stay tuned. We're going to talk about that later this morning. So, yes, we are expanding those, working with our partners in the FDA and FSIS. We're working toward

expanding those categories so that they are more relevant, as you said, and capture more foods and capture foods at the level that are of interest from a regulatory standpoint. So, that's one of the projects we're going to present this afternoon, or this morning, sorry.

MR. DiNAPOLI: Thank you, Dr. Cole.

Our next speaker is Dr. Christopher Braden. Dr. Braden is a medical epidemiologist at CDC, where he currently serves as the Director of the Division of Foodborne, Waterborne and Environmental Diseases. Dr. Braden earned his Bachelor of Science from Cornell University, and M.D. at the University of New Mexico School of Medicine. He is a commissioned officer in the U.S. Public Health Service, a member of the Society for Microbiology, and an Associate Editor for the Emerging Infectious Diseases journal. His major areas of interest include molecular epidemiology of infectious diseases, infectious disease surveillance and outbreak investigation, and national programs in food and water safety.

Please welcome Dr. Braden.

(Applause.)

INTRODUCTION OF THE INTERAGENCY FOOD SAFETY

ANALYTICS COLLABORATION (IFSAC)

9:45 - 10:10 a.m.

DR. BRADEN: Thank you and thank you for your interest in this topic today. What I'm going to talk about is really: What is IFSAC? Why did we form it? How does it work? Who are members of IFSAC among our agencies? Just to give you some background in that regard. We have to get this question. It seems like a black box out there to a number of people, and I hope I will make it more transparent.

Next slide.

So when we talk about analytics and Food Safety Analytics Collaboration, what are we really talking about? Well, there are a lot of different things that we could talk about as far as analytics are concerned, and some of the things that are analytic projects and analyses that we've done in the past. You've already seen, for instance, the estimates of the incidence of foodborne infections in the United States, determining trends in foodborne illnesses and food contamination over time, economic analyses.

What we did for this particular group was to say, well, there are a lot of things that we could do, but we

know we're not going to do at least a few things, and that is, these are not analytics that are part of acute outbreak investigations; that is not what we're talking about in this regard, nor is it the traditional risk assessment. There is another group that is a collaboration, it's called the Interagency Risk Assessment Collaboration that does the traditional risk assessment, and we're not going to try to overlap with that effort.

And then according to agency needs, we decided to concentrate on the attribution of illnesses, hospitalizations, and deaths to food commodities, is what we're going to be really purposeful in trying to focus on in this particular collaboration.

Next slide.

So in our approach to the Interagency Food Safety Analytics Collaboration, we wanted to build on a history of source attribution -- and some of that information you've already seen -- apply advances in source attribution methods, leverage knowledge expertise and data among agencies, build on efficient structures that are guided by strategy, and prioritize communications.

Next slide.

So when I talk about building on a history of source attribution, Dana went through nice examples of how that's

happened and really used some of these examples here about outbreak investigations and how that has been used to attribute illnesses to foods and then to guide policy, for instance, *E. coli* O157 from ground beef, *Salmonella* enteritidis infections from eggs. So, these are things that we have done ongoing in the past in order to attribute illnesses to foods that have affected policy.

In addition, there have been epidemiological studies, as she mentioned, case-control studies, for instance, that link campylobacteriosis to poultry. *Campylobacter* is another one of those illnesses that isn't really captured well in our outbreak investigation surveillance.

And then, of course, there are risk assessments certainly inform source attribution. For instance, there was a large risk assessment, for those of you who are familiar, of listeriosis that identified processed meats as a high-risk food for that particular illness.

Next slide.

And then, as Dana also suggested, there are a number of advances that we've seen more recently in food source attribution, including, as the questions are asked, improved food categories, statistical analysis of data from foodborne outbreak surveillance. We're getting more sophisticated in how that analysis can be done. There's

the Hald model again that was mentioned, estimates of uncertainty, and expanded data sources. And this is a number of advances that have happened over a number of years, and there is a growing body of literature around each of these.

Next slide.

So the agencies have been doing this type of attribution for a number of years, and, more recently, have done more in the way of more sophisticated analysis, for instance, of foodborne outbreak data that has been shared by CDC, other types of data, prevalence of contamination of foods, but doing that independently we knew was fraught with problems. We knew that we needed to come together in order to have a shared understanding of where illnesses were coming from.

So, we formed IFSAC in order to leverage our knowledge, expertise, and data among the agencies. There is a shared environment to develop the methodology and conduct the analyses, to apply the data from all applicable data sources. No one agency has a complete set of data sources that we would use.

The shared results interpretation and use is incredibly important. One agency can't come out with one method and estimate and another agency with a different

one; we have to work together on this to have shared interpretation and use. And, of course, when you do that, and all agencies are involved in the conduct of these analyses, you get a deeper understanding of how these can be used for policy decisions.

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So, this is some of the processes that we built for a shared structure and strategy for IFSAC. Some of you may have seen that the charter for IFSAC is actually posted on the FSIS website for this meeting. There is a steering committee that's been set up. There are two members from each agency able to commit resources, and as Dr. Goldman said, he currently chairs the steering team, the annual rotation of that chairperson among agencies. And the steering committee is charged with assessing, approving, and overseeing IFSAC projects.

There is a technical working group of analysts among the agencies that has been formed. This is a designated group of analysts that really have been very fruitful in recognizing the needs of each agency and bringing that together in our planning. They also develop proposals and plans for the IFSAC projects that the steering team then considers, and they coordinate IFSAC activities within each agency. This is a very important group. These are the

people that actually do the work.

And then there are project teams that are developed around approved projects, and these are assigned personnel from each agency that conduct the specific projects.

Next slide.

So planning and implementation of IFSAC really revolves around a -- the first thing we did was to conduct a needs assessment for all three agencies to make sure that we satisfy the needs of all three agencies in this collaboration. It is responsive to directives, especially most recently the Food Safety Modernization Act has a number of directives there that the IFSAC needs to consider carefully. It drafted the Strategic Plan, and that again is available for you to look at, at the meeting website, and we really welcome feedback on our Strategic Plan so that we know what all the stakeholders are looking for.

And then we implement projects based upon the project proposals that are developed and the quality of those proposals, the scientific merit to those proposals, and the fact that those proposals meet the needs of the three agencies. So they're quite detailed plans, including timelines and the resources that we would put towards them. And then there is a lead agency that is designated for each of those plans.

I want to stress that IFSAC was developed with existing resources. There is no specific funding that the agencies have in order to support this; however, we do believe that by doing it through this collaboration, it will be more efficient and effective.

As you will see, there are several projects that have been approved.

Next slide.

And we know that it's important to communicate what IFSAC is, what IFSAC does, what the products are, and obtain stakeholder input. There were a series of public listening sessions in 2010; I believe three of them. One was mentioned earlier in Washington, D.C., was one of these metrics meetings they're also called, and about 300 people participated, and we know that this topic on analytics is important partly due to those meetings.

We also consulted the Risk Communications Advisory Committee at FDA to determine the best methods for communication of these rather complex issues. We've also at CDC formed a multidisciplinary surveillance workgroup of external stakeholders to guide processes of surveillance at CDC but also looking at this particular topic of source attribution.

There is additional FDA, and then this IFSAC public

meeting in which we seek your input. And then tomorrow there is a multidisciplinary forum that is being hosted by Pew and the Robert Wood Johnson Foundation to delve deeper into some of these issues and give us feedback.

There are planned web-based information and communications so you can look forward to that to get some information about what we're doing. And we would like to be able to communicate that there are risk foods, but that many of these foods are also healthy foods, and so how do we balance the communication between both safe and healthy foods and eating?

So with that, I will finish and answer any quick questions you may have.

(Applause.)

MR. WALDROP: Chris Waldrop, Consumer Federation of America. I'm pretty sure the applause was for you and not for me just standing up here.

(Laughter.)

MR. WALDROP: Dr. Braden, I had a question in terms of this is very important work, and it's going to take some time to work through the process of looking through your Strategic Plan where you have long-term and short-term goals. What elements have you put in place that ensure that this will continue over time, and maybe even across

administrations, if that's the case? Are there ways to just ensure that this work will continue?

DR. BRADEN: Well, I think, you know, it's recognized at multiple levels at all three agencies that we have to come together on these type of analyses because it doesn't work that agencies come out with different methods with different estimates and so forth; it would just create confusion. We have to do this together. So, this is not a level that is subject to the kind of political appointment types of changes that we might see over administrations. This is really quite technical and scientific-based career professionals that are doing this, and in our Strategic Plan, we have the short-term and the longer term outlook.

I anticipate that this collaboration will grow and mature over time. I have been really impressed with how much has happened just within about a year of forming this collaboration, and the amount of interest just cements our understanding of the importance of this work going forward.

Okay, thank you very much.

(Applause.)

MR. DiNAPOLI: I will not hold you up since we have a break, so why don't we come back 15 minutes or so from now? Thank you all, and we'll see you shortly.

(Break.)

MR. DiNAPOLI: Welcome back, everybody. Like I said, we're going to try to at least stay on time. I think we'll be able to give everybody a little bit of extra time at lunch, I think that will be welcoming. We may actually get outside to go to lunch. I don't know if it's quite 60 yet, but it's supposed to be gorgeous outside. Not quite like Atlanta, right?

Our next speaker is Dr. Kara Morgan. Dr. Morgan is the Director of Public Health Measurement and Analysis Staff in the Office of Planning at FDA. Dr. Morgan's work focuses on developing and evaluating data-driven decision support for effective risk management decisions. She has a Ph.D. in Engineering and Public Policy from Carnegie Mellon University. She has been working on supporting risk-based decision-making at FDA for over 8 years.

Please welcome Dr. Morgan.

(Applause.)

REVIEW OF IFSAC STRATEGIC PLAN

10:25 - 10:45 a.m.

DR. MORGAN: Thank you, Greg. So, I am here today just to orient you to IFSAC's Strategic Plan, which hopefully all of you have seen, it's been up on the public meeting website for a couple of weeks, so I hope that folks were able to review it in advance, but we wanted to take a

little time today to just give you a summary. A lot of the things that you will hear me talk about you've heard Dana and Chris Braden talk about, and you'll hear more about projects later, so this is just right in the middle to kind of give you a picture of what we've actually put into that document.

I wanted to follow up on some of Dr. Farrar's comments about the importance of attribution in risk-based decision-making, and I've got an important piece of that that hasn't been mentioned yet that I wanted to mention here -- and this comes back to my role in the project. I'm in the Office of Planning in the Office of the Commissioner at FDA, and we are charged with helping FDA plan activities, not just for the Foods Program, but in other parts of FDA as well, and with a focus on developing performance measures to share with our stakeholders and with the public to report on our work.

And the focus now with my staff, the Public Health Measurement and Analysis Staff, is to link those performance measures to public health outcomes and improve the way that that is actually (inaudible), so it was really a key component of the work we're trying to do at FDA. So link the story we tell about the activities we've got to the impact on public health outcomes.

So, before I get into basically going through the document, which is what I want to do, I wanted to just focus on a few overarching themes that I wanted to make sure that you all got from your review of the Strategic Plan. One is that the agencies are working together. There are comments about what we've accomplished in a year, in a little less than a year, and that has been a huge accomplishment, to have this forum for really sharing and aligning our work on attribution.

Another theme in the document is that attribution is really hard to do. And I know that you all know that; you're here because you want to hear about how we're planning to solve that, but the reason that we need such a complex approach is because it is a complex problem.

Another thing that you will learn in your review of the Strategic Plan is that there will be shared estimates of foodborne illness source attribution that the three agencies will be using to inform decision-making. And in the beginning, in the short term, there will be considerable uncertainty for a lot about the uncertainty that exists in the outbreak data, which is the available information we have now, but also that work under IFSAC in the long term aims to reduce those uncertainties by improving data and advancing methodologies.

So, with that, this is an outline of the document, so I'll just take you through each step.

The introduction talks about how there are many existing approaches. Chris Braden talked about lots of advances in the literature recently. All of these approaches are informative. None is the final answer. All of them have limitations, and the idea of doing this work jointly within the three agencies, and, of course, jointly with engagement with our stakeholders, is to take advantage of the strengths of each methodology and try to counterbalance the limitations to come up with what we hope will always be the best current estimates being used for decision-making.

And also in the introduction, we talk about how the goal of IFSAC is to work to improve data and leverage these resources within the agencies to work together to advance those methods most effectively and efficiently.

There were some comments earlier about the work that we did to develop statements of needs within the agencies, and this was a really important part. This is why it takes a year to do these things. We spent several months within each of our agencies talking with folks about what their needs were in terms of attribution, how they were going to use attribution, how they did use attribution. And so we

took all those, the three agencies brought those together, and we developed a shared statement of needs so that we could really have this goal post for us to be aiming for as we're making decisions about IFSAC projects. So, we grouped those into two categories.

There are a lot of things that came out of the statement of needs, and we realized that we couldn't just kind of lay out this big list of things, we needed to prioritize and focus, so we developed a list of things that we thought were doable in the short term, in the 1- to 2-year timeframe, and then we developed some that were going to take longer.

So, in the short term, as I mentioned, we will have foodborne illness source attribution fractions for the priority pathogens, and I'll talk about that in a minute. And, also, we will have a strategy for engaging stakeholders, acknowledging that there is lots of knowledge and experience and data that exist outside the three agencies, and we want to make sure that we leverage that.

In the long term, we want to develop not only these attribution estimates, but also uncertainty bounds that can be used in quantitative analyses that are required by the agencies. And also, of course, we want to continue to improve the data and methods so that over time we'll be

reducing that uncertainty.

So, you heard Dana Cole mention earlier the fact that there is a small set of pathogens that are accountable for a large portion of the illnesses from known pathogens, and these four pathogens were the ones that were identified by the agencies as the most important in terms of our ability to really understand which foods are responsible for contributing to illnesses in these four areas. And so, the idea, of course, is that if we focus on these four -- well, there is a recognition that there might be different methodologies needed for different pathogens because of the *Toxoplasma* example was one that that will be one that we can't necessarily rely on outbreak data for, so we're going to need to take each pathogen separately and really look at it carefully to understand what methods are going to apply there.

So, instead of trying to do that for 30 pathogens in the short term, we decided to focus on these four, which do account for a large amount of the public health impact from foodborne illness, as you can see here, and so, of course, interventions in those areas could possibly really show some results. And then, because of this fact, of course, regulatory agencies have been focusing in these areas. FSIS and FDA both have regulations and policies and

standards for these pathogens for certain kinds of foods, and, so, another thing that attribution will allow us to do is do a better job of being able to see the impact of those interventions. So, that's why, for those reasons, we've decided to focus on these four pathogens in the short term.

So, then the document moves into a discussion of the objectives, and, so, those are shown here. Timely estimates for foodborne illness source attribution, the recognition of what are the needs, being really specific about what the needs are and helping focus effort to help bring about those needs, the validation of the current methods that are available and adaptation of those to these pathogens.

We also needed to make sure we had the resources available. As Chris mentioned, there wasn't a budget line for this item, that each of the agencies that brought in new folks were using folks that were at the agencies working on similar things, but not in this shared capacity. And, we've brought more resources to the table because this interagency effort is going to be a really important thing going forward in terms of setting our priorities.

And, finally, one of our objectives was to enact this strategic communications plan to engage the stakeholders.

So Dana presented these as a pallet of data sources.

This is where we're starting, this is where we're at, these are the data sources that we have, and there have been methodologies that have been developed to utilize each of these data sources, all generating, as you would expect, different estimates of foodborne illness source attribution. So, the idea would be to try to leverage those and bring those together, and that's part of the long-term strategy. And this is really a state-of-the-science in terms of attribution approaches, and so we're building on this.

So, then the last section of the document is a planned path forward in the short term. You're going to hear more about these projects in the next two sessions, so I'll just summarize them here. One is to improve the commodity groups to meet the needs of the regulatory agencies. We've mentioned that before. The other one is to develop the estimates, of course, the shared foodborne illness source attribution estimates.

Another project is related to examining the uncertainties of using outbreak data, given that's where we are now in terms of being able to create these estimates for all pathogens. We want to understand where those estimates are of high quality and where they are not of adequate quality. And, finally, the strategic

communication plan.

And then for the long term -- and these are less well defined in terms of projects because, of course, these projects will continue to develop over time, but we recognize that we want to develop these methods using the wide variety of data sources that we do have available, and then really using those approaches in ways that, like I said, really balance the strengths and limitations to come up with the highest quality estimates.

And then at the end of the document is something that we called an appendix, which is a summary of the current projects which includes the description, the timeline, the output for each of the projects that has been approved by the IFSAC Steering Committee. The idea is that this will be a living document. Currently, this entire document is posted on the FSIS public meeting website, which I'm not sure, I don't think it lasts forever, it's more of a temporary place, but the idea will be that we will have a place, we're not sure where the website is going to be exactly, but it will be an IFSAC-devoted website that will have this content updated as new projects are approved and as projects are completed.

And like I mentioned, in sessions later this morning and this afternoon, we'll describe those projects in more

detail by the folks who are leading those projects.

I did want to mention that we did have some expert review and stakeholder review of the Strategic Plan. We finished the first draft in October, and we had three technical experts provide detailed comments, and then we also did take it to the FSMA Surveillance Workgroup in Atlanta in early November, and we received comments back from those folks. And we were able to incorporate responses to those because we had enough time then to revise the document in response to those comments. And, of course, we'll continue to receive comments through this process.

We're going to have a panel discussion today at 1:45. We've invited panelists to reflect on the Strategic Plan and the projects. We'll also have the public comment period today. And then we're going to have a docket associated with this meeting open until March 1st, so at that point we'll take all those comments and again turn back to the Plan and be able to make the needed revisions.

So in summary, the Strategic Plan, while it wasn't really a part, I don't think, of our original thinking in IFSAC, has turned out to be an incredibly valuable tool in that, first of all, it really was this shared process that helped our agencies come together, it helped provide

direction to the interagency group, and really facilitates the internal coordination, gives us this goal post to keep turning back to as lots of ideas come up for projects and plans and all kinds of exciting things that are going on, even outside of IFSAC, and trying to kind of sort through it all and make decisions about where we should be focusing this Strategic Plan, it will really help to provide that guidance.

And that is all I have.

(Applause.)

DR. MORGAN: Any questions?

MR. CUSTER: Carl Custer. How did you decide to pick only O157:H7 and not the other Shiga toxin-producing *Escherichia coli*?

DR. MORGAN: I'm going to turn to some of my colleagues for that.

DR. HOEKSTRA: Mike Hoekstra. We reviewed the estimates of foodborne illness and the major pathogens and unspecified sources papers for the volume of data, the severity of illness, our ability to measure change, and we concluded that the non-O157 *E. coli*, at this point in time, was not on a par with the other pathogens as far as understanding disease and implementing interventions to reduce it.

DR. SCOTT: Morgan Scott, Kansas State University. It may be an abridged list, but on your eighth slide, "Summary of Data Types," you mention foodborne outbreak surveillance data, lab-based human illness, data describing food contamination products, data describing food consumption, and expert elicitation, but what seems to be missing here is the ecological niche of most foodborne pathogens, animals. So, are you not including the animal sources of for, for example, the *Salmonella* or Campy or *E. coli*, or are you mostly concerned about testing product either at processing or retail?

DR. MORGAN: Well, I'll try that one, and then maybe FSIS can help me out, but my understanding is the bullet describing food contamination includes that in the broader because things like the Hald model include a broader picture on the animal side. And I'm on FDA, the other food side, so anyone want to add to that from FSIS or CDC?

DR. HOEKSTRA: Lovely question. So, we have as our phrase of the day "foodborne illness source attribution," and to my mind, this question raises the issue of: Where are you in the distinction between foodborne illness source attribution and illness source attribution? That is, are you talking about specifically illness that is caused by food that was contaminated when you ate it? Illness that

was caused by food whose contamination has resulted from contamination that occurred under processing, under production, or back at the reservoir? And our emphasis in general has been on point-of-consumption contamination; that is, most of our information sits around the point of consumption. Outbreak data is the only direct link we have between illness and a specific food that was eaten proximate to the event. So, animal reservoirs we are very interested in, we are looking at them, but at this point in time, we can't say a whole lot about them.

MS. SMITH DeWAAL: You might not want to sit down yet.

(Laughter.)

MS. SMITH DeWAAL: My question is that I see that you selected four pathogens to start your work, which is excellent. And, by the way, this is Caroline Smith DeWaal, with CSPI.

On the *Salmonell*a data, or on the *Salmonella* information, are you also considering the antimicrobial resistance profiles that you have been monitoring over times in your NARMS database, which is across all three agencies?

Thank you.

DR. MORGAN: Thank you for that question; it's a great question. And I have just recently connected the NARMS

folks with the IFSAC project, so stay tuned.

MR. DiNAPOLI: Thank you, Dr. Morgan.

We've got three folks that will be coming up, so I'm going to go through the first two, and then Dr. Cole, I've given you the bio earlier this morning.

Dr. Neal Golden is a Senior Risk Analyst and has been with FSIS for 10 years. He graduated from Tufts University with a Ph.D. on *Campylobacter* virulence. He currently leads the *Salmonella* and *Campylobacter* workgroup that develops, coordinates, and manages policies to reduce these pathogens in FSIS-regulated foods.

Dr. Antonio Vieira is a doctoral epidemiologist responsible for the conduct and analytic studies of source attribution. Antonio received his Doctor of Veterinary Medicine from the Universidade de Santa Maria, in Brazil, his Master of Public Health from the University of Georgia, and his Ph.D. in Epidemiology from the University of Copenhagen. Dr. Vieira worked with foodborne disease surveillance and source attribution models and methods at the Danish National Food Institute before joining the Outbreak Surveillance and Analytics Team in CDC's Enteric Diseases Epidemiology Branch.

And, again, Dr. Cole's bio you have, and I mentioned it before.

Dr. Neal Golden.

(Applause.)

DESCRIPTION OF IFSAC PROJECTS--PART 1

10:45 - 11:45 a.m.

DR. GOLDEN: Great. So I very much appreciate the opportunity to speak to you today. I would first like to start with just something that our previous speakers have already said, that this is an IFSAC-approved project, and that essentially means that the three agencies have designated resources, personnel resources, and time to this effort. And though FSIS is leading this project, we certainly want to acknowledge the important collaboration and partnership that we have with CDC and FDA.

So, by way of introduction, what I'm going to do today is speak to you about evaluating the potential limitations of the current foodborne illness source attribution. And we've had a little bit of a prelude to this from several speakers already. And the question that we really want to ask is: Is outbreak-derived attribution representative of the larger population of human illnesses? And, of course, I'll get into that a little bit more.

Now, for the overview slide, what I'd like to do is first give some definition about terms I'll be using again and again, then talk about the purpose and the background,

and then try to give you some more detail in terms of what this project actually entails, what we really will be doing, and then I'll really end on the illustrative examples of the type of analyses which we're going to do, but then I'll give you a brief step-through of the timeline.

The next slide, please.

So, the two definitions that I want to make sure that we're all on the same page are outbreaks and sporadic illnesses. And for the purpose of this project, we can really think of an outbreak as a case of illnesses that share a common cause, so any two or more cases that share such a common cause, and in this case, it would be the food, then that would be in our definition of an outbreak.

And just to give you a little bit more context, we're talking about the Foodborne Disease Outbreak Surveillance System, or otherwise FDOSS, and this was introduced, again, by a previous speaker, so when you think of outbreaks, think of that particular database from where the data are coming from for this analysis.

Now, the next is sporadic illness. In a sense, you can almost think of the converse. This is an illness that's associated not with a common source, such as food, but as an isolated source, and so that would be in sporadic

illness, and these data are housed in FoodNet and in LEDS. And I'm not going to talk about the second one, that's really just to give you a sense of the complexity that sporadic illnesses actually are housed in two databases.

The next slide, please.

So, by way of purpose threefold, this is to assess the degree of confidence in the use of outbreak data to estimate foodborne illness source attribution, so again to take a look at that assumption, is outbreak-derived attribution representative of sporadic illnesses or the larger population of illnesses?

The next thing is to assist in developing criteria to prioritize pathogens for which outbreak may be sufficient. So, you've seen that we're going to focus on four pathogens. So, perhaps after this analysis, we can say that some of those pathogens are more or better represented by the outbreaks than others. So, this would be a relative comparison.

And then, lastly, contribute to an analysis of uncertainty.

Now, to juxtapose this from the next two presentations, this is not to estimate foodborne illness source attribution. This is to estimate or to understand, explore, the impact of the assumptions that go into

estimating foodborne illness source attribution.

Okay, so, the next slide. In terms of the background, I'm sure that many of you have seen this before, but in order to estimate source attribution, you really need two key pieces of information: you need to know what the pathogen is -- so was it *Salmonella*, was it O157:H7, or was it *Campylobacter*? -- and you need to know the implicated food source. And if you have those two things, then you can start to move forward in estimating foodborne illness source attribution.

So, if we take a look at the databases, where is this information housed? And I already gave you an introduction on that, but in the context of these two key pieces of information, well, outbreaks and sporadic cases, they have the pathogen, but really the outbreaks only has the two key pieces of information, as has been indicated by some of our previous speakers, and, again, that's the implicated food and the pathogen.

So what gives us pause, then, if we have such an outbreak with these two key pieces of information? Well, again, it's been prelude quite a bit, but the outbreaks represent overall about 5 percent of the illnesses which are out there, and so as Dana showed, a relatively small slice, a small silver slice, of that blue or purple pie,

and, therefore, food source is implicated in only a small fraction of the illnesses.

The next slide, please.

Okay, so what are we actually doing when we're testing the hypothesis of outbreak-derived foodborne illness source attribution as being representative of sporadic illnesses? What we're actually saying is that we're assuming that the exposure pathways -- in other words, the foods that result in illnesses from outbreaks are the same foods that result in illnesses in sporadic cases, and so that's really the key assumption in which we're saying, and we can ask this, we can hypothesis test, is this a valid assumption?

Now, to take that 5 percent from the previous slide and show some of the complication of this, let's take a look at the histogram here. And what we actually have is the ratio of sporadic illnesses to outbreak illnesses, and the numbers on top of the bars are the number of sporadic illnesses per outbreak illness.

So if we start on the right-hand side, we can see that STEC O157:H7, we see about 20 percent of the illnesses are from outbreaks, and so you might say perhaps that's not so unreasonable, 20 percent outbreak, 80 percent from sporadic cases, but as you move from right to left and we look at *Salmonella* nontyphoidal, then that's about 6 percent, so

that's closer to that overall 5 percent we saw on the previous slide. Keep on going. *Lm*, or *Listeria monocytogenes*, about 1.4 percent. And then, finally, less than half a percent for *Campylobacter*.

The next slide, please.

Okay. So, is foodborne illness source attribution derived from outbreaks representative of sporadic illnesses? Well, this is a very difficult question to answer and, ideally, we would have some representative source of food information from the sporadic side and we would derive attribution from that, and then we would compare it to the attribution that's derived from the outbreak side. However, we do not have that. So, this is a major source of uncertainty, and we can test this.

The next slide, please.

Okay. So, what does this project really look like in terms of getting down to the nuts and bolts? Well, we're going to evaluate the similarities in the distribution of outbreak-related cases to sporadic cases, and we're going to use the following pathogens in which you've already seen. And I'll show you an example of what I mean by distributions.

Now, the key thing to keep in mind is that if outbreak cases look like sporadic cases across an array of

epidemiological factors -- and I've listed the epidemiological factors underneath, but what I mean by that is things that we can compare, things that are shared between the two databases -- then this suggests that the causal exposure pathways are similar in identity and degree. Or another way to put it, that outbreak-derived attribution is suggestive and representative of sporadic illnesses.

The workgroup is considering the following comparisons. We basically have six key comparisons. There is a seventh one for *Salmonella*, and that's serotypes, we obviously can't do that with some of the other pathogens that are listed.

The next slide, please.

Okay. So, what are some of the limitations of this project? Well, the FDOSS database, which is that of the outbreaks, there are simply fewer outbreaks that are captured in that database, so we're limited by that right from the start. The lack of variables for direct comparisons, I showed you that there are six, there might be seven depending on the pathogen, but we would ideally like more, but we looked through the database, and these are the main ones that we think that we can make direct comparisons to.

And, finally, this issue of national versus regional. Now, for those of you familiar with outbreaks, these are data that come in nationally to the FDOSS database. However, so FoodNet is broken down into about 10 states, 11 sites, and so you can actually start to make comparisons between national versus regional, state versus state, or site versus site.

The next slide, please.

So, let's try to get down to some visuals in terms of to give you a sense of what are the type of analyses that we're going to do. So, the first set of illustrative examples are temporal examples, so we're going to look at some monthly impact and yearly impact. The databases, as you are well familiar with now, are the FDOSS database and the FoodNet database. Eventually, we will go and also make comparisons with LEDS, which is a passive-based surveillance, which is the one I started at the beginning, but I said I wouldn't mention it a whole heck of a lot.

Etiology, we're going to look at *Salmonella* in this illustrative example, but, obviously, we're going to start with the four pathogens. And then the years are from 1998 to 2009.

So, this is a comparison by month of simply looking at the number of illnesses, and what you can see is in the

seasonality, which we have on the X axis, and the number of illness on the Y axis, you can see that these are relatively similar. And we have outbreaks that are in red, and we have sporadic cases that are in blue, and you can see that the peaks are slightly off, but this is the type of analysis that we would do and the type of comparison to say, is outbreak-derived foodborne illness attribution representative of sporadic illnesses?

The next slide, please.

This is the same type of comparison, except instead of over a month now, so we're looking at it over a year. And again on the Y axis, we still have the number of illnesses. And you can see that actually there is just a visual distinction that you can actually see between these two things over the years, but we've drawn a line at 2004 because prior to 2004 the FoodNet catchment sites, or the population site for FoodNet, was still growing, and after that, it stabilized. So, this gives us pause to say perhaps we need to do more complicated analysis to address the fact of the growing FoodNet catchment site prior to 2004.

Next slide, please.

Another comparison that we can do is gender. Again, on these epidemiological factors.

The next slide, please.

Everything else was the same on that previous slide. And we can look at the fraction of illnesses that impact women and impact men. And if you were to assume that the exposure was heterogeneous and there weren't any behavioral difference, that you would get about 50 percent of women being exposed and 50 percent of men being exposed, and we can generally see that. If you look at the blue bars, the sporadic cases are relatively even along that 50-percent marker for the percent female who were impacted.

However, if you look at the outbreaks, you can see that it's a little more varied. And again we've drawn that line in 2004, but if you aggregate these data over the 12 years' worth of information, you actually see that they're quite relatively close to one another in terms of the percentage of women becoming ill.

The next slide, please.

So, this is essentially my conclusion slide. Again, we're evaluating the potential limitations with current foodborne illness source attribution, and, in particular, our outbreak-derived attribution representative of sporadic illnesses. In terms of timeline, this project was approved in the fall. We acquired the data, these three databases, which have been mentioned previously. And our next big

challenge is really to do the comparisons between the six epidemiological factors over the four pathogens, and you can start to begin to see how the number of analyses can simply balloon.

And then really once we have the data all in front of us, then we're really going to consider what additional analyses need to be made. At this point, we're going to step back and do the simple approach, but then decide if we need a more complex approach after we have the data laid out. This will be done in the winter of 2012 and then the project hopefully completed by spring 2011 (sic). So, I thank you so much for your time, and I am going to sit down, and we'll take questions at the end.

(Applause.)

DR. VIEIRA: So, good morning, and thanks for this opportunity to be here today and present this IFSAC project that we call the investigation of the Hald model as a method to improve foodborne illness source attribution estimates.

This is an overview of my presentation today, I will start with some background information on the Hald model, that we also call the Danish model. I'll say a little bit about what has been done so far here in the U.S. to adapt the model to our data. And then I will list some of the

purposes of this project, and I'll move to project description where I will try to illustrate how the model actually works.

From there, I will try to list our estimated deliverables for this IFSAC project, and I will finalize my presentation with our timeline for this project.

So this model is a mathematical approach that is based on Bayesian statistics, and it's used to estimate contributions of different food sources to reported foodborne illnesses. It was first published in 2004 by Tine Hald and a group of Danish researchers in an international peer-reviewed journal.

The uniqueness of this model is that it links human illnesses to food contamination not only at the consumption point, but at different points in the food chain. It has been used and has been adapted by several countries to estimate foodborne illness source attribution, and each country that adapts the model, they try to make improvements to fit better into the type of data that they have, but perhaps the most successful story here is the Danish story, they have been using this type of approach to monitor their progress towards reducing *Salmonella* in that country.

Next, please.

So, as I said, the model links the number of reported foodborne illness caused by *Salmonella* to two main factors: one is the contamination in food products; and the second one, to food products consumption. So we'll be linking illnesses to these two factors, but it also takes into account that there are other two factors that will impact this association, and these two factors, they are called for this model, food source factors and pathogen factors. These food source factors, they would account for the different food processing and preparation practices that are associated to each commodity; and the pathogen factors, they would account for the severity of illness that would be caused by each type, and in this case, since we are focusing on *Salmonella*, for each serotype of *Salmonella*.

This is not a new work. CDC and FSIS have been working on this approach, adapting the Hald model using U.S. data sources for a few years, and since the original Danish model relied on data sources that were specific to Denmark, both FSIS and CDC had to work together to identify appropriate data sources here in the U.S. to determine what are the data gaps, and actually more important, to change the model in order to accommodate the different data sources.

The main difference to the original model is that the

U.S. model attributed *Salmonella* illnesses to food commodities using contamination data from food products in processing plants, not directly from food animals. And, also, it's different from outbreak-based approaches that would use information about foods at the time of consumption.

This is a graph from the publication. It was published in January 2011, again by CDC and FSIS. These are the results of the initial work done working with the Hald model, and this figure has two graphs. The upper one shows the estimated source attribution over time for six FSIS food commodities over the years between 1998 and 2003. And in the bottom graph, you have the estimated commodity consumption over time again for the same food commodities and for the same years.

And, again, this is just initial work, but what I would like to highlight here is the increasing consumption of chicken over this time period, and because the model accounts for consumption and contamination, we have a response in the upper graph showing the increase in the relative number of cases attributed to chicken.

So, as a purpose for this project, we want to expand the model to incorporate additional food sources of *Salmonella* and have a model that is better fit to our U.S.

data sources. We also want to explore whether the Hald model can provide a reasonable estimate and measures of uncertainty for foodborne illness source attribution here in the U.S.

I'll try to illustrate now how the model works. As I said before, it estimates the expected number of illnesses attributed to specific food products using three data sources mainly: human illnesses data, food consumption data, and pathogen isolation data, in our case, from food products.

So, what we have here, we have data on the observed human case per *Salmonella* serotype, where for this specific model we call "lambda," but what we want to know is the number of human cases per serotype and per food source.

We also have data on the amount of *Salmonella* serotypes in each food product that for this model we will call "p," but we need three translation keys to understand how "p," how the amount of *Salmonella* serotypes in each food product will impact actually the human cases per serotype per food source. So, one of these translation keys would be the amount of food products that are consumed, and we'll be calling that "m."

Then, the next translation would be the ability of the serotypes to cause an infection for this model we call

variable "q." And third, we need to understand the ability of the food products to cause an infection, and for this model we call "a."

Please go back.

So, we do have data on the variable "p," amount of *Salmonella* serotypes in amount of food products consumed. We have data on the observed number of cases for *Salmonella* serotype, but in order to understand our number of human cases per serotype per food source, we need to have estimates of the ability of the subtypes to cause infection and food products to cause infection, that's "q" and "a," and that's what the model does.

Please.

So, here's the basic simplified form for this model, "p" times "m" times "a" times "q" equals "lambda." And then from there, we use a Bayesian technique in Markov Chain Monte Carlo simulation, MCMC, to estimate the model outputs. And what are these outputs first? We will calculate the food-dependent factor and this pathogen-dependent factor, the "a" and the "q" variables. From there, we will calculate the number of cases that are attributed to each food product in the model for each year of the study.

These are possible data sources. We are currently

working and evaluating each one of them for this newer version of the model. For human *Salmonella* illnesses, we are mainly focusing on CDC data from the National *Salmonella* Surveillance System, data from FoodNet, also from our Outbreak Surveillance System. For food product *Salmonella* isolated data, we have been working with data from slaughter plants from FSIS, some traceback of contaminated products from FDA, samples of produce from the USDA, and we are trying to work with some food industry data.

For food consumption data, we have mainly relied on data from ERS, from the USDA Economic Research Service, but we are also experimenting with some data from NHANES, the National Health and Nutrition Examination Survey.

As deliverables for this project, we hope to deliver a full evaluation of a method of source attribution in the United States for *Salmonella* that has been successfully used in other countries. We think that this is a great opportunity for us to develop an approach to foodborne illness source attribution that will allow us to evaluate the differences in source attribution over time -- something that other methods cannot provide us.

It's important here to say that this is a method that provides us something that other methods cannot provide.

First, it gives us a mechanism to understand the relationship between food contamination, food consumption, and human illnesses. And, second, it's a method to estimate source attribution at a point in the food chain other than at consumption, like the outbreak-based methods do.

As a timeline for this project, we are currently working on collecting and evaluating the possible data sources to be included in the model. We are working to refine the model and to make adaptations to better fit into our data. We are learning from work that have been done by other countries, by other research groups, to adapt the model to better fit into their reality, their surveillance systems. And we expect that the first *Salmonella* source attribution estimates for FSIS- and FDA-regulated food commodities will be available by the end of this year.

Finally, it's important to say that the model will meet the IFSAC long-term plan to develop foodborne illness source attribution models using not only outbreak-based data, but using a variety of data sources.

That's it. Thank you.

(Applause.)

DR. COLE: Okay. Thank you. I'm going to talk about another of our projects, trying to improve how foods are

categorized into commodities, and I mentioned this earlier when I gave my earlier talk. So I'm going to go with the same template: background, purpose, project description, deliverables, and timeline.

So, first background, going back to what we were talking about earlier, in that we use the data in outbreak investigation reports that are investigated by the local and state public health departments and submitted to the CDC to give us a lot of information about pathogen-commodity pairs, and we publish this data then in annual summaries. And I showed you earlier the hierarchy, that we publish this data lumping the individual foods, or when it's simple foods, into 1 of 17 commodities, and so here is a look at those 17 commodities again. It's a hierarchy in that we have the commodity groups, gross commodity groups being aquatic, land, and plant, and then we subdivide those into smaller groups, and then each year we report out the simple food vehicles, and the 17, the red, commodities.

And I already defined our definitions between simple foods, those where there's a single ingredient, or all the ingredients in the contaminated food belong to a single commodity, and then complex foods, those that we don't really know which commodity was the causative, was the contaminated ingredient.

Next slide.

So, our purpose of this project is to improve the accuracy of the source attribution estimates derived from outbreak data by categorizing foods into commodity groups that are useful for regulatory agencies for decision-making.

So, our project description. First, we need to determine the changes that were needed to our basic 17 commodity hierarchy, through our work, our collaborative work, across the three agencies. We're working to build a new hierarchy. And then also part of this work is actually improving our process that we currently use at CDC for identifying the reported food or the contaminated food in the report, and I'll go into a little bit more detail about that. So, that's another component of this project.

And then the ultimate goal, by improving both the process of determining the food in the outbreak report that was likely the contaminated food and causative of the outbreak, and then improving the way we categorize that food into a commodity, we plan to improve the utility of our outbreak-based source attribution for both FDA and FSIS decision-making.

So, here is a snapshot of the reporting form. The standard reporting form that is used by the local and state

public health agencies to report a foodborne outbreak, and, thus, the results of their foodborne outbreak investigation to us. And so I've highlighted here just the food fields, the portion of the report where they report the actual foods that were associated with the outbreak.

And you can see that there are actually three different food fields in the outbreak report. First, there's the name of a food -- so this could be, for example, lasagna, going back to my earlier example -- and then the ingredients. If during the investigation, they know all the ingredients of that lasagna, then they can put those ingredients here. And then, even better, if they know the contaminated ingredient in that lasagna, then they can put that in the contaminated ingredient field.

In every outbreak report, obviously, not all of this information is known. Obviously, it's not always known in the case of a complex food what the contaminated ingredient was, so we may only get a food report and the name of the food and then the ingredients, and then the contaminated ingredients may be left blank.

But just as an example, as I mentioned earlier, if you just look at these fields, the combination of the contaminated food and the ingredients and the contaminated ingredients, there are over 1,800 different foods listed in

these three fields. And right now, our current scheme for determining the food that was actually associated with the outbreak is to evaluate these three fields and decide, based on what the data entered in these fields, how to commoditize that outbreak and its associated illnesses into a commodity.

However, if you look at other parts of the report form, there are other opportunities for the local public health departments to report food information that we're not currently capturing with our current system, so I have a couple other snapshots of the other parts of the report form that might have useful information for us, especially as we go forward and try to improve the actual level of commodity or the specificity, if you will, of a category that that food commodity is indicating. For example, I have a snapshot here, there's a traceback part of the form. So, if the outbreak investigation resulted in a traceback of food, there is an opportunity for the local public health agencies to put in the traceback information, and they can put in the type of item that was recalled. They can give us a lot of comments, free text field comments about the nature of that traceback, how it was conducted, what was found on the traceback. So, that is obviously potentially very useful data from the food standpoint.

There is also just a remarks field at the end of the outbreak form where they can give us more detail about their investigation and the decision-making process in determining what was the implicated food, and we can mine that field also in the report as a source of information regarding food.

We also have an egg-specific section of the report form. So, obviously, it's possible that they can fill out the form and put egg-specific information in the egg section. And then we also have a ground-beef-specific section, and they can put information in the ground beef section of the report.

So, you can see that the report form itself has a variety of variable fields where we collect information, and by limiting our current method to only those three food fields, we may be missing an opportunity to really get more informative food information.

We found if you drill into these reports on a one-to-one level, for example, we found individual outbreak reports where a comprehensive traceback was done, the implicated food, the contaminated food, was identified as part of the outbreak, but, yet, the food fields in the front part of the form were left blank. And if you're thinking of it from the standpoint of a reporting public

health agency, you're providing the information in the report, you're providing all the information in the report, but from your standpoint, you're not necessarily aware that if it's in this part of the report, we look at it this way, and if it's in that part of the report, we look at it that way, and that sort of thing. In other words, the people reporting these outbreak investigations are reporting them as a report, not as individual variable fields, but at the CDC, we tend to look at these as individual variable fields, and so now we're expanding that search, if you will, to try to capture the information across multiple variable fields. This is a very long report with lots of tables generated, and when you have a data system that goes back to 1973, you can imagine there are a lot of individual reports in there with a lot of data, and so it's a process of mining all the various variable fields that are in that report so that we can pull out all the information and inform our attribution.

So, this is an example of an algorithm that we've developed, just a sample algorithm, where it shows how we're using some electronic tools. We're developing electronic search tools to search through this database where we check individual foods starting again with that food table that I showed first and looking at, "Was the

food reported? Were there contaminating ingredients reported?" But then going beyond that and looking at the eggs table and pulling out data from the eggs table and putting that data in one area of a spreadsheet, and then pulling out data from the beef area and putting that data in another part of the spreadsheet, and just really mining that, if you will, database in its entirety to look for anyplace on the report form where there may be food information that we can use to determine more specifically and accurately the food that was the source of contamination of that outbreak.

The other thing that we're working on is then, how do we commoditize that? What are the commodity groupings? And this is just an example. We're still in the process of determining the best hierarchy going forward. And this is just a snapshot on what I call the high-level hierarchy. As you go through these boxes, they get more and more specific, so that we can actually determine more and more specific categories of food products, food commodities, that are of interest, more specific information to FSIS and FDA.

But, at the higher level, as I call this chart, you can see that we are adding new commodity categories that distinguish between ready-to-eat foods, for example, and

raw foods. We are expanding, we are separating -- we are probably going to separate out fruits and nuts, for example, because we recognize that fruits and nuts, as a single commodity, probably doesn't capture the information that we're really interested in. And we are adding a category, for example, for dried herbs versus fresh herbs, and that sort of thing.

So, you can see that, again, this not the 30,000-foot view, but perhaps the 20-foot view of the hierarchy. But underneath this, we drill down into much more specific categories so that we can try to capture the breadth of information that we get out of those reports.

So, deliverables. Again, we're trying to improve our method to identify the food itself, harvesting information from the entire outbreak report, investigation report, rather than just focusing on the food-specific fields. We're changing our food commodity categorization so they're more useful categories, and pull out the foods and distinguish foods from different types of processing and different commodity categories so it's more useful for decision-making. And then we're applying this, working hard right now to apply this, to the foods and outbreaks reported since 2009, but we plan to apply the new methods to the data going all the way back to the electronic, our

current use of the electronic surveillance system in 1973, so that we will have both a prospective and a retrospective view of the outbreak data using the new methodology and the new commodity scheme.

Our timeline. This project was approved in the spring of 2011. Our methods and results are currently under review. We developed an algorithm for pulling foods from the different part of the outbreak report, and we're now in the process of manually reviewing some of those just to determine how our algorithm works and decide on changes that are needed as far as the accuracy of that algorithm. So, we're reviewing that, the project team is reviewing that, and we're also currently trying to put the finishing touches on the hierarchy and present that and get cross-agency review of that as well.

So, then once we finish this process of review, our improvements, we're going to apply again, as I said, to data that's been reported since 2009, so it will incorporate 2009, 2010 data, and hopefully soon, as we continue to close out data, we'll include 2011. So, looking forward, we'll be applying this as the data comes in, but again, as we review the methods, we're going to apply it retrospectively to 1973.

So, this project will meet the IFSAC short-term need

to increase the accuracy and the utility of the food commodity assignments used to generate illness attribution estimates from outbreak data that reflect both FDA and FSIS regulatory perspectives on food.

Thank you.

And I think now we are open for questions on any of these three projects.

(Applause.)

MR. WALDROP: Hi. Chris Waldrop, Consumer Federation of America. Dr. Vieira's presentation was the first time I heard the term "severity of illness" used when talking about attribution estimates, and this might actually be a broader question than just your project, so maybe, Dr. Cole, you can hearken back to your earlier presentation. How else is severity of illness being incorporated into the agency's thinking and estimates of attribution when they're looking at this?

DR. VIEIRA: So the term actually "severity of illness" was some sort of adaptation to make it easier to understand. What we really mean is the ability of the serotype, or in this case, the subtype, to cause the illnesses. Like as if it is found in that food product, like how is the strength that that specific subtype has to go all the way until cause the illnesses in humans? So

that's why we use this term.

DR. COLE: And in answer to the broader question of how we use severity of illness, again, when we established the priority pathogen, severity of illness was considered at that time, and with regard to you saw that in choosing those four pathogens with regard to the estimated number of annual illnesses, we encompassed 20 percent of illnesses, but we really focus -- when you're talking about preventing hospitalizations and death, those four pathogens accommodate approximately 50 percent of the estimated total number of illnesses. So, we use it with regard to decision-making as far as choosing our priority pathogens, you know, the hospitalizations and deaths, with regard to burden of illness, and, then again, I think Neal can talk about how we're trying to also look at that question with regard to our comparison of outbreaks versus sporadic illnesses as far as proportion hospitalized. As one of the questions, are outbreaks unique potentially because one hypothesis could be they're more likely to be associated with more severe illness, so they're detected? and that sort of thing. So that's part of the exploration there, and I don't know if Neal wants to expand on that.

DR. GOLDEN: That was just simply that one of the epidemiological factors in which we are looking at is

hospitalizations and perhaps duration of stay, so that would be able to get to the issue of severity of illness.

MR. CUSTER: Carl Custer. In addition to serotypes, will you be collecting genetic data, PFGE, MLDA, virulence factors?

DR. VIEIRA: The first version of the model went only on serotypes. For the second version, we are studying maybe using -- there is a possibility of using even NARMS data for subtyping in terms of microbial-resistant different subtypes, and we are also looking for the possibility of having PFGE data.

MR. CUSTER: Good. But you'll now be picking up the PFGE and maybe comparing PFGE relatedness?

DR. VIEIRA: I'm sorry?

MR. CUSTER: Will you be collecting, say, PFGE or MLVA and the relatedness between the different --

DR. VIEIRA: Yeah. The stage that we are right now is finding out how much data available we have in the sources, human illnesses, in order to link. If you have enough PFGE data in both, then we can do that. If you don't, that's where we are now.

DR. BOOREN: Betsy Booren, American Meat Institute. Dr. Cole, this question is directed to you. I'm glad to hear that you are expanding the categories. Do you have a

mechanism in place in communicating when those changes have been made? I know I've noticed changes in your outbreak database, but I continually mine that information to make sure our internal data is kept up or kept current. Do you have a mechanism in place to let stakeholders know as that improves?

DR. COLE: Yeah, that's an important question and important issue that we're still -- Dana Pitts is going to talk to us later about our communication strategy, but we do recognize that as we make these changes, it's very important to spell them out, be transparent about the process, and that sort of thing, so we are already trying to plan how we're going to describe the new process and how we're going to present that data as we move forward because there is a need to, as you mentioned, as we change things and we come up with improved methods, to both communicate the new method and the process as well as the estimates that come out from that. So, we're hoping with the assistance of our tri-agency communications, collaboration, that sort of thing, the best way to get that information out there so that it can be used.

DR. McDERMOTT: I am Patrick McDermott. I am currently the Director of the National Antimicrobial Resistance Monitoring System at FDA's Office of Foods.

Antonio, I wanted to say something I'm sure you probably already know, but maybe others don't, which is in your source of information for estimating exposure or contamination levels, I'm sure you know NARMS has been collecting that on a monthly basis in raw retail meats for 10 years now, so I would just -- well, one thing that it showed us is there are pretty stable differences in prevalence rates that you see at retail meat outlets than you see at carcass swabs, say, in the slaughterhouse.

So, I would just encourage you to look at that data and see if it can help you understand maybe some of the weaknesses in the model that come from using these swabs to represent the microbial status at retail.

And then along with that, of course, as someone referred to earlier, it's a rich dataset with PFGE information. We know Caroline pointed out the resistance data. All these things, when you get to the bacteriologists on your panel, I think it would be interesting to see how they can work on source attribution as well.

So, thank you.

DR. VIEIRA: Thanks. And we are exploring exactly this sort of approach, using NARMS data, using PFG data, and trying to find out what we have. Thanks.

DR. SINGER: Randy Singer. I'm an epidemiologist at the University of Minnesota. And my concern is really related to model accuracy and model validation. Ever since the Hald model came out, many of us have felt that the "q" and "a" parameters were basically black box parameters, and yet the models keep getting more complex, but there doesn't seem to have been any real study of how you validate such a model. You'll never know truth. You've assumed causality and perfect testing. So, how do you intend to develop this more complex model and yet somehow test it with a known dataset, for instance?

DR. VIEIRA: You're right, and somehow it is some sort of a -- it's called a black box calculation for these two factors, but our idea, to make it more clear, it's both -- since our first version of the model, we are actually publishing what are our results for both our "a" and our "q," our parameters that are estimated. In the original model, they usually don't do that.

Another thing, to help to clarify this process, we are currently ready to adapt the model to a different softer program. We're moving from something that's really restrictive, WinBUGS, to something that's more popular, SAS, and letting people play with the data and get to understand better how the model works will help us actually

to receive feedback on what we are doing.

DR. SINGER: Sure. I mean, I would hope actually maybe you would leave it with AR since SAS is private software, to make it freely available, R would be more appropriate.

DR. VIEIRA: Yeah. WinBUGS can be called from AR, so it's not a problem. Using AR, you can call WinBUGS.

DR. SINGER: Right, but if you're going to convert to SAS, then you've left a lot of people out who might use Freeware.

DR. VIEIRA: But anybody that works with AR can call WinBUGS from there --

DR. SINGER: But not if it goes to SAS.

DR. VIEIRA: Without going to SAS, yeah.

DR. SINGER: I'm still concerned, though. I haven't heard how you are going to have a dataset with which you can actually test the accuracy of the model. I mean, you haven't -- are you going to maybe make up a simulated dataset of foods, "q" and "a" factors, et cetera, that would allow you to assess how well this model can predict the truth?

DR. COLE: I think, in answer to that, we take a variety of approaches. There is one, the factor that you're talking about, just the model itself and the

uncertainty associated with that, and so we have spent and we are planning to spend a lot of time testing just the model characteristics itself. How stable is it to including and pulling out data? Do things dramatically change? Does the model seem unstable? We did that with the first iteration and noted some instabilities. Again, it is very data reliant, as you know, and so we can test it somewhat by evaluating the instability associated with the model, associated with the data itself.

But, again, I think it's important to note that as we explore this, we are not saying that it's going to be the model, so I hope that we come away with the idea that we are exploring a variety of methodologies and a variety of approaches to cross-inform, if you will. And right now, for example, the first iteration of that model, we look at it as sort of relativistic, you know. If you accept, for example, that the probability of foodborne illness is a function of those parameters, which I think even though the "a's" and "q's" are by boxes, if we have data inform the "a's" and "q's," we can have them be informed parameters, and to the degree we get data sources to inform any of these parameters, we'll pull it in, but then again, going back to the cross-information, how do they inform each other? And then relative to the different foods that are

in the model, relative to each other, how do they look? And that's sort of how we approached it the first time, was like relative to the other foods in there, how does this look? As far as producing actual estimates, we consider it one of several approaches that we have to cross-inform.

And Dr. Braden mentioned risk assessment is another method that is very systematic in the way it walks through a sort of cause-effect, if you will, relationship between contamination and number. And so we can use these different estimates derived to kind of cross-validate.

DR. SINGER: Okay. Thanks.

MS. SMITH DeWAAL: Caroline Smith DeWaal, Center for Science in the Public Interest. I think the degree of public interest you have on this topic and the very excellent questions certainly shows the importance of this, and, clearly, as these methodologies are being fed into the new implementation of the Food Safety Modernization Act, and the fact that it requires FDA to identify high-risk food products, it's very important to get these methods right.

I am very interested in the work that all of you have presented, but, Dr. Cole, I do have really a core question for you. The food categories that CDC developed a number of years ago are not terribly intuitive, and I noticed in

your discussion of how you're updating the food categories and improving on them, you haven't actually put in the food categories a checklist or a call-up sheet of food categories into the reporting form, and I suspect you're not doing that because it's not a terribly intuitive tool that you've designed, and we are very interested because we've seen that you do have call-up boxes on the epidemiology questions, "How did the investigation progress?" You had a number of call-up boxes there, but you don't have one for the food category. Is CDC considering adding intuitive food categories that you could have as a call-up box in that first category? Because I think it would greatly improve the data coming in. As you know, two-thirds of the outbreak coming into your reporting system from the states today don't have an identified food product. So, are you considering having that kind of call-up box?

DR. COLE: Yeah, that's a good point, and it is consideration of how we can improve the interface as a result of our improved processes that we've identified is also on the agenda for that project downstream.

We do have within the NORS, the National Outbreak Reporting System, we do have dropdown menus for picking foods, but it's exhaustive, again, because it's not based

on categories, it's based on foods, and so if you can imagine trying to find the food in that list as a reporter, it's exhaustive, and so you end up -- because we don't want to limit the future by our past, by having something so proscriptive in the dropdown menu that we may miss an opportunity to identify a new food vehicle, for example. So we do want to preserve the free text option so that reporters can report something new, but yet standardize, as you point out, to some degree some of the other food boxes.

So, we are definitely looking at that trying to both provide a little bit more standardization in our dropdown menus that we currently have for entering foods and identifying opportunities to make that more clear. One, just through the interface itself, and, two, just through interacting with the local public health and state public health agencies through webinars and that sort of thing where we talk about our use of the data and do outreach and talk about their issues.

We have an upcoming webinar where we've asked them to talk to us about their issues with entering foods so that we can also use that to inform future iterations of the interface because that is very important. Where is that balance between having easy food classifications that they can choose from and it's clear, transparent, they know what

we're asking for, and we know what they're entering, versus having the flexibility where if something new emerges or that we can capture that also? But, yeah, that's part of this project, too, moving forward.

DR. TALL: Hi. I'm Ben Tall, from the FDA. I have a comment and then a question. The comment is I'm glad to see that the working group is moving forward with current data on sporadic illnesses and outbreak information because I think that's probably the best data to use. And then my question is, would the steering committee and the working group be interested in using data that's been curated from the 1950s onward to 2011 that contains information on roughly about 37,000 isolates of the various foodborne pathogens? And if so, this information is located in a database that the FDA has been working on for the last 2 years called PATRN, Pathogen Annotated Tracking Resource Network, and that's freely web-based accessible and easily downloadable for your purpose. So, we can talk further about that later if you'd like.

DR. COLE: Mm-hmm.

DR. BEALS: Dr. Ted Beals, diagnostic pathologist and epidemiologist and somebody that uses the output of all of your data. I'm very interested, it's obvious to all of us here that in any one given incident, there is a relatively

one-to-one correspondence between a food, however finely you categorize that, and the incident, but I'm increasingly alarmed by the fact that, as we focus on the foods, are you missing the fact that in many of these incidences that occur over time, it's not the food, but how the food is handled?

And so I'm asking, in your databases, are you looking for crossovers where the same thing is happening, but they're fundamentally different food categories?

DR. COLE: Yeah. In the Strategic Plan, we recognized that component and actually sort of our framework of operations, if you will, we recognize that we really need to get, ideally, estimates from different points in the food chain so that we can really identify where are the points of contamination, the points of crossover, and that sort of thing. Again, the reason this is a challenging subject matter is having data to inform all those points, so another reason why we rely a lot on outbreak data as a sort of basis for a lot of our estimation at this point is because it does capture setting data and it does capture something about where the food was prepared, where the food was consumed, and so we can start to inform that, but, again, there are a lot of uncertainties even with that and how accurately they reflect the settings and food

preparation practices. So, case-control studies also help get at that somewhat in that we have the relationship between poultry and non-poultry meat in restaurants and that sort of thing.

But we recognize in IFSAC this need for informing that where the different points in the food chain -- and this is why -- but it's all data-driven, so having data at each of those points is a challenge, and we're exploring the Hald model because we know we have food product data, but the question was asked about farther back in the chain. As we identify data streams and data sources and ways to inform that, we definitely want to be able to have more than just an estimate of a food and a pathogen, but actually estimates of the food and the pathogen and where that contamination is occurring over time. That's part of the framework that IFSAC is operating under and sort of, I guess, you'd call it our long-term plan, but right now we're really working on informing. You know, we have these projects where we try to accommodate multiple -- most of our data comes to us from consumption, but also look at other models at other points.

DR. SCOTT: Morgan Scott, Kansas State University. This question is for Dr. Vieira. I've been following the Hald model for quite a while, and I truly value the effort

put into trying to tackle this very complex and difficult question. One of the things that's concerned me not so much is the source attribution objective, but actually using it to potentially measure success of intervention programs, et cetera, because one of the things that you see in the Hald model is the reliance on serotypes of *Salmonella*. And for those us who have been interested in *Salmonella* from a historical perspective, one thing we do know is that even though the rate of clinical salmonellosis in the human population is pretty stable over long periods of time, the dominant serotype actually varies quite a bit. And one could jump to the conclusion that that's because, well, we're getting more or less problems in different commodity groups. But, if you look at the commodities themselves or the animals that host these *Salmonella*, in fact, the serovars wax and wane in those animals as well.

So, what I guess I'm asking is, is it perhaps a fool's progress to rely too heavily on the idea that a serotype is affiliated with a commodity, ergo, we can estimate the attribution in the human population when the dominant serotype in different agricultural species is changing over time, and the dominant serovar in the human population is changing over time, and what does this represent in terms of problems for us proceeding forward?

DR. VIEIRA: Yeah. We got analytics for this question. The model, usually it runs like iterations for every year, and these two factors, the serotype-dependent factor and the food-dependent factor, will be recalculated by the model every year. So, we do have a serotype-dependent factor that will increase or decrease over the years regarding their association with the number of illnesses. So, that kind of helps us to move these changes over time on their occurrence of specific serotypes as more relevant for human illnesses or commonly in animals. That's for the analytical part. And I understand your concerns, and that's what we try to do.

DR. DAVID: Julie David, Public Health Agency of Canada. For the Hald model, how will you handle the problem of the imported products or other sources, such as waterborne? And, yeah, how would you handle that?

DR. VIEIRA: I think that we're currently using only domestic data -- right? -- we don't have data on -- we actually are working with one dataset, we're evaluating one dataset, a domestic and imported one that was from USDA, but most of our datasets regarding food contamination, they are domestic food.

DR. COLE: So, we're not directly trying to estimate the proportion imported as far as the illness estimates.

We're trying to build a model that actually, again, similar to the Scallan estimates that defined food, domestically acquired foodborne illness, we're also trying to develop models that will estimate the domestically acquired foodborne illness. We're not directly estimating imports at this time.

DR. DAVID: And to handle with that, other than foodborne-acquired diseases, did you consider the comparative export assessment?

DR. VIEIRA: I'm sorry?

DR. DAVID: Did you consider the comparative export assessment methodology that has been developed I think in Holland?

DR. VIEIRA: Comparative export assessment?

DR. DAVID: Yeah.

DR. VIEIRA: That could be one of the future IFSAC projects that we'll develop.

DR. DAVID: Okay. Thanks.

DR. HOEKSTRA: If I could just make a quick comment about the Hald model since we've gotten a whole bunch of questions on it, and I view it in some sense as my favorite model, and the reason is not so much that it is going to prove to be truth, but that, in fact, of all the models that we consider, it is the experimental sandbox in the

sense that in having three pieces -- human illness on one side, food consumption in the middle, contamination as the route through which food consumption yields human illness -- it provides us with an experimental sandbox that in some sense we can use to background all of the other methods that we are going to pursue. So, the issue about, "What is the meaning of the 'q's' and 'a's'?" a good one, but not necessarily key to our use of this model. The other issues about the epidemiology of the Hald model, not completely relevant to our focus in its use as we progress down the line with a greater and greater understanding of foodborne illness. I just wanted to make sure that in some sense you don't get the impression that we think the Hald model will win in the end and beat all the other nasty models.

(Laughter.)

MR. DiNAPOLI: Great. I want to thank our presenters from the whole morning and also for you being here.

We're going to break now and then just stay on schedule and come back, and we will begin promptly at 12:45, so if you could be here before that. I did mention that should you leave the building, because it is so nice out, that's fine, but know that if you don't have a government ID or a visitor's badge, which most of you who came from the outside do not have, you'll have to enter

through Wing 1. Wing 5 is now closed. So Wing 1 will be open, but you'd have to call and get an escort. So we can do it if you go outside, it's just a little tricky, it's going to be a little bit harder, so if you do, do that, I would really request that you come back a little bit even earlier to get here so we can get you escorted and come back in. So, it's not impossible, but, again, the cafeteria is probably your best bet, Wing 2 and 3, and we'll see you back at 12:45. Thank you.

(Lunch break.)

MR. DiNAPOLI: Thank you. Welcome back. I'll give you about 30 seconds or so to just find your seats. Thank you all for coming back so promptly, especially if you went outside. I didn't get to go outside, but I'm sure it's nice.

(Laughter.)

MR. DiNAPOLI: Before we begin our next session, I would like to have the Under Secretary from the Office of Food Safety, Dr. Elisabeth Hagen, to deliver brief remarks to you.

Dr. Hagen.

(Applause.)

DR. HAGEN: Hi, everybody. There are no actual remarks, but I'm happy to see you. I'm sorry I couldn't be

with you most of the day. This is one of my favorite topics. Anybody who has ever heard me talk about it knows that I like to talk about attribution and the importance of it.

So I'm so glad to see so many people here. And it's great to see some old friends that I haven't seen for a while. Thank you for coming.

I'll just keep it simple. Attribution is clearly one of the most challenging endeavors that we engage in, in the world of food safety and in food production, but it's one of the most significant and important endeavors that we engage in, for obvious reasons, I'm sure it's all been said, but -- hi, hi, everybody -- you know, for obvious reasons. For regulators, it's incredibly important because it tells us where we should be directing our resources, and as science based as our policies and our decisions are, sometimes we're really going based on experience and based on instinct, and so it's incredibly important that we continue to get better and better data about which specific foods are causing which illnesses. Obviously very, very important to the industry that produces food as well because they need to know where to put their resources and they need to know where they are accountable in the farm-to-table continuum, and clearly important for everybody who

eats because better policy comes out of better data in this area.

So, this is really, really hard work. And I will admit that I was one of those people when I first came into the world of food safety who also had no idea how hard this was, I just thought that, you know, you just figure it out, you just sort of ask questions and you figure it out and you tally it all up and there's attribution for you, but this is very, very challenging and I have so much respect for the people who engage in all of the rainy work that is required to try to figure out these puzzles.

So, thank you for coming and thank you for your participation, and I'm going to leave it to --

David, are you coming up next?

(No audible response.)

DR. HAGEN: Okay. Greg. Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Dr. Hagen. Part 2 of this Description of the IFSAC Project is coming up.

Our first presenter is Dana Pitts. Dana leads scientific communications for the Division of Foodborne, Waterborne and Environmental Diseases at CDC. Dana came to CDC as a policy analyst in the Center for Global Health and later led communications for its division of Global Disease

Detection and Emergency Response. She began her career as a Foreign Service Officer at the State Department and has worked for over 20 years building strategic communications in a variety of fields and settings, including academia and private industry. Dana completed a Master of Public Health from the University of California, Los Angeles, in policy and management.

The next presenter is Dr. Mike Hoekstra. Dr. Hoekstra is a mathematical statistician in the Biostatistics and Information Management Office of the Division of Foodborne, Waterborne and Environmental Diseases at CDC. He has served as primary statistical consultant for the Division for the last 12 years.

The next presenter is Dr. Mickey Parish. Dr. Parish has served as a Senior Advisor for Microbiology in the FDA/CFSAN Office for Food Safety since 2009. Prior to coming to FDA, Dr. Parish was Chair of the Department of Nutrition and Food Science at the University of Maryland and a Professor of Food Microbiology at the University of Florida. His research expertise is related to the processing of foods, especially juices, beverages, and produce, for control of microorganisms.

And I welcome Dana to the podium.

(Applause.)

DESCRIPTION OF IFSAC PROJECTS--PART 2

12:45 - 1:45 p.m.

MS. PITTS: Good afternoon. I'm very glad, actually, that Dr. Hagen spent the time introducing this afternoon and the day because what she said about the complexity of doing this work is quite a communication challenge, and I want to assure you that I'm not up here doing it alone, and in fact have partners in crime, and Greg, who is doing a great job moderating, is our contact from FSIS, and Dani Schor, who is at FDA and has worked at FSIS, is a very important collaborator and partner in this project. And this definitely, as the science is marching together with the three agencies, so is the communication.

I want to also let you know that I don't have an M.D. or a Ph.D. after my name, but I am a diplomate, and as I got involved in all of this, I realize I think that's the most important skill in all of this, but I did want to start off with a quote that I think is great, and let's be honest, that communication isn't easy, and why it's not easy, there are a lot of reasons, but one of the reasons is I think there is a lot of assumption that goes on in what we communicate and how we communicate. And I was sort of introduced to this when I jumped on the team here, the foodborne illness source attribution team, and I thought to

myself, well, I don't know when I google words like "attribution" or "commodities" or "vehicles," you know, that's not necessarily coming up and connecting with all of this, and I thought, hmm, I think they're assuming that a lot of us that are sort of jumping on this and haven't been part of a decade-old sort of club in doing this, you know, we have to kind of quickly come up to speed. And, so, I wanted to start this off and sort of pose I don't think I'm the only one that had that, I don't think I'm the only one before this conference who looked up and said, "Hmm, how does the word 'attribution' actually connect here?"

And also I think there's a lot of you that have been savvy and are savvy. Dr. Kowalcyk asked a great question: As you change your methods, are you going to communicate that or are you just assuming that we'll know? Excellent question.

So, the point of my talk is this, that communications is essential, and it's also essential that we work on this together hand-in-hand with science, not just one type of communication. There's communication databases. There were some great comments about putting fields in databases we already have. What about databases that are developed? And not just to one type of group of people, too. There are obviously a lot of great questions about scientists,

but I know you're not the only ones out there asking questions and that communication needs to be relevant to a wide variety.

I actually had -- FSIS did a great job in putting everybody who registered, and we kind of quickly tallied to look at the variety of people that are here, and it's clearly not just Federal Government, it also is local and county and there's industry and there are consumer groups. There's a wide variety of people interested.

So, one of the things I want to pose -- and we can look at this at the end, and I would really like your feedback here -- is, should communications be a formalized part of this Interagency Collaboration? Right now, it's not. There's a way -- right now, we have proposals, we have projects, and communications is not really formalized, and maybe it should be and maybe it shouldn't. We would like your response on that question.

But what I would like to do in this brief amount of time is to just go through what I call my roadmap. How are we attacking this, the communications issues associated with communicating source attribution? I want to talk about how we merge science and communications and how do we keep it relevant. I want to talk about the importance of making a plan, not a plan as complicated as the Hald model,

but there are communication plans and they can be rather complicated, too. And I also wanted to spend a lot of time looking at some of the examples that we have of how we've taken things that were very complex and how we've communicated that out to a wide variety of audiences. And, lastly, just look at some of the potential that we have in marching together with science and communications and pose some questions that hopefully will generate a conversation.

So, there is a tension, I'll be honest. Scientists look at things very differently a lot of times than communicators do. They like to communicate primarily through scientific publications. Just in the office that I work in, we have nearly almost 200 publications a year, and that's a lot of publications. Is that communication? Absolutely. Is that the only kind of communication? No, it's not.

And, so, communicators, what we like to do is we like to break things down. We like to translate for many different people and many different audiences. I have to tell you this, even though it can be a tension, it's very important that both sides be in harmony, or it will be confusing.

So, something wonderful does happen when we communicate together, and we can attack a problem with both

of our ways of looking at things. And I have to say this isn't just a march of science and communication, but what I've really enjoyed is the interagency collaboration and, also, collaboration with industry and with consumer groups and academia. Because when we look at this problem together, we could sort of take what we're uniquely good at and attack it as a whole, and that really works. And it's really been interesting to see the process of how that's been working together with the scientists and with the communicators.

One of the things I do really want to make a point about -- and you can write this down -- is that communications really can't be an afterthought. It does not work. It's too hard to catch up. And you're always doing things quickly, you're making mistakes, and in my experience, that really has to be on the front end of science. It definitely is a team approach.

We talked a lot about process, and that's good, but it's the only thing. I really think it needs to be relevant. And a lot of the language to me is obtuse. It's very hard. It's hard for me to wade through, it's hard for me to wade through quickly, and hard for me to sort of make sense of its relevance if I just look at the way that it's been communicated. So, what I like to do is -- and I know

some of the scientists here, when I worked with them on their presentations, I said, "Okay, you're telling me how, but tell me why. So what? Is this really about public health?" Because when all of the conversation is about the process and the data and the problems, I had to ask myself, what's the end value? And that's why I love it when Dr. Goldman and Dr. Farrar talk about the end result. FSMA has great language in it, prevention-based, and that's so important to keep at the heart of this. That this is about preventing illness, this is about public health, and this is about the health of industries, too, if we can really get this right.

It's not theoretical. There is a tension, but this information is used by many different types of people. So, let's look at some of the different types of people that use this, the "who."

So, communicators, I always ask Dr. Braden, when there are people visiting CDC, I say, "Please invite me. I need to hear what people are saying, I want to hear what people are needing." And outbreaks are a way that we do learn about that. Every time we have an outbreak, we have an outbreak team. We learn, we really examine where are the points of weakness in the farm-to-table continuum. But, also, people tell us a lot.

I had an experience when I was getting ready for this presentation. I'm from California. I haven't been back in -- well, I haven't visited that much, but I had some friends visit me that I haven't seen in a decade. And one is my godmother, 90 years old, and I brought her to CDC, and there are a lot of fact sheets in front of our office, and she was taking one of everything. I got a little nervous because I thought, oh, my goodness, I can't make a lot of copies, maybe she'll leave them at our house and I'll put them back afterwards. So, at the end of the weekend, she sits me down, and she goes, "Dana, I just want to have a talk with you," and I'm thinking, "Okay." And she said, "I read everything." And I thought, "Oh, that's so good." And she said, "But I have a question. I didn't realize that there was such a problem. What's the one thing you would recommend that I shouldn't eat, or what should I be careful of?" That was a great question. It's a hard question. It's a hard question especially when people ask, "What shouldn't I eat?"

Now, she's not the only one who asks questions. I do, as I said, I really like working with my regulator partners here because when Dr. Hagen spoke, it's so important for us to understand, especially at CDC, where does this all translate to? What kind of rules and regulations will this

data be used for?

And, of course, it's not just regulators, it's academics. And I'm so glad to see that there is a middle school here. I have a 7th grade boy, and I'm really excited to hear about the LEGO project. We've had quite a few schools contact us. And it's a wonderful project. And, of course, not just a middle school, our future leaders, but we also have thought leaders here. Mike Batz, I know, has done so much research, and there are really a lot of priorities that have to be sort of taken by academics. And there's also some new research by academics. There are a lot of legalities. And how do we answer it? How do we make this relevant for a lot of the research being done in academia?

And, lastly, industry. We had Cargill come to CDC last Friday, and it was a great visit. And they asked, Dr. Frieden asked, asked them, "What's the one thing you really need from us?" and they said, "We need more information. We need to know where contamination is. Where should we be putting our prevention efforts?"

Also, I had a talk here with Joan, and she said, "You know what? What we really need, too, is we need for this work, your science, to be translated so that industry understands it."

This is all very, very important ways that communication can march along with science.

So, I want to transition here a little bit to structure. When I was first asked to join this team, they said, "Well, we need a communication plan." Now, we had a communication plan with our estimates of illness, our burden of illness estimates, that were released last year. And I remember Patty Griffin, when she saw this 18-page communication plan, she said, "Oh, that is just too much, too much," but, like scientists, communicators do have a plan. Now, when I proposed a plan, it was just the bare bones of a plan. So here is just the skeleton.

Internal communications. This is important, and I have to say this has been happening far before I even joined the team, but what I like about what I saw within the IFSAC technical group is that they really had worked hard to align their thinking. They really had spent time. They have weekly meetings. They said, "Well, we don't really even consider this communication." Well, anybody that sets up weekly meetings with a devoted agenda, that is certainly communications. And I do want to applaud them. They've done a great job on that.

The use of consistent terminology. This is confusing. I mean, what is this called anyhow? Is it food

attribution? Is it foodborne illness source attribution? And that's really important. And we're looking to some other groups. I'm hoping that Mike Batz talks about that a little bit.

Shared processes. We do have that. We have common projects. And now, even more, we're talking about we need some project management. All of this is a part of internal communications.

External communications. I think we need to do a lot more with this. I think we can't externally communicate what we're not really sure about what we're doing, but there is a lot going on. I mean, even these meetings. There have been meetings for many, many years, and so, right now, we're looking and seeing. Do we do blogs? Do we do fact sheets? Do we need a glossary? How do we talk with media? So, there's a lot that goes into this sort of structure about external communication.

There are a lot of food safety issues in the news. How do we use that to leverage what we need to know about foodborne illness source attribution?

And, finally, partnerships. This is such a critical part of any endeavor, but particularly communications. You know, to do partnerships well, it takes a lot of time, and who is going to answer the e-mails? Who is going to answer

the requests? It's not just a response, it's a lot of initiative, and we really need to make that a priority.

So, we have had a lot of expert input. We've had these meetings that Dr. Farrar talked about earlier today, and I just have a slide on that with some information because there is so much gold in the comments generated from those.

And we also have -- I think Chris mentioned this -- that we have at CDC an FSMA working group. A lot of good feedback has come in that form in terms of comments about the Strategic Plan. And we've had expert review also outside of that.

And we have had -- FDA hosted a phenomenal risk communication meeting with their group that meets three times a year. I'm going to talk about that a little bit later, and that there is a connection to ongoing body of work. There are people globally that are doing this work. I had a chance to talk to Sara Pires at the Danish National Food Institute, and she really helped me to understand that even all of that work had to be grounded in consistent terminology.

Just a quick glance at this. This helped me. I wanted to see what kinds of people were interested in a series of three meetings. Well, 600 people were. I was

really interested -- and I'm hoping Paul Cieslak can talk about this -- but Portland, Oregon, that is mostly county and local health departments. That's fascinating to me, what the interest and what kinds of issues they really want to tackle. Some of the things I read that they were interested in was they want coordinating, they want reporting by pathogen, they want uncertainty accounted for, they want more than outbreak data, but I love this one, they want communications training, particularly for media.

So, how do we make something complex simple? I don't know if we could ever make it simple, but we can get to the essence, and this is an art as well. So, I don't know how many of you know about this wonderful resource. I'm hoping all of you do. Foodsafety.gov does a great job in getting the word out to consumers. It's mostly focused on food and food handling, but it does have a lot of variety of information also in there. It does talk about risk. It talks about what agencies are doing. Even, just in December, it had 400,000 page views. This is a tremendous resource, and maybe we should consider how we can use this.

Dana Cole talked about this, our burden of illness estimates released last year. This was very, very complicated. Talk about a communications challenge. Here we have, for those of you who don't know, in 1999, our

estimates were 76 million people were ill per year, and then in 2011, 48 million. Now, how do you explain that without using the word "lower"? Because it wasn't lower, it was in comparison.

And, so, we did a lot of research into this, and this was really hard, but we did get the message out that people needed to understand that this was not a direct comparison, but we had better data and better methods. Maybe this is something we need to look at as you roll out your data for foodborne illness source attribution.

How do we do this? Well, one way is we were prepared with a website. We broke things down. And it's been interesting, in one year we've had over 200,000 page views. Ten percent of people spent over 5 minutes. That's unheard of in a world of...if you're an amateur and you're looking at data. So we're communicating well.

How are we doing this? Well, first of all, what we did, it's very, very important, we had to understand that methods matter, and one of the things we did was we embedded one of our communicators with the science team, and they sort of broke down what the methods were used in 1999, then compared those to what the methods were in 2011, looked at the differences -- it's very, very important -- and then looked at what findings, and then improvements and

differences. But you can't show your findings without showing your methods; that's something that's very important.

And one of the things I like to pose is, do you like this way of communicating? We've had 17,000 downloads of these fact sheets. There are obviously people who like this, but is this something that we want to consider as we're waiting for final estimates? Because we're seeing that the methods do matter.

Then later in June, every year we work with our partners on messaging our trends. This is our FoodNet data. Maybe that's a model that we want to look at. What we did this year is we translated that, we not just translated that so we opened it up to another, wider audience, but in translating it, we had to pick the story.

So, what was the story? Looking at the data, the story was about *Salmonella*. *E. coli* dropped, *Salmonella* didn't. We worked with our partners and we released this a little bit ahead with our consumer groups partners, and they said, "We are so glad you picked *Salmonella*." Because I think a lot of times we just accept that *Salmonella* is not dropping. So, how do we pick the story of what we communicate?

I love this. So this is the product of FSIS and many

partners here, "Be Food Safe," and they did a wonderful release about what do we use for behaviors, and they worked with a private ad firm, but let's see what you can do with some pretty complex data.

(Playing video clip.)

MS. PITTS: So I think that's very, very good, and I really appreciate FSIS and the variety of partners who are involved in that.

So, as I said, we did have a meeting with the risk communication group at FDA, and one of the things -- they had many, they had a lot of great advice, but one of the things that they said was “know your audience.” When you have multiple messages, use a tiered approach. Test those messages, and evaluate them. And they did compliment the group that they did a really good job sort of bringing in communications on the front end.

Also, visuals are very important. So, that's one of the things that the group is committed to. How do we show this? You have a cube and your Strategic Plan. Some people like that, some people don't. So, how do we visualize that?

And there's many more of outreach that we've done. This is just a list. One of the groups, I really appreciate that at the National Food Policy Conference,

Chris Waldrop reached out to us and the other agencies and said, "How can we begin to link healthy and safe?" That's a very important question. If we're going to begin to assign risk to foods, how do we communicate that? How do we make sure that people are aware of the safety as well as aware of the importance of eating healthfully?

And when we look at all of what we've done together. And we look at how we go from taking something complex and trying to make it simple or getting to the essence. There are some things that we really need to apply when we go ahead and bring communications in with this effort here. And that we need to learn by listening, that's so important. And that's why these meetings are very important. And there are different ways of examining data, that good communication and science do go hand-in-hand. It does take a lot of time to do this and it takes a strong team; that is such an important message. And that communicating data is ongoing: how are we going to communicate along the continuum? And we need to be strategic. We need to work with each other, and we can't afford not to communicate well.

And for me, the potential is, it helped me to see that I can't visualize this in a cube. That did not work for me. But I can envision it from the farm-to-fork, or now I

understand that contamination might even happen before. But as we work together with science and communications, how do we share this? Is it through visuals? Is it through conferences? What works for you? And we want to hear from you what works. I know that a lot of time has been devoted to many, many people, including this group, but we do need to understand what works for you. So, I'm hoping that as part of the dialogue, you'll give us that feedback.

Thank you.

(Applause.)

DR. HOEKSTRA: Okay. So by now you're wondering, "Can these guys do a short presentation?"

(Laughter.)

DR. HOEKSTRA: The answer is yes, and this is it.

(Laughter.)

DR. HOEKSTRA: Could I have my title back just because -- there we go. So title of the presentation and the project that I'm summarizing, "Develop Shared Illness Attribution Estimates Using Tri-Agency Methods and Simple Food Outbreak Data." I could almost stop there, but that would seem a little too fast, so let's go through this because each piece means something.

Akin to my colleagues, as you might expect, this is no

surprise here: background, purpose, project description, deliverables, and timeline. And there will be even a repetitive quality to that.

Okay. Somewhat embarrassing: currently there are no foodborne illness attribution estimates consistently used by all three agencies. Give me a product! Do something for me! We're going to do that in this project.

There is a need for source attribution estimates that reflect the best current information available. And by that, I mean the most current data and the best methods combined into a defensible source attribution.

At this time, the Foodborne Disease Outbreak Surveillance System provides the best information on which to base estimates.

So, our purpose then is to develop foodborne illness source attribution estimates to be used by all three agencies. My goodness, across three agencies of the Federal Government? Whoo!

(Laughter.)

DR. HOEKSTRA: Based on outbreak data, using the recently updated food commodity categories. So, this is one of the projects that feeds in. I think a quick side note is that, in essence, you are not seeing everything today. There is a lot of discussion within IFSAC where we

are painting a picture of the overall problem. This is the part of the canvas that we have ready for you now, but there are other things taking place that we hope will weave all of our efforts into a coherent whole in time to save us all from foodborne illness.

Project description. Use most current method of grouping simple foods causing foodborne disease outbreaks into commodities. So, that's a feeder piece. We want to use this information to estimate food source attribution. That's the thing, the product, an actual source attribution, using commodities that make sense and are amendable to the use of our partners.

Determine weaknesses in the method by answering these questions. There are weaknesses, and to promulgate an attribution, you must understand those weaknesses because those weaknesses provide you with the basis for decision-making in a rational fashion.

So, we will answer some questions. Does the outbreak data adequately capture information about illness caused by each pathogen? Is there enough data in the Outbreak Surveillance System to generate a reliable estimate? Can these methods be used to measure change in source attribution over time? That last one is kind of a biggie, isn't it? If we do something, we would like to know that

it has achieved some result so that if it hasn't, we can do something else, and if it has, we can go, "Wow."

So, something of a reiteration. The outbreak data will be used to generate most current estimates using the recently updated commodity categories and the most recent data. So, this is, in some sense, new from what we have available now.

Criteria will be developed to define weak attribution estimates -- that is, those with greatest uncertainty -- using the results of the project entitled. You know, our project titles are slick, aren't they? This was a communication challenge, to actually embed all of the sort of obscure stuff that we have into the title so it wouldn't just be "Project 14."

(Laughter.)

DR. HOEKSTRA: I mean, you could go with a TV show, "Project 14," but for our work, I think we need to be a little more concrete.

Other published estimates produced by different methods. We know that there is a large body of subjective information out there that we need to weave into the process, and we acknowledge that we will do that.

And steps to improve estimates will be identified, or my name isn't (thumps podium).

(Laughter.)

DR. HOEKSTRA: Best current estimates, the deliverables. Here's what you get. We are going to get something. Best current estimates of foodborne illness attribution to be used by all three agencies based on the commodity classification and the recent data. This is an actual thing, and common decisions can be driven off of it, and that's an important accomplishment.

Criteria for defining weak estimates. We do need to be able to do triage on pathogen and commodity. What can we make a reliable statement about and what can we not, and how do we communicate that?

And an outline of the next steps required to improve those estimates and determine changes over time using new methods and additional data.

Project plan approved winter 2012. That is not 12 months from now; that is now. Initially, winter -- what is it now? 2011? 2012? That's now. We're approved. We will update the outbreak data available in February 2012. If you look at your watches -- whoo! -- that is very soon.

(Laughter.)

DR. HOEKSTRA: Determine criteria and identify uncertain estimates by fall 2012. That's the triage. And the project will meet the IFSAC short-term needs, develop

best current estimates of foodborne illness source attribution for priority pathogens.

That would be thank you.

(Laughter.)

(Applause.)

DR. PARISH: Thank you, Mike, for the setup.

(Laughter.)

DR. PARISH: How do you follow a talk like that?

(Laughter.)

DR. PARISH: Perhaps let me start by saying thank you to IFSAC for the invitation to speak today. I'm going to take a slightly different approach and talk about how IFSAC and the attribution figures will be used in our efforts to implement FSMA Part 104.

As you know, the implementation of the 2011 Food Safety Modernization Act is currently underway at FDA. The implementation approach is to maintain transparency in the process, to focus on public health, and to engage with stakeholders to ensure provisions are reasonable and practical.

This is an organizational chart showing the team approach that FDA is utilizing for implementing FSMA. The implementation is headed by the Implementation Executive Committee, which is composed of agency senior management

and is supported by six different teams that implement various parts of the law and by the Strategic Communications and Outreach Team.

As you can see, Dana, we have a special team just for communication and outreach.

Each of the six teams is then composed of a variety of different workgroups. And I just wanted to point out that I am leading the Contaminants workgroup, in the lower left, where our job is to determine the most significant foodborne contaminants. And that's a little different than the team that is being led by Dr. Sherri McGarry, in Tracing, where that team will do a variety of things, but one of them being to identify high-risk foods to inform recordkeeping that would be used in tracking and tracing.

It's important to remember that the rulemaking process is open to the public. We truly want your input; we need your input. And we look forward to receiving input on the draft rules, which will be published at regulations.gov. And there will be a particular time for each of the rules for public comment. And we encourage you to visit the FSMA website to see what is open for comment at the current time.

So now, the task on hand is to talk about Section 104 related to performance standards. This is a relatively

short section of FSMA and the law and requires that the agency determine the most significant foodborne contaminants.

This is Section A. Here is the complete text. And if you're like me, if you read anything legalese, you look for a subject, a verb, and an object. That's the first thing, you know; it always helps you in understanding what it says, and it says the Secretary shall determine the most significant foodborne contaminants. Note that the activity must be conducted not less than every 2 years and requires that we review data and information from a variety of different sources. We anticipate publishing guidance on the first list in January of 2013.

So, Mike, we need that attribution data really soon.

Here we have Section B, 104B, that’s based on the list generated in 104A, the Secretary shall issue guidance or regulations as needed. Note that 104B will be an ongoing activity and is designed to address performance standards and action levels. These must be contaminant-specific and science-based and shall apply to food products or product classes for both humans and animals.

The word "risk" is highlighted here since this is the only place it occurs in Section 104. And it's to remind us that our goal is to conduct activities that will reduce

risk of serious illness or death. While we plan to address pathogen-food pairs in our analysis that will inform senior management decisions on high-risk foods and resource allocations, and while we will coordinate our activities with the Tracing workgroup working on high-risk foods, our primary efforts in this activity is to emphasize contaminants.

In 104C, this requires coordination with the Secretary of Agriculture. This is a key role where IFSAC is going to be very helpful and will help us in our efforts to engage FSIS and CDC in how their activities may impact the most significant foodborne contaminants list.

The other key role that IFSAC plays in our effort is to provide the source of attribution data that our Contaminants workgroup will analyze for implementation of FSMA 104A analysis to rank pathogen-food category pairs.

Section D of 104 is finally that the Secretary shall periodically review and revise the guidance documents or regulations. Keep in mind that the most significant foodborne contaminants list will be revisited every 2 years. It will be an iterative process whereby we will do our best the first time. We will look and see what we did perhaps that could be improved and make improvements for the next time, and continue in that realm; whereas, other

guidance and regulations that may be developed under 104B will be periodically reviewed and revised as needed.

Okay. So, here is our current thinking on 104A. While we are currently engaged in the process of obtaining and evaluating the data, we're interested in obtaining public input on our approach, and we will be publishing a Federal Register Notice to open a docket for that purpose in the, hopefully, not too distant future.

The guiding principles for determining the most significant foodborne contaminant list is to utilize objective public health data in a science-based approach that is informed by public comment and is transparent. Our current thinking is that we will be taking a three-track approach that will address, first of all, food-pathogen pairs in human food, chemical contaminants in human food, and animal food and feed contaminants, both microbial and chemical.

The pathogen-food pairing activity is based on an analysis of CDC public health data -- that is, numbers of illnesses, hospitalizations, and deaths -- from CDC and attributed to the 17 food categories that Dana previously described and previously discussed.

Obviously, we will not be doing all of the analyses for all 17 categories since some of those categories are

FSIS-regulated foods, and we will be coordinating with FSIS through IFSAC on this activity so that we can hopefully be approaching this in a similar manner.

Our analysis will result in a ranking of pathogens within food categories based on medical costs and loss of quality-adjusted life years. Because there are fewer public health data for chemical contaminants, we anticipate that this effort will require a more qualitative approach for chemicals, and we may be using things such as compliance data from FDA to address some of the chemical issues.

At present, we are considering groups of chemical contaminants. These being specifically allergens, elements such as heavy metals, mycotoxins, seafood toxins, pesticide residues, and other chemicals. These groups are partly defined by the data sources. For example, the CDC databases also address things such as marine biotoxins and mycotoxins; whereas, we may have compliance data in our own files related to metals, heavy metals, and other toxicants.

Other issues that we'll be addressing. We want to emphasize that we look at this in a way that we want to have robust public health data and will use public health data, objective public health data, when it's available.

We are considering how to address the level of

significance that's related to certain contaminants that may have effective regulatory controls in place, such as pesticide residues and mycotoxins. For example, how would you deal with carbendazim in orange juice, which we are currently facing? Would that rise to the level of being most significant or not? We're also considering how to address and compare contaminants with acute reactions versus those with chronic long-term exposure health effects. And we're considering the approach to differentiating contaminants that are most significant from those that are significant, but may not rise to the level of being most significant.

For additional information, I ask that you please visit the FSMA website, www.fda.gov/fsma, and watch out for our open docket for FSMA 104. We strongly encourage you to provide comments. We are very interested in the comments that we can receive and will consider them in our deliberations.

Thank you for your attention.

(Applause.)

MR. DiNAPOLI: We have a little time for some questions for the speakers. So if you have a question, please come to the mic. Or if you want to come to the podium, you can come to the podium.

(Laughter.)

MR. DiNAPOLI: Caroline, please.

MS. SMITH DeWAAL: Thank you. Thanks so much for the presentation on the most significant foodborne contaminants. I think that's a very important -- it may be short, but it's a very important piece of the new act.

My question, Dr. Parish, is, has the agency thought about the question of how you should organize new data that might be coming into the agency? For example, under the Reportable Food Registry, you're getting signals or data coming in from the industries when contaminants are present in the food supply. And in addition, under the FSMA, you're going to get mandatory laboratory reporting data delivered to the agency. Have you considered how you might collect that data and organize it in a way that it would be useful for feeding into your 2-year process of setting performance standards?

Thank you.

DR. PARISH: Thank you, Caroline. It's always a pleasure and I can always count on an interesting question from you. Yes, we have considered at least the Reportable Food Registry. And I happen to serve part of my time on the Reportable Food Registry and am quite involved with that particular aspect of FDA, so I know that we have data

there to look at. We, frankly, have not specifically considered how we're going to deal with incoming data; however, I think it's a very valid point, that if we have data coming in from the labs, that we should be able to develop a mechanism by which it can feed back into the most significant foodborne contaminants, and I look forward to your comments when we open the docket.

MS. SAMARYA-TIMM: Good afternoon. Michele Samarya-Timm, Summerset County Department of Health in New Jersey. I would like to address this to Dana. Your question at the beginning of your presentation was: Should communication be part of the plan? First of all, with my health educator hat, thank you so much, that was a great presentation, a talkative one, on communication.

I need to tell you, and I think you answered it, but the answer is yes. From a local health department's perspective, all the information that we can get directly from the federal agencies is so helpful to us in doing our job.

You also put up the quote that said George Bernard Shaw -- I'll paraphrase -- that one of the problems with communication is presuming that it has happened. Even though there is a lot of information that does come out regarding foodborne outbreaks, potential recalls, possible

problems from federal agencies, from a local perspective, we get our information more accurately, quickly, and reliably from the Barfblog than we do from the federal agencies, and I really would prefer getting it from you. Due respect to Doug Powell, I'm so glad he's out there doing what it does, but when it comes to communication, yes, more, directly to your partners. We're here to help and support what you're doing. Thank you.

MS. PITTS: I really appreciate that, and I do look forward, I know we all do, the agencies, to feed us, what can we do to help? That would be great.

DR. KENNEDY: Shaun Kennedy, University of Minnesota. This is a follow-on question for you, Dana. One of the things you mentioned was that there is no coordinated communication plan currently across the agencies. Given that the coordinating consistent communication plan will increase consumer confidence, what are the barriers to accomplishing that?

MS. PITTS: Well, again that's a great question. We really just stood up and we're trying to figure out how we actually formalize this between FSIS and FDA and CDC, but there are challenges. I mean, even, how do we define certain terms? And I think what would help is if you all fed us and said let's not let perfect be the enemy of the

good. That would really help us because do we really have to get -- you know, Mike took a shot at just a glossary. Do you want a glossary? Do you need a glossary? And if you say yes, then we then need to respond to that. So I think the more that you can tell us specifically what you need, and that can help. You know, there's nothing like a deadline to make things happen. So that's a quick answer to that question.

DR. JACKSON: Tim Jackson, Nestlé. Just a question. Is there a plan within the IFSAC structure or protocols to harmonize with international approaches to food source attribution, for example, FSO or some other country regulatory bodies?

DR. HOEKSTRA: We are aware of and track what is going on in the international community, but our general impression to date is that the data stream defines the method set available and that our data streams are unique to the United States, and, thus, our methods will very likely be tailored to them. That said, the degree to which what we do follows what goes on in the international food safety arena and makes all of us more effective, the better, and so we hope to network with people in the international food safety community and so on and so forth, but I think for the most part we have found that our data

sources define what we are going to do, and those data sources are rather unique to the United States.

MR. PRINCE: Gale Prince. Looking at the slides today and looking at recall information and outbreak information, we talk about food safety education. We have identified September as "Food Safety Education Month." If you look at the outbreaks, we need to be thinking about May or June because there's an increase in the summer months, and so that's something I would suggest you take back and you talk about as we increase education along these lines before these particular events instead of after the fact.

MS. PITTS: Thank you. I think one of my points that I want to support that is that it does take time to do communication well, and that's something that I'm hoping that we can really build into IFSAC specifically.

MS. GROOTERS: Susan Vaughn Grooters, with Stop Foodborne Illness. I have a question about the choice to use QALYs, quality-adjusted life years. And I'm wondering if you will also consider the ERS data on cost of illness. I think people understand dollars very easily, but have a harder time sort of understanding QALYs, and so I would just like to know how you're considering the body of evidence at ERS with the cost of illness data.

DR. PARISH: Yes, thank you for the question regarding

the quality-adjusted life years. It is my understanding that our economics team is well versed in using QALYs and finding a manner in which they can monetize so that they can actually be added into the cost of illness to come up with a total. That's our current thinking. Again, all of this, when I say "current thinking" is subject to potential change. And if you have comments, again, I look forward to receiving them when we open our docket.

MR. DiNAPOLI: We'll take one more question if there is somebody out there.

(No audible response.)

MR. DiNAPOLI: No more questions? And I do hear the air has been turned off, I believe, so you all can take your coats back off.

I want to thank our panelists for their great presentations.

(Applause.)

MR. DiNAPOLI: At this moment, I would like to invite Dr. David Goldman to the podium.

PANEL DISCUSSION OF IFSAC STRATEGIC PLAN,

FOODBORNE ILLNESS SOURCE ATTRIBUTION AND IFSAC

1:45 - 2:45 p.m.

DR. GOLDMAN: Thanks, Greg. We want to move now to a panel discussion. And I said at the beginning, all of us

in the room are students of this foodborne illness attribution issue. Some of the panelists that we're going to ask to come forward are actually some of the professors of foodborne illness source attribution; that is, people who have spent years representing their various perspectives in attribution issues. So we're very pleased to have this panel. What I'd like to do is ask the panelists to come up to the table here, and then I'll introduce them as a group. And then what we've asked them to do is to consider attribution from the perspective that they represent. You'll hear in just a minute the sort of diverse representation among the panelists. We've asked them to think about attribution from that perspective, how they might use attribution information in their current positions, if they have suggestions about the Strategic Plan or about any of the projects. We've sort of given them an open invitation to comment, and so you'll hear from them each in turn here in just a minute.

And then if there are other questions, we have a few questions here at the podium we can pose to them if they haven't covered all of the issues. They may even ask each other some questions.

But let me introduce you to our panel here, and I'll start from your left.

Dr. Paul Cieslak graduated from the Ohio State University College of Medicine. He trained in internal medicine at the University of Washington in Seattle and completed a fellowship in infectious diseases at Washington University at St. Louis. In the early '90s, he was an Epidemic Intelligence Service officer at CDC's Foodborne and Diarrheal Diseases Branch, sort of the forerunner to the current branch and division now. Since 1995, he has been at the Oregon Public Health Division and managed the Communicable Disease Epidemiology section there, and served as the principal investigator for Oregon's participation in FoodNet. He also chairs the FoodNet Attributions Work Group, which has been active for probably 7 or 8 years at least.

Dr. Barbara Kowalcyk is next to Paul. She is an internationally respected expert in food safety and foodborne illness and is the Chief Executive Officer of the Center for Foodborne Illness Research and Prevention. With her degrees in epidemiology and biostatistics, Dr. Kowalcyk brings a strong analytic background to the numerous government committees she has served on, including two National Academy of Sciences committees and the current CDC's Board of Scientific Counselors Surveillance Working Group. Dr. Kowalcyk also has faculty appointments at both

NC State University and the University of North Carolina at Chapel Hill.

And to Barbara's left is Mike Batz, who is a researcher and head of the food safety program for the Emerging Pathogens Institute at the University of Florida. Prior to joining that university, he worked on food safety issues while at the University of Maryland's School of Medicine in Baltimore and at Resources for the Future here in Washington, D.C., which is a nonprofit research institute. Mr. Batz has a B.S. and Master of Science degree in Electrical and Computer Engineering from Carnegie Mellon University. And I should also say he was one of the peer reviewers of our Strategic Plan.

And to your far right there is Joan Menke-Schaenzer, who is currently with ConAgra Foods since 2007, and she serves as their Global Chief Quality Officer. Before coming to ConAgra, Joan was vice president of Food Safety and Defense at Wal-Mart, where she was responsible for the food safety in 3,000 stores and 200 clubs worldwide. Prior to Wal-Mart, she was with Kraft Foods for about 20 years and last served as vice president of Kraft Foods North America Quality and Food Safety. At Kraft, her accomplishments included leading the development of worldwide quality and food safety programs and policies

throughout the Philip Morris Worldwide Quality Council and the development of the company's crisis management/quick response team.

So I think you'll agree with me, we have a diverse and expert panel who will provide you their insights into foodborne illness source attribution. And I think we can go in the order that I've just introduced them if that's what you'd like to do. And I'll sit down and let you all -- you can either come to the podium or you can sit where you are if you're comfortable there. I know Barbara has some slides, so we may ask her to come up, but I'll turn it over to Paul.

DR. CIESLAK: Thank you very much. I'd rather not come to the podium because I have my brain in front of me right here.

(Laughter.)

DR. CIESLAK: We were asked to address several issues about the IFSAC Strategic Plan and about the issue of attribution in general, and I guess I'm going to be speaking from my role as communicable disease epidemiologist for the Oregon Public Health Division. So every state has epidemiologists who work on communicable disease, and I think I can sort of speak for that cohort of people.

But, also, my work in FoodNet has extensively involved attribution, because back in 2003, we decided that the question of attribution was important enough to establish a separate workgroup comprising members of the 10 FoodNet sites as well as CDC, FDA, and FSIS, and so we've been wrestling with that issue ever since then.

The first question that we were asked to address: Why is foodborne illness source attribution important to you? And my response is something like Dr. Hagen gave earlier: this is what it's all about. I was sort of surprised by the question. I feel like it's like, "Why do you like oxygen?"

(Laughter.)

DR. CIESLAK: It's basically what we need to do in order to perform our public health functions. We need to know where is the foodborne illness coming from so we know what to pay attention to, where to aim our public messaging, where to aim our regulatory efforts.

The other thing that is going to be a recurring theme that I'm going to dwell on is that it's not only outbreaks. Most of the cases that we get are so-called sporadic cases. And when we investigate sporadic cases, we like to ask them, for example, about usual suspect food exposures that might have caused the illness. So, what are those usual

suspect exposures? Is it food in restaurants? It is undercooked ground beef? Is it the poultry that they had? Is it leafy green vegetables? And, so, knowing some approach to interviewing these sporadic cases is important, and that ultimately stems from what we know about the sources of foodborne illness from previous experience.

And to the degree that we're able to identify these things, in addition to the investigation efforts, they're going to affect regulatory efforts. How much of our attention should be spent at the farm as opposed to working on the restaurants?

I can tell you that the biggest foodborne outbreak that we ever get is norovirus, and that has only a human reservoir. And most of the time we infer, I think correctly, that there's a human involved who didn't wash his hands after using the bathroom. So that's a very different intervention than one would use if you think that most of the foodborne illness is coming from contaminated poultry, for example, and so knowing those things is what's going to allow us ultimately to prevent the diseases.

How might private stakeholders and academia partner with IFSAC to improve data sources and methods? I think that the main problem that I see with the current Strategic Plan, as I've read it, is that it focuses on the outbreak

attribution, and I realize that that's stated as a short-term need, but from my perspective, we've been looking at this outbreak attribution for some years now because it's basically been the only source of data that we had, and we already know some of the flaws in it. And all of the improved methodology that we can bring to bear and all of the statistical finesse that we can bring to bear isn't going to relieve us of the underlying doubt that we have about the representativeness of those outbreak-associated cases. In Oregon, something like 1 percent of *Campylobacter* cases are outbreak associated; 22 percent over the 5 years of *E. coli* O157 and other STEC infections have been outbreak associated, and 20 percent of salmonellosis has been outbreak associated. So, that leaves this great mountain of cases that aren't outbreak associated, and we have a lot of reason to believe that the outbreaks that we look at aren't representative of what's causing all the sporadic cases. For example, a lot of the outbreaks have found fruits and vegetables, leafy greens, cantaloupe has come up several times, tomatoes, but every time we do a case-control study of sporadic illness, we find that eating lots of fruits and vegetables is protective, it's associated with not getting foodborne illness. And, so, nothing that we do to these outbreak

data is going to change those underlying doubts about the representativeness of them.

So, even as we talk about presenting that outbreak attribution, I think we're already ready to say it's inadequate and we need to move on with trying to attribute the sporadic cases. Our group has worked with Chuanfa Guo, who is in the audience here, who produced the first U.S. adaptation of the Danish model that I think in Denmark successfully looked at these sporadic cases and was able to attribute them. And they were able to take regulatory action based on their findings.

So, we attempted to adapt this, and we have a lot of experience wrestling with it, and there are some very serious problems of using U.S. data to do this. Number one, the U.S. data are relatively thin. We don't have systematically collected data across the food sources that we're interested in. And they're also thin in terms of subtyping. We do have *Salmonella* serotypes, but we didn't systematically use antimicrobial resistance profiles or molecular profiles to try to delve a little bit deeper into the sources of these illnesses.

So, I think that nothing we do is going to make the problem of lack of data, lack of microbiological data systematically collected and intensively subtyped in order

to inform that attribution model. And I think that's the main thing that we're going to need to get.

Industry data perhaps could go a long way toward filling this. I'm not totally familiar with what sorts of data industry produces. And I don't know to what degree they would be willing to share them and allow them to inform our attribution models, but that is one way that industry data could assist.

So, as far as the IFSAC Strategic Plan goes, I do like the pathogens that they've chosen. I think they did focus on those that caused most of the severe illness in the United States and that are most readily addressed by federal regulatory action, but the main thing I'm concerned about is that we not delay the attempt to collect the more extensive data that we need in order to inform our attribution models.

I think I'll end there.

DR. KOWALCYK: So, good afternoon. My name is Barbara Kowalcyk, and I'm the CEO of the Center for Foodborne Illness Research and Prevention.

So, first slide, please.

So, I am invited here as a nonprofit group. And if you know anything about consumer advocacy and nonprofits, our role is to really make people aware of the situation

and help improve the system, and for the benefit of the public. And that's really our role. So, I come at that from this perspective today.

Now, as mentioned earlier, I have served on a couple of National Academy of Science committees. The first one here is the IOM committee that recently issued the report "Enhancing Food Safety: The Role of the Food and Drug Administration," and I wanted to start with a couple of slides from that report because I think it puts it into context. Again, I'm looking at it from the 10,000-foot level; I'm trying to improve the system for the benefit of the public.

So, one of the things that the committee recommended is we acknowledge the fact that everybody says we want a risk-based food safety system. Well, great. What does that look like, and how do we do that, and how do we systematize that? And so the committee came up with this chart, and I'm not going to spend a lot of time on it, but, basically, we came up with a six-step process that really is based on continuous improvement and is rooted in strategic planning, public health risk ranking, targeted information gathering, analysis and selection of interventions, design and implementation of the interventions, monitoring, and review.

Next slide, please.

And, really, we acknowledged in the report -- and I do recommend that you at least read the Executive Summary, but there are some targeted chapters that would be very relevant, one is, which I believe, Chapter 5, which is on an integrated information infrastructure where we talked about really the foundation of a risk-based food safety system is data, and specifically an integrated information infrastructure. And I'm not going to go through this, but data applies, you need data to address each one of the steps in the system that we recommended.

Next slide, please.

We also said that if you're going to develop an integrated information infrastructure, you're have to think about you're going to need surveillance data. You're going to need food data, behavioral data, economic data, and data across a lot of different sectors. And I think you've heard this today through some of the comments and presentations that we've had. I mean, we obviously need surveillance data, but we need it to be beyond just human surveillance. We need surveillance of public health data, animals, food, environmental, molecular. We need information on food production and consumption and regulatory data. We need to understand how people are

actually -- what are their practices? What is their knowledge? What are their beliefs? What are their perceptions around these issues? And then we need to understand what are the health impacts, not just on the individual, but population health as well. And what are the market impacts?

Next slide, please.

And so the committee actually recommended these things. That we need strategic data collection. We need improved access to data. We need to modernize information technology, and we need to increase analytic capacity.

Next slide, please.

So, now I'm just going to give a few brief remarks because I know we're going to have questions again later, and on the IFSAC Strategic Plan. I think it's a really good first step. It's a good step in the right direction. I know I heard today that it was designed to present a vision. I think I get a sense of a vision, but I'm still a little confused on a few things. I appreciate Mike's point earlier, that this is really a plan about source attribution. And I recognize the need for having short-term goals and addressing those. But if we really want to move from the reactive system we have to the proactive system we all say we want, we also need to be thinking into

the future and deciding what kinds of data are we going to need 10 years from now. And we need to be addressing that now, not later.

So, I think developing attribution that does look at reservoir and vehicle and so forth, that discussion also needs to start happening now.

Here are just some of the goals that I pulled out of the Strategic Plan when I reviewed it, and I think they're all really, really good goals. And I just think we need to take it one step further.

Next slide, please.

And here are the short-term objectives. I think they're really great objectives to start off with. I think that improving methods to identify and commoditize food vehicles is a really good thing to do, and I understand that IFSAC is trying to build consensus around that. I would like to see it taken outside of just the government and build consensus across everybody that's working on that, and also do sensitivity analyses. How do the changes to how you commoditize food vehicles change your estimates? And, certainly, I've been advocating for uncertainty analysis for a very long time, and I think that's fantastic.

Next slide, please, because I think I'm running out of

time.

Points to consider. Again, I think we need to really be thinking long term about the integrated information infrastructure. We do need to go beyond outbreaks, and as I said before, we need to move from reactive to proactive.

One of the things that I found that was interesting, that wasn't mentioned in the IFSAC Strategic Plan, is burden of disease estimates. We really need a systematic way of updating these estimates. It was about 12 years from the 1998 estimates to the new estimates, and they're a critical part of attribution. A lot of people use those. And, so, how are we going to have more timely updated estimates?

We also need to improve our estimates on population health impacts and cost and et cetera. And so as many people who know me know I'm very interested in the long-term health impacts, which kind of goes to severity, and I think one of the points that Susan raised earlier, QALYs versus actual costs, and how does that fit in here?

And it's been mentioned, of course, several times, that linking attribution to public health goals is a critical component. And then we also have to step back and say, okay -- I fully appreciate Mike's point, that our methods depend on the data streams available to us. So,

one, we need to take a look. What data streams are available to us? What data streams are out there, but we don't have access to? How can we get access? Are those data streams fit for a purpose? Where are the gaps? How can we proceed in filling in those gaps?

And, then, my other point to consider is, how are you going to systematically incorporate this into decision-making? I didn't really feel like that was clearly explained in the Strategic Plan, and, of course, that's one of our ultimate goals.

And, then, I really enjoyed Dana's presentation. Information dissemination, know your audience. It seemed to me when I read the plan that there was a heavy emphasis on peer-reviewed journals and publications, but that's not the way most people will consume this. Policymakers, particularly here in Washington, D.C., don't always have the opportunity or access or time to read those kind of documents. Certainly the public doesn't, and they don't understand it, and so how do you present it to them? I would agree, the most frequent question I get asked is, "Okay, I'm convinced food safety is a big problem, and I don't want foodborne illness. So, what shouldn't I eat?" And then I stand and I look at them and I say, "Well, it depends, and I can't really tell you, but I can tell you

what I don't like to eat or what I won't let my family eat." Because it's a question that makes me really uncomfortable, because I don't feel there's enough science behind it for me to answer that in really an unbiased way. So, I think that that's really great.

The Steering Committee. I think the Steering Committee is a very good idea. I do wonder if you might want to consider having an advisory committee to pull in some of the outside expertise. I mean, one of the questions we were asked to answer is: How do you engage academia and other researchers? And that might be a good way. I did think that the Steering Committee has an awful lot on their plate. I was very impressed by the agenda.

And the last thing, and then I'll conclude here, is funding and other external factors. I wasn't really clear how you were going to deal with that. And funding goes beyond just funding attribution efforts, which I think is critically important. As a new academia, trying to find funding to take on a research project of this nature is very difficult, but what about funding for the states? I mean, we talked a lot about outbreak data and there's a lot of incomplete data. It doesn't get reported in a timely way. How is the impact of funding cuts to the states going to impact your efforts to do attribution?

What about other external factors like funding cuts in the labs or the development of nonculture-based methods? How is that going to affect our ability to detect outbreaks? Will outbreaks go down just as an artifact of that? And what will be the implication for attribution activities?

So, in conclusion, I think this is a really good first start, and as people have said throughout the day, this is a very complicated issue. It's not easy to do. And I do really think that we need to have long-term vision while we try and tackle the short-term solutions.

Thank you.

(Applause.)

MR. BATZ: Thanks, Barb. I think you said everything, and I'll just pass.

(Laughter.)

MR. BATZ: No, I won't, not pass. Okay. So, foodborne illness source attribution -- which I didn't quite realize until today that people had come to consensus on what to call it -- is all about linking agents that are affecting people and causing illness with the vehicles of that exposure. So, it makes intuitive sense, and is even a requirement, that the agencies that deal with those different pieces be working together to solve it. That is

much easier said than done. I think every organization has its own mission, its own responsibilities, and these kinds of collaborations often require a lot of travel and meetings and talking and stuff that isn't actually doing the work. So, they can be costly and difficult to do, but for problems like this, I think it's critical to expand on those kinds of efforts and to build trust and analytical foundation for this stuff moving forward. I think these issues are going to be bigger moving forward. If you look at emerging foodborne hazards, I think the likelihood that they need to require all parties at the table is only going to grow.

So, I am incredibly happy -- thrilled maybe -- although maybe that's not the right thing to say in an environment like this, but that the agencies have formed this collaboration and that they're working forward on this. I think that deserves not just a patently "Oh, I'm glad to be here" kind of thing, but this is an incredibly difficult mountain to climb, and I'm very happy that the agencies are doing it and that they've opened up the process today to give us the chance to help them lead it off. And if I can strain this metaphor even further, I'm no Tenzing Norgay or Edmund Hillary, but I've been up this mountain or tried to climb it a few times, and I do have

some opinions about the pathways to take.

Back in 2002 -- we might have even started in 2001 -- we were trying to rank pathogen-food combinations in terms of their public health impact. So, there are three pieces to this. One was trying to estimate the burden of disease to the 31 pathogens in meat, et al., in terms of QALYs and dollars, and we wanted to attribute those down to food categories.

We quickly found the same data issues and, really, at that time, the only data source that was available on a compiled form was actually by CSPI and Caroline, who is the true Tenzing Norgay of outbreak attribution.

So, we struggled with this data. We used their data. We used their food categories to develop ours, but we still ran into troubles immediately with *Campylobacter*, right? And, so, we decided, as part of this project, that we were going to conduct an expert elicitation to do alongside of it, and we did that. We held a workshop in October of 2003 on attribution, and a lot of the methods discussed here were discussed there. We talked about outbreak data and case-control studies. We talked about subtyping. Tine Hald's model wasn't published yet, but we talked about that. We talked about risk assessment, comparative risk assessment, and predictive microbiology, and we talked

about expert elicitation. That was 8 years ago, and we're still wrestling with some of these same issues. Hopefully, that doesn't speak to my laziness, but the scope of the challenge.

But, finally, we did finally publish that work in a report last April, and I have a couple of journal articles accepted that hopefully will come out shortly. So, it took us a long time to put those out, in part, because the analysis takes a long time and, in part, because there is a lot of uncertainty associated with it, and you're putting yourself in the crosshairs when you do put that stuff out there. But I do believe it is important to put that stuff out there.

So, a few of the lessons -- and these are may be a little bit of a scattershot approach, but a few lessons that we learned along the way.

First of all, outbreak data can be cut a lot of different ways. There is not just one outbreak attribution estimate. This is dirty text-based data where outbreaks are attributed to ethnic food or hamburger where you don't know whether that's a sandwich or ground beef or cougar jerky.

(Laughter.)

MR. BATZ: There is a cougar jerky outbreak in there,

but it's, I think, in the early '90s. Toxo, I think.

In any case, there's a lot of uncertainty about the assumptions you use in analyzing this data, and I do hope IFSAC -- I'm sure they're wrestling with them -- sort of address them publicly when they do decide on some of these things. For example, there's how many years of data are sufficient, whether you're using simple foods or complex foods, how you're dealing with complex foods. We used a complex foods bin, and then there's a recipe option that they're pursuing. There are dishes that have multiple foods, whether you drop them or keep them in. Whether you're attributing outbreaks to sporadic cases based on number of events or based on number of outbreak cases by food-pathogen category because outbreak size varies tremendously by food and because there are some extremely large outbreaks in this dataset that can really throw numbers off. You know, an outbreak with 1,600 people in it where the bulk of them are actually, you know, I think the mode is 4 or something; the skew is off the charts.

So, to the extent that these large outbreaks are influencing data, what are we doing to deal with that? And a lot of that is separate from the related issue of whether outbreak issues are representative of sporadic illness at all.

So, I'm very glad to see that IFSAC is squarely addressing this challenge of, when is outbreak data good enough? When is it not? I think we have some intuitive feelings about it, but I really like what I heard today about trying to use some analytical approaches to help make that decision, to make that sort of what we called in our decision in our ranking where we ended up using our expert elicitation for 4 pathogens, outbreak data for the remaining 10, and we developed some heuristics based number of outbreaks, ratios, comparisons with our expert elicitation and so forth that helped inform what we chose. And it was very helpful to go down that pathway of developing these kinds of heuristics.

I will also say that some of the recent data on outbreak reporting does not look good, and I would like to hear, at some point, somebody from IFSAC talk about how they might expect some of these drastic cuts in state and local public health budgets, how that affects not only the ability to respond to these things, but the ability to analyze the data.

Another issue that's not particularly addressed, although it's mentioned in the Strategic Plan, is that there is not just this attribution among foodsk, but to foods overall. There are a lot of non-foodborne pathways

-- animal contact, environmental contact, person-to-person contact. And the percent foodborne that is in Scallan is pretty rough; in my opinion, it's pretty rough. So it's based largely on case-control studies with some informed by outbreaks. And when we were producing our risk-ranking results, we decided to use these numbers, but we started to look around and find that there was quite a lot of variation in estimates about just this percentage that's foodborne. And, so, I didn't hear anything about this today. So, just for example, this is not directly comparable, but Arie Havelaar, in their work, to do some of the stuff that we did in terms of prioritizing foodborne pathogens, did an expert elicitation of experts to ask them what percentage of food was travel, person-to-person, environment, et cetera. Now, because they asked experts, and experts aren't going to want to put zeros in there, I think the numbers on food are lower, but they're drastically lower than what are estimated here. Different country, very different everything, but, whereas, for *Salmonella*, Scallan, et al., estimates 94 percent foodborne. In the Netherlands, it's estimated to be 64 percent. *Campylobacter*, 80 percent in Scallan, 47 percent -- this is of non-travel domestically acquired cases. *Listeria*, 99 percent here, 79 percent there. It's always

lower there, and I think that just wrestling with this issue should be part of this process.

Okay. How are these estimates going to be used? Barb touched on this. I think there are two very different decision-making contexts that attribution estimates are used. One is resource allocation, broad prioritization. The second being targeted risk management. And I think the quality of data, the food category granularity, all of that stuff changes based on what the risk management question is that you're actually trying to answer.

This is maybe not related, but this past week FSA announced that they had reduced *Salmonella* across Europe by 50 percent in 5 years. I think it was last December, New Zealand announced that they had reduced *Campylobacter* infections by 50 percent in 4 years. These problems are solvable, and both of these situations involved an intensity of attribution approaches that were connected to regulatory approaches and which fed back into defining these priorities.

Now, there are some big differences there. Both of those countries focused on farm controls and culling and things like that that I think people aren't talking about in this country and don't fit into what we could do here, but my point is merely that if these attribution models are

built into these risk management operations, I think they can be much more successful.

Some of those models, like Hald and some of them, I do have some questions about their relevance to FDA concerns. There has been some talk about using these for produce items. And some of the foundational work on microbial source tracking and some of these reservoir models depend on the idea that serotypes and specific substrains, phage types, or whatever, are endemic to a specific animal species because they're zoonotic pathogens. And so saying that you can take a sampling from lettuce and use that in an attribution model, I have some pretty big questions about that given some of the other uncertainties in there, some methodological questions, as well as just some plain feasible questions.

So, as we go down that advanced modeling, because the way these Hald models work is they identify animal reservoirs, I really would like to see this point addressed explicitly about how it's going to be applicable to FDA and how when consumers get sick from produce, this point of attribution upstream to animal source is very different than what they consume in the home. There is clearly a role for cross-contamination, and that role is one directional. Chicken might contaminate produce; it's very

unlikely to go the other way. It's possible through the environment, but, you know, it's a zoonotic pathogen, it's going to move one directional, from animals to produce, and I think that should be a part of how we interpret outbreak-based results.

I'm glad that IFSAC is pursuing these advanced modeling approaches because I think sometimes these consensus-type arrangements, large collaborations, end up with people working on things that everybody can agree on. And that's not a particularly great environment for taking risks or being innovative, but it doesn't seem to be a problem. I see a lot of sort of pushing the boundaries on these things, and I think that's important despite our concerns with these advanced models.

There are other models out there. The Dutch model is a little bit simpler than Hald. There's the Island model. I don't know to what extent these things are relevant, but there is some talk on the Strategic Plan of looking at other models, and I would certainly like to hear a little bit more about what those models are.

And just to throw it out there, I think there is a bounded nature to this discussion on attribution, in part, because of today and, in part, because of a number of publications that I've been involved with where we're

trying to categorize these approaches, but there are a lot of new approaches that I think we haven't thought of. There is the ability to combine some of this microbial subtyping and this fingerprinting with case-control studies. So, we have combining the ability to look at these similarities across strains based on food consumption data with human illness data and involving case interviews. That can be an incredibly powerful source. Nobody is doing that because I think it's very challenging, but there are other things that we can do that just aren't part of this discussion that I hope, at least, are a part of -- not part of the long-term plan, but, at least, that we continue to think of when we think about attribution.

And the last thing I wanted to do, if I can get this, was to end with a quote that has been rattling through my mind quite a bit. And it's not from John Snow or an epidemiologist, since I'm a computer engineer, but it's from a physicist. It's from Richard Feynman, and he says, "I can live with doubt and uncertainty and not knowing if we only allow that as we progress, we remain unsure, we will leave opportunities for alternatives. We will not become enthusiastic for the fact, the knowledge, the absolute truth of the day, but remain always uncertain. In order to make progress, one must leave the door to the

unknown ajar." To me, this just speaks to the fact that even though these things are uncertain and we don't have exact answers today or tomorrow or probably 5 or 10 years from now, that doesn't mean we shouldn't try to do it. And it doesn't mean that the answers that we do get aren't incredibly valuable.

So, sorry for prattling on so long. I don't think -- well, two people fell asleep maybe.

(Laughter.)

MS. MENKE-SCHAENZER: Well, I'll try to keep people awake here.

(Applause.)

MS. MENKE-SCHAENZER: So, let me begin my comments by first of all thanking the IFSAC team for the opportunity to be present here today to have industry together on this panel. I think that's really, really important. And like my friend here, Michael, who says that we're here because we want to learn about food attribution, we want to make it better. I don't want to say I can speak for all of industry, but, absolutely, food attribution is an essential part of information that industry needs on an ongoing, very quick manner to continue to move from being reactive to proactive.

I think sometimes we feel like we're driving down the

highway. We know it's our responsibility to deliver safe, wholesome food, but we can't predict the potholes. We can't predict how the highway changes. And, so, I see that the food attribution and the IFSAC work will help us have transparency into those potholes that are unseen today. I really applaud the work that's being done.

So, those are my opening remarks. And what I'll do is I'll just give a little bit of background. I think that some of the folks in the industry, particularly the youths that just arrived, may not know about industry and the background. I'm going to talk about why IFSAC food attribution work is so important to industry in a more detailed manner, and I'm going to talk about how food attribution data is used today in industry. And then, finally, I want to close my remarks just talking a little bit about the collaboration. And I think the magic and the value in the collaboration that's coming together with the IFSAC project.

So, as background, as was highlighted in my introduction, I have the honor of leading a team of food safety professionals. We call ourselves kind of public health warriors out there. We ensure that the food that's made in our manufacturing facilities is safe and wholesome each day. Like other food manufacturers, we have both FDA

products and USDA products, and we source ingredients, because sometimes ingredients are only available from the other sides of the world, we source it globally. So we live in a complex world.

At ConAgra Foods, we process both single-ingredient products, such as, say, flour or spices or potatoes, as well as complex packaged foods that contain multiple ingredients. So, an example would be Kids Cuisine, where we have corn, a hot dog, and say a french fry type of thing. So, there are complex products and there are simple products, and we understand there is complexity out there.

So, moving to the IFSAC Food Attribution Strategic Plan and its importance to industry, really what we do, and I think the thing to remember is that understanding food attribution and understanding those potholes makes good business sense, right? Nobody wants to be the cause of an outbreak. When outbreaks happen, categories decline, customer and consumer confidence erodes, sales decline, people lose jobs. And as a mother and a businesswoman, you know, we're not in the business to make people sick. We want to keep people safe and we want to keep our employees safe.

So, the food attribution work, really the objective, to take the best illness source attribution data and be

able to combine it, the food with the source, is just phenomenal. What that allows us to do is to establish priorities to implement preventative controls and really to set new food safety plans for our plants and for our suppliers. It also allows us to understand new technologies that we might embrace to keep the food safe.

I'm going to highlight one of the examples that we've used where we understood a couple years back there was a bump along the road where we had an outbreak involving cookie dough. And it gave us a wakeup call to say, hey, we better look at our flour. We've been in the flour milling business for a long time, several decades, but we can't keep doing what we're doing; otherwise, we're going to get the same thing. So we embarked looking at new technology. We came up with a technology where we today have a product that we call Safeguard Flour that's ready to eat. We can render a flour safe to eat, and then have the same functionality. We've also looked at new practices that we can impart, and the food attribution work helps us drive to new practices. So, maybe there are new sanitizers we need to use in flumes when we're handling potatoes or things like that.

And also that food attribution work is what we use when we're developing our HACCP plans. It's really, really

helpful to know when you're doing your hazard assessment for each ingredient to understand the risks, the true risks, that are associated with those ingredients.

So, new practices, new technologies.

It also enables us to understand where we need to go do research, because I think all of us, we talked about there are a lot of unanswered questions. So, where do we go look? Where do we invest? Where do we, say, have a university go help us understand things?

So, really the collaboration that's here today I wanted to call out because I think bringing the different groups together, the tri-agencies together, is really important to help us understand the unknown. I'm excited about the opportunity to be part of the collaboration with the three agencies, and I know it will move us from being reactive to proactive.

Thanks.

(Applause.)

DR. GOLDMAN: Well, thank you very much to each of our panelists. The audience doesn't know this, although Paul alluded to this, they were given about six or seven questions in advance, and I think that each of them covered all of the questions, maybe not in order, but I think in the course of your comments, you did cover those things.

So I don't have any particular questions.

A couple of things came to mind I just wanted to maybe pose or throw out there, and then I'll also give you an opportunity to perhaps ask each other. So, Paul, you got to hear three people after you, maybe you developed some questions for your colleagues there, but we'll get to that perhaps.

I think overall we heard -- I hope I got this right -- we heard a general endorsement of what we're doing, both overall strategy, as well as some of the particulars. I clearly heard lots of suggestions, which is exactly what we want from not only you, the panelists, and several of you have been an expert in this topic for some years, but also from the wider audience here today. So, I think you represented your various stakeholder perspectives very well in that regard, so we're pleased with that. And I would encourage you to send us your written comments as well, although we are capturing all this, just as a reminder, through a transcription service. We'll have all of it down, but if you have particular comments you want to send to us, we'd be interested in that.

I'll just throw out a question. I've had my own concerns because I've been involved, as I mentioned at the beginning, with attribution issues for some number of

years, And we have been talking about this for years, and I guess in particular Paul and Mike, who have been sort of in the weeds on this issue for some number of years, are you still optimistic that we can get there, wherever there is? It's sort of an open-ended question. But I sense some optimism. I sense some concerns about maybe some of the particulars, but overall it was maybe guarded optimism? I mean, do either of you want to comment on that, or anybody on the panel? Because I've had separate conversations with each of you individually, and I just want to hear you if you want to elaborate on that a bit.

DR. CIESLAK: I guess I'll take a crack at it. If success is measured by being able to come closer or to get an idea as to what are the major food-pathogen pairs, the major foci of regulatory efforts should be based on attributing, you know, is it chicken that we should be focusing on? Is it beef? I think we can get enough information in order to make intelligent decisions along those lines. If success, on the other hand, is measured by precision around these estimates, I don't think we're ever going to get there. I think it's essentially unknowable to some degree. So, we can triangulate in and come up with ballpark estimates, but I don't think we're going to come up with the sort of epidemiologic precision that many of us

are accustomed to in, say, a case-control study.

DR. GOLDMAN: Okay, thanks. Anyone else want to offer a comment?

MR. BATZ: I mean, my biggest response to that is that I think we only get these things better by continuing to do them and to, sort of, put them out there. So, we've been working on this stuff for a long time, but a lot of it, especially on the outbreak side, isn't out there. I think John Painter is, I think, somewhere -- I'm sure that's somewhere in a journal somewhere in that process, and those things are going to come out. I think we can only have those conversations the more that data is there to drive the conversation.

So, I think so far a lot of this conversation has been almost philosophical, and I think it's tough to put these numbers out there because there are real industries affected, real people getting sick. This is important stuff. But I think the only way we can move forward is continue to talk about it.

So, yeah, I have guarded optimism. I think for some pathogens we're a lot closer than others. And I hope that some of the analysis that look across these things, look across the board, and start combining outbreaks and putting it side-by-side with case-control studies and seeing what

different modeling approaches do. When we get those numbers sort of done by the same people, put out at the same time and we see how they vary, I think that's an incredibly important thing to do and will advance the discussion a lot.

I think maybe for *Campylobacter*, it's a little bit tougher because outbreak data are probably not useful. For something like *Toxoplasma,* I think we're largely in the dark. And, so, I think it really varies by pathogen, but clearly for *Salmonella,* there are some serotype issues that get lost in some of this, the outbreak analysis, unless you start really treating each serotype like its own pathogen.

But, yeah, so guarded optimism.

DR. GOLDMAN: Barb or Joan? Barb?

DR. KOWALCYK: So, I'm just going to echo Paul's and Mike's comments in that I would have guarded optimism as well. And I think that the points that they made are very good. I mean, it's absolutely true, we're not going to remove uncertainty, but we do need to talk about uncertainty and be able to quantify it. I mean, Mike made a very good point earlier, that needs to be part of the message to decision-makers so that they can actually weigh the evidence in front of them and what they're going to do. Policymakers need not the -- they don't want to wait for

perfect data, they just need to know the best available data at the moment. And as a nonprofit advocate, that's what I need. When I'm in meetings with policymakers, I need to know, what is the best information we have right now?

I think people know me. I'm a big proponent for continuous improvement, and I think that that's one of the reasons that I think people should look at the NAS report. That cycle is continuous. We're not going to do attribution once and be done. So, how do we set this up so that we can systematically revisit this on a regular basis? How can we get burden of disease estimates more often, improved burden of disease estimates more often, than once every 12 years? How can we keep adjusting and moving the cycle forward? And that goes for whether you're talking about production or whether you're talking about this.

I mean, to me, continuous improvement, we're never going to get to zero. We're never going to have no uncertainty. We're never going to completely remove foodborne pathogens, as much as I would love to, but we always need to be striving for that as the goal and working towards continuous improvement.

MS. MENKE-SCHAENZER: And just to echo what the panelists have said, I think we'll never get there, but the

learning along the way is really, really essential to drive continuous improvement. And industry hungers for that learning, they hunger to learn more, get better data. And directionally, if we just learn, hey, poultry is a place to stay away, or more importantly, poultry is a place to manage more carefully, then we know how to prioritize our resources.

DR. GOLDMAN: Thank you for those comments. I had another question somewhat related to what especially Barb was just saying. In our agency, when we develop performance measures, as an example, we have to convince many people who aren't familiar with the science or the data analysis that we've done about the conclusions that we've reached. And what we've learned is that we often, just like Barb was saying, we are changing our methods. We're improving our methods as we go. And, so, we're challenged to explain how it was that last year we said X percent and this year we're saying Y percent, and show the pathway from one year to the next when we have changed the method. And I guess the question I was going to get to is, in this clearly changing landscape, are you comfortable with that fact, and should the public be comfortable? They're the people we're trying to serve here.

And, in particular, to make the point, Mike Hoekstra

said, basically, within a year, we're going to have agreed-upon outbreak-based attribution fractions that all agencies will agree on. And we're going to start moving out presumably on those estimates knowing, though, that we are going to refine those estimates. We're going to try to incorporate sporadic case data as we go along. I just want to make sure that everyone, if you represent a wider audience, everyone here is comfortable with that.

Go ahead, Barb.

DR. KOWALCYK: So, I think most of you know I used to work in the pharmaceutical industry before I became involved in food safety, and my very first boss sat down, and I was doing clinical research, and my first boss sat down and said to me, "Sometimes consistency is better than being right." And it was a very valuable lesson because our goal was to really take all of these different clinical trials and combine them and assess the trend over all the trials. If that's your goal, then consistency is very, very important. Okay?

I do think there's a balance there. You need to be consistent so that you can assess trends, and that's one of the objectives in the Strategic Plan. I don't know the answer of how to balance that because we do need new methods developed at the same time, but it depends on your

goal.

I mean, one of the things that policymakers are going to want to look at is measuring the progress of the various agencies and the industry over time on preventing foodborne disease. If you change your methodology all the time, it's really hard to do that. But this may be opportunity to validate. I mean, if you use the same methodology over and over again and actually put that systematically into place, you may be able, as you develop new methods, use that as a way to validate those new methods and see how you get better precision. I honestly don't know the answer, but it is a trick and it does come down to balance. So I don't think it's clear-cut.

DR. GOLDMAN: Anyone else want to comment?

DR. CIESLAK: Ditto.

(Laughter.)

DR. GOLDMAN: So, Paul, you're okay with us using outbreaks even though you're very concerned about the use of outbreak data.

DR. CIESLAK: You know, I mean, as Dana Pitts was articulating earlier, I mean, it's important to be thinking about this now and to get all the appropriate caveats out there and to let people know that there is a lot of uncertainty around these data and these are sort of best

guess right now and they're subject to change at any time.

I think most of the public is fine dealing with that kind of uncertainty, although when you get your first hundred calls about it, it's not going to feel that way. And, certainly, the industries being regulated have a lot more at stake in general, so you need to be careful and put it out there with all the appropriate caveats.

DR. GOLDMAN: Joan or Mike?

MR. BATZ: I mean, I generally agree. I think there are a lot of other examples of other agencies that make estimates, you know, whether it's on energy or weather or anything else that they're not certain about. And I think that if they're done regularly and there's a systematic process for updating them that people are aware of, people become aware that they're estimates and people become comfortable with -- there may be uncertainty in the estimates, but there is certainty in the way that they were estimated. And I think that as those things gel over time, I think the first couple of years maybe are rough, but I think that that stuff evens out, and I'm fully in favor and very comfortable with that stuff being out there.

MS. MENKE-SCHAENZER: Yeah. And from an industry perspective, I'm comfortable as well. I think we all know we live in an imperfect world, and if we have the direction

and the focus we need, that will help us move to be preventative.

DR. GOLDMAN: All right. Well, I want to thank our panel. We really appreciate your insights and we look forward to your further comments. And we're going to transition now to the Public Comment Period, and I'm going to ask Greg DiNapoli to come back up to moderate that.

Thank our panelists, please.

(Applause.)

PUBLIC COMMENT PERIOD

2:45 - 3:45 p.m.

MR. DiNAPOLI: Okay. As Dr. Goldman said, we're going to move into the public comment. We have our principals here in front of you. They are here to listen. They are not there to actually take more questions. So, just to clarify that.

So, we're going to go right into it. We've got 5 minutes per public comment, and I want to remind everybody that if you don't get your comment in now, you've got until, I believe, March 1st to get your written comments to the public docket.

So, Charles Joseph McClure, I believe you're the first.

If you can, again, when you come up to the podium, go

ahead to the podium right there, and for everybody else, when you come up, state your name clearly and your affiliation, so say who you're with. That would be great.

MR. McCLURE: Good afternoon. My name is C.J. McClure, and I'm here with my LEGO Robotics teammates: Austin Hwa, Thomas McClure, Jonathan Nguyen, K.C. Simmons, and Dev Singh. Our team name is the Chef Bot-Ardees, and we are 6th graders at Charles F. Patton Middle School, and Thomas is a 4th grader at Chadds Ford Elementary School in the Unionville-Chadds Ford School District in Pennsylvania.

The theme of this year's LEGO Robotics Challenge is "Food Factor," or "Keeping Food Safe." An integral part of the competition is the requirement for each team to identify a problem associated with the theme, conduct research, and create an innovative solution that prevents or solves the problem.

You might wonder why there's a research project in a Robotics competition. Throughout the project, teams learn more about the science behind the theme and can better understand the work of professionals in the field. It gives teams the chance to take what they learned and apply it through research, critical thinking, and creativity.

Another integral part of the project is the requirement for each team to share their research and

solution with others, which is why we're here today.

We believe our research and findings are particularly applicable to the topic of foodborne illness attribution. We agree with the FSIS's findings that most foodborne illness is not associated with detected outbreaks and a great deal of it goes unreported. The milder cases that are unreported are still significant because of the physical discomfort experienced and the potential for lost wages or lost time from school due to the effects of the foodborne illness.

The greatest risk assessment identified by our team was the mishandling of beef, poultry, and pork in the home by the consumer, particularly with respect to refrigerating or freezing these foods at an improper temperature. It would be safe to say that nearly every home in America has a refrigerator; therefore, every member of the household is at risk for foodborne illness due to improper food storage temperatures.

Our research is focused on beef, but our findings are applicable to poultry, pork, and other temperature-sensitive foods, such as milk and eggs. We chose beef because all of us on the team eat beef and because the USDA statistics show that Americans eat an average of 60 pounds of beef in a year, and that's a lot of beef.

(Laughter.)

MR. McCLURE: We focused on food safety in the home because the consumer is the last line of defense against foodborne illness. Beef is inspected by professional inspectors from the FSIS and/or state or local inspectors from everywhere along the line, from the ranch to the slaughterhouse, the refrigerated trucks, to the supermarket, and even restaurants, except in the home. Consumers are on their own to take care of storing beef safely in the home.

Beef has to be stored in the refrigerator at 40 degrees Fahrenheit or below, and in the freezer at zero degrees Fahrenheit or below, or potentially dangerous bacteria can multiply exponentially in as little as 20 minutes. You can't see these bacteria, and the beef looks normal, which makes the danger even more serious because you can't tell by looking at the beef that there's anything wrong with it. Of course, the consumer wouldn't eat beef that was moldy or smelled bad, but beef that has been stored at an unsafe temperature usually gives no outward indication that there is anything wrong with it.

Our team started our research within our own families. Each of us has gotten sick at different times from something we ate. Thankfully, none of us were so sick that

we had to go to the hospital. However, we were sick enough to miss a day or two of work or school. We did not report our illness to any government agency.

We found that none of our parents knew the safe temperature for beef storage, and those of us with letter or number temperature settings, had their refrigerator set too warm when measured with a refrigerator thermometer. We wanted to find out if this was a common phenomenon, so our team surveyed parents of 6th grade family consumer science students at our middle school and found that almost 100 percent of those adults surveyed did not know what temperature the refrigerator or freezer should be set to in order to keep their food safe. Also, if the refrigerator or freezer used letters or numbers and wasn't digital, the adults did not know what temperature it was actually set to.

Next, we wanted to find out if the refrigerator or freezer manufacturers gave their customers any information about food safety in their manuals. We reviewed a sampling of manuals from every U.S. refrigerator and freezer manufacturer and found that only one, Sub-Zero, a very high-end model, included any discussion of food safety or why the appliance should be set to the manufacturer's suggested temperature.

Our team has written to these manufacturers about our findings and urged them to include food safety language in subsequent manuals and references to foodsafety.gov and the FSIS's website. So far, we've heard back from GE, Miele, LG, and Samsung, who said they would forward our suggestions to their engineering departments for consideration.

We also wanted to see if the public was made aware of the proper refrigerator and freezer temperatures for beef from any information on the packaging of the beef itself. Our team examined the safe handling instruction label that is mandated by law to appear on all beef, poultry, and pork. The label simply reads, "Keep refrigerated or frozen," without any mention of what temperature to keep the product refrigerated or frozen at. And as you know, the temperature matters. Refrigerating beef at a too warm temperature is one of the main reasons that beef can be rejected during the inspection process, but there are no inspectors in the home to check the consumers' refrigerators or to remove beef that is stored improperly.

Our team is preparing a petition to amend the safe handling instruction label in 9 CFR Section 317.2 through rulemaking to read, "Keep refrigerated (40 degrees Fahrenheit or below), or frozen (at zero degrees Fahrenheit

or below).

Our team submits that the public is much more aware of issues such as handwashing, cross-contamination, and cooking food thoroughly than they are of the importance of proper refrigerator and freezer temperatures. Adding the recommended temperatures to the safe handling label will increase public awareness of this issue and prevent many instances of homegrown foodborne illness.

In summary, our team believes that its research shows that the public's lack of knowledge of safe refrigerator temperature constitutes a major risk factor for potential foodborne illness and the source for the illness. The good news is that foodborne illness attributed to unsafe food source temperatures in the home can be overcome by educating the consumer.

We urge the newly formed IFSAC to examine the last link in the food safety chain, namely, the consumers' food safety practices in the home, as a significant source of attribution. We welcome you to use the tagline we came up with for educating the consumer about our research, "Set It Or Regret It!"

(Laughter.)

MR. McCLURE: Our team sincerely thanks you for the opportunity to address you today.

(Applause.)

MR. DiNAPOLI: Thank you very much. I don't think that we're going to be able to give that much time to our next following commenters, but I was a little liberal there. I'm sure you all would have done the same.

(Laughter.)

MR. DiNAPOLI: Our next commenter is Cindy Roberts, from the Center for Science in the Public Interest here in Washington.

MS. ROBERTS: Wow. Difficult to follow a group of brilliant 6th graders.

(Laughter.)

MS. ROBERTS: But anyhow, I want to thank the agencies for sponsoring this meeting and for the work you're doing in IFSAC and the work you're going to do in IFSAC. This is a very important issue, attributing foodborne illness to specific foods is critical to understanding hazards across our food supply and to designing risk-based interventions.

My comments today will focus on the food categorization scheme that Dana has already shown us what CDC currently uses, the 17 food commodities, and has given us a little preview of some of their updating that they're going to do. But, still, this categorization scheme is commodity-based and not very intuitive to consumer or to

outbreak investigators. CSPI suggests a more consumer-oriented categorization scheme, such as the one described in outbreak alerts and used by Michael in his research.

A food categorization scheme should be intuitive to those responsible for ensuring food safety along the farm-to-fork continuum. A categorization scheme aligned with the consumer end of the food supply would also be useful to food safety regulators. Focusing on foods, as eaten, would help elucidate processing and preparation risks that can be added to a food as it moves along the continuum.

For example, an outbreak from a bakery product could be categorized as a grain outbreak under a commodity-based scheme. But as the majority of outbreaks in bakery products are due to norovirus, *Staph aureus*, or *Salmonella*, it is more likely the result of post-processing contamination, food handling, or the addition of other high-risk foods to the product.

A categorization scheme should include a category for complex foods, again, those that do not fit into a single category, such as Dana's lasagna, sandwiches, salads, casseroles. And as we learned, about 50 percent of the outbreaks were due to complicated foods.

Although very broad categories can be useful to distinguish broad trends, to best analyze risk and

categories, categories should be broken down into subcategories. For example, it would be useful to know if the outbreak vehicle was apple cider rather than just apples. Likewise, it would be useful to know if the food was milk or cheese and not just a dairy product, and if the milk or cheese was pasteurized or unpasteurized.

Further categorization could include imported or domestic processing type, raw versus ready-to-eat, fresh versus frozen, organic versus traditional, or species for meat products, such as poultry.

Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Cindy.

Next is David Webber. I think we actually clapped just for that.

(Laughter.)

MR. DiNAPOLI: I'm kidding. I've never heard an audience clap for -- unless it was really good.

(Laughter.)

MR. DiNAPOLI: But that was good.

(Laughter.)

MR. DiNAPOLI: David Webber, with Pennsylvania Regulatory and Political Affairs.

I'm sorry, it says "Brussels." Is that -- is it

Brussels, Pennsylvania? Brussels way over -- I guess he's not here.

Chris Waldrop, CFA.

MR. WALDROP: No need to applaud.

(Laughter.)

MR. WALDROP: Chris Waldrop, Consumer Federation of America. Just a couple quick comments. They won't be nearly as thorough as the LEGO team's.

I just think it's terrific that the agencies have come together around this initiative. It's clearly a very important element and aspect of our food safety system that needs to be addressed and has needed to be addressed for a long time. So I'm glad the agencies are doing this.

As we heard, we have had meetings about attribution in the past, and then things have kind of gone away. So, I think we have some momentum here and some energy around here that I hope will kind of carry us through. You putting out a Strategic Plan and asking for public comments; I think is a very good first step to try to harness that and move forward. And as I said in the questions, I just hope we can identify ways to continue to keep this momentum going through administrations and through the next several years so we really can make good progress on this and not have the same meeting again in a

few years.

A lot of this meeting talked about what we do with the data when we have it in order to better analyze it and give us better information in terms of attribution, but the end result depends on the data that comes in. And there was some discussion about better standardization, better reporting. So I think that may be an element that IFSAC wants to take a look at. There may be other venues in terms of the Food Safety Modernization Act has I think a requirement to look at surveillance, and that may be a venue to look at this, but I think it is important to continue to remember that -- or to look at, are there ways of standardizing the data, better ways to collect the data, more timely data, making sure we're getting the right data? All those sorts of inputs, I think, are going to be important to the outcome that you're trying to get here. So, I just encourage IFSAC to keep that in mind.

Thanks.

MR. DiNAPOLI: Thank you, Chris.

Michele Samarya-Timm, Summerset County Department of Health, Summerville, New Jersey.

MS. SAMARYA-TIMM: I want to thank the folks that put this together for scheduling a meeting to better educate us all on Interagency Food Safety Analytics, which is

certainly a mouthful. And prior to coming here, I'm not sure that everybody did have a good handle on what the whole concept of what this project is going forward. And I also want to thank you for allowing me a moment to go ahead and to comment on this.

On the train coming down here yesterday, I reviewed the documents for this particular meeting, and I also reviewed a number of the documents from the previous meetings and some of the work that the folks here have done on this issue prior to this. And while reviewing the past and present documents, I found little or no reference to local health.

I just want to remind folks that local public health does have complementary responsibilities to the CDC, to the FDA, to the USDA, and a large burden of the foodborne illness and foodborne outbreak data collection falls on the shoulders of the dedicated local public health workforce. In many respects, this local public health workforce is the extension of these federal agencies. At a local health level, we are a partner with the CDC, with the FDA, with the USDA, in foodborne illness prevention, and we would like to complement these activities however we can.

Given the important role that local public health agencies play in food safety and the food protection

system, please explore effective means of two-way communication with local health on this and similar issues. And I urge you to please consider making your local public health colleagues part of the team working on the IFSAC priorities. I also invite you to ask 11-year-olds to join the team because I think they've done more for moving forward some aspects of health communication that even I, as an educator, did.

Thank you.

And, also, please bring the next public meeting to the wonderful State of New Jersey.

(Laughter.)

MR. DiNAPOLI: Thank you, Michele.

Patty Lovera, Food & Water Watch?

MS. LOVERA: Hi, everybody. My name is Patty Lovera, and I work for a consumer organization called Food & Water Watch here in D.C. And, actually, our comment is very compatible with the previous comment, which is a coincidence. But we appreciate the chance to learn about the Strategic Plan and the new efforts to really deal with research and attribution, but we did just want to mention, you know, we can't forget the immediate situation we face unfortunately all too often of trying to figure out what is making people sick at a given time, and that's something

our members and supporters and lots of other consumer organizations deal with every day, is, what advice do we give when there is something in the news and it's not clear what's making people sick?

So, we thought of a couple things we wanted to bring up. We understand the tension between the need for a rapid response and to tell people an answer and the tension that creates with knowing, with any accuracy, what the source is. And we are aware of that, but it seems like we seesaw back and forth between how to deal with that tension. And that causes a lot of confusion for consumers, and it's just becoming more critical every year that goes by. We have more and more multi-state and national and large recalls. We have these rolling recalls because of processed food ingredients. So, we don't want to forget, as we do the Strategic Plan, about the attribution process, the need to deal with this day-to-day response that we keep having to do.

And, finally, we were going to make the exact same point that we just heard about from a local health department regulator, is that we have a lot of public health infrastructure on the ground, but currently it's under an enormous amount of budgetary pressure. We need state and local health department folks who are the boots

on the ground, who are the ones asking questions of people, what they ate. We need them to be able to do what we ask of them, and they need the resources to do that. And it sounds like we also need to standardize, a little bit, what they're asking. So, we just wanted to inject that into the conversation.

Thanks.

MR. DiNAPOLI: Thank you, Patty.

Kate Arding, from American Cheese Society, Denver, Colorado.

MS. ARDING: Well, firstly, thank you for inviting the American Cheese Society, the ACS, to present the views of small cheese producers on foodborne illness source attribution and product traceability. I'm Kate Arding, and despite my accent, I'm a current board director of the American Cheese Society --

(Laughter.)

MS. ARDING: -- the leading association supporting and promoting North American cheeses and cheesemakers.

ACS has some 1,500 members, including artisan, farmstead, and specialty cheesemakers, as well as many dairy farmers, retailers, distributors, academics, and enthusiasts.

There are several aspects of foodborne illness source

attribution of concern to ACS members, and when considering traceability, we hope the FDA will consider the following three points.

Number one, science-based risk assessments which consider where the highest risks have statistically been and which recognize the unique traditional techniques of artisan cheesemaking. Ready-to-eat processed food, high-volume producers, and post-production contamination are where the highest risks have statistically been, so ACS suggests that new and potentially costly tracking requirements be focused on those areas and relevant businesses.

Small dairies and cheesemakers create products that meet all state and federal safety parameters and requirements, but they achieve these successful ends through means which differ from those of commodity producers. Studies have shown relatable low pathogens associated with small farms and food processors, including farms-to-cheese facilities. ACS hopes to work with the FDA to develop sound, science-based safety protocols for this specific industry and to create the best practices for monitoring and mitigating risk.

Cheesemakers are hard working, passionate, and conscientiously dedicated to continuing their successful

track record of producing safe, healthful, diverse, and delicious foods. Many ACS members are third-party certified to help ensure their practices are safe and current. The American Cheese Society asks that the FDA keep the unique traditional methods of artisan producers in mind while developing any system for foodborne illness traceability.

It is ACS's position -- and the epidemiological data confirm -- that raw milk and pasteurized milk cheeses can be and are routinely made safely. Production processes with clear steps, monitoring, testing, and well-designed and implemented safety or HACCP plans are reasonable and can be created while still following many traditional methods.

Number two, establishing reasonable recordkeeping protocols with a direct correlation to scale and risk. FDA has stipulated that reporting requirements may not require a facility to change business systems to comply. We rely on this and on the FDA to follow recordkeeping parameters established by Congress.

We also hope the FDA will consider the differences that are integral to artisan production and which allow small businesses to operate, providing viable livelihoods and economic structures for farm communities. Any changes

or additional recordkeeping requirements that overburden small businesses will ultimately adversely impact local economies and communities.

In ACS's first industry-wide survey, conducted in 2011, 73 percent of responding cheesemakers said they plan to grow their operations in the next 5 years, and 23 percent strive to retain their current size. This stability in growth will further strengthen communities and boost the economy.

Dr. Catherine Donnelly, at the University of Vermont, has examined the benefit of small cheesemakers to their communities and found that for a farmer with 50 cows, annual gross revenues from food milk would total $100,000. Making artisan cheese from that same milk would transform that into $1 million and employ many more people.

Given the importance of small businesses to local communities and the overall economy of the nation, ACS asks to be kept abreast of any recordkeeping requirements which could inordinately impact these small producers so they have time to plan and adjust accordingly.

And, lastly, education outreach for the farm, facility, distributor, inspector, and state departments of agriculture. ACS is growing along with its members and is offering the most relevant and timely educational

opportunities to our cheesemakers. We actively seek FDA's cooperation and collaboration in this educational process, and, to that end, we have invited John Sheehan to participate in a panel discussion on working proactively to assure cheese safety at our annual conference this August in Raleigh, North Carolina.

As an industry resource, ACS recognizes the important educational role we play. This year, we will continue our emphasis on food safety by further defining best practices for our members and providing more tools to help them create and improve HACCP plans. Per our 2011 survey, almost three-quarters of ACS member cheesemakers currently have a HACCP plan in place.

Through outreach, education, training, resources, and certifications provided through land-grant universities, some 2,900 extension offices nationwide and associations like the American Cheese Society, we can ensure that cheesemakers have the tools and information they need to proactively adhere to industry best practices and comply with regulations. We recommend active FDA participation in industry education and expanding outreach exponentially through collaborative efforts.

Thank you.

MR. DiNAPOLI: Thank you, Kate.

Theodore Beals, from the Farm-To-Consumer Foundation.

DR. BEALS: Yeah, Ted Beals, physician, retired diagnostic pathologist, educator, and researcher at the University of Michigan. Since retirement, I've devoted my professional activities to food safety. I am on the Board of Directors of the Farm-To-Consumer Foundation, serving as a health consultant to that national and other nonprofit organizations that are focused on quality food.

One of my roles has been to make food safety science more understandable to consumers and to farmers. It is extremely difficult to find additional comments that have not been presented in the years leading up to this meeting and the comments that have been made at this meeting. And I support the need to harmonize attribution activities. I urge that attribution rely on settled science, and I promote coordination of the agencies represented here by the principals. And I applaud the use of the word "contaminants" for the first time today.

As an educator, you all know that I have a hard time speaking less than 55-minute segments, but I am going to confine to the rules, so I will only speak on a few of the points that I have made in my extended written remarks.

My first has to do with public perception. I think everybody in this room understands the degree of

uncertainty that is present in much of the data that we're talking about today. However, the interested audience includes health care workers, producers, consumers, journalists, lawyers, and even insurance adjusters. They are attracted to tables with numbers, and naively believe that since they are numeric, they must be solid fact. This communication inefficiency must be addressed or the considerable efforts needed to generate useful information will become discredited and considered a waste of resources.

Don't blame the messenger or source versus vehicle. I've heard a number of times today -- and it's a perfect example of it -- the statement, "Which food is responsible?" Published reports of attribution to food, most importantly, warnings about possible health risk to consumer, blames specific foods. There is unacceptable collateral damage to the reputation and marketability of those foods. The effect is even more damaging to consumer choice and producer income when the actual potential threat is not from the food itself, but from the handling or processing of some innocent food that happens to be in the chain.

You need to be certain that the attribution is specific and does not disparage the generic product or the

product category, particularly when the food that is targeted is not the actual source of the risk. This is more onerous when the announcement or attribution occurs after the cluster of illnesses is waning and the vast majority of the blamed product has already been consumed. Fallout from misdirected attribution to a food has far more social and economic impact than the potential risk of the illness.

There is a category that I have called "Bad Attribution Leads to Flawed Mitigation," and I only want to summarize by saying opinion leaders and elected officials are focusing risk-avoidance laws based on attribution without evidence that the enacted actions have been shown in practice to actually mitigate the risk that they fear.

One final comment. My most significant concern about the process of attribution, whether intended or not, is that we end up blaming food, food which is not a luxury or a convenience, but a fundamental necessity for the proper development and well-being. The finger is pointed at the food and animals, occasionally at processing, but attribution rarely points the finger at the most important source reservoir of the specific virulent organisms, people with infectious gastroenteritis.

The largest numbers and highest concentrations of the

virulent organisms that we are specifically interested in are shed from sick people, not animals. This has been dramatically demonstrated by the European outbreak this year which was associated with the unexpectedly high incidence of hemolytic-uremic syndrome.

When asked what I would pick as the single most effective risk management policy, I reply, "Keeping people with diarrhea away from our food, our food processing, our food distribution, and our food elements." There are some foods that cause illness, but most of the so-called foodborne enteric infections are not caused by the food itself.

Thank you.

MR. DiNAPOLI: Thank you, Ted.

Betsy Booren, with the American Meat Institute.

DR. BOOREN: Hi. I'm Betsy Booren. I'm Director of Scientific Affairs for the American Meat Institute. AMI's members slaughter and process more than 90 percent of the nation's beef, pork, lamb, and veal, and a majority of the turkey produced here in the United States. AMI and its member companies support achievable public health objectives based on sound science that significantly improve public health through quantifiable metrics. The use of science and food safety metrics is critical to the

food industry to design and implement preventative food safety process management systems.

In September 2010, the AMI Foundation, the research foundation supported by AMI members, sent Dr. Braden a letter stating, among other things, accurate, more timely foodborne illness attribution data is critically needed to improve the safety of the U.S. food supply. AMI is here today to reiterate that same message.

Food attribution data is essential to better understand the relationship and the associated risk between microorganisms and food.

Dr. Braden, you have said that knowing more about the types of food and the foodborne agents that have caused outbreaks can help guide public health and the food industry in developing measures to effectively control and prevent infections and help people stay healthy. AMI agrees with that and believes food attribution data is critical in a preventative process management food safety system.

Having and utilizing objective data allows food safety stakeholders to allocate food safety resources appropriately and scientifically justify the decisions made in their food safety systems. By having timely, credible food attribution data, the food industry can accurately

identify and improve any food safety gaps that may exist. It may also help identify emerging foodborne risks, especially when no such risks have been previously identified before. This rapid adjustment to improve food safety can only occur if accurate data is made available as soon as possible to all food safety stakeholders.

That said, AMI recommends the following.

Accelerate the release of food attribution data beyond the current status of 1- to 2-year delay. This delay does not allow for rapid changes -- the industry food safety systems does not allow for rapid changes for the industry to make to their food safety systems that may likely prevent future foodborne illnesses or events.

Two, expand food attribution categories, as needed, to accurately characterize and report the causative agent in a foodborne event.

Three, there should be a yearly stakeholder briefing with CDC, FDA, FSIS, and the food industry. This should create a dialogue to exchange information and share lessons learned.

There are many differences in the processes each of the groups go through during an outbreak or other food illness events, and those differences are sometimes not clearly understood among the groups. This knowledge may be

the key in improving the attribution process during a foodborne event.

And, finally, there should be a clear communication regarding changes and revisions to the CDC Foodborne Outbreak Database. AMI uses this as a resource as a way of providing information to members to improve their food safety process management systems. AMI recommends changes to this database or other future or similar tools be communicated to stakeholders in a clear, transparent process that is easily extinguishable.

We believe our recommendations have merit and are important to improving the safety of the U.S. meat and poultry supply.

We do recognize the challenges of accurately estimating the burden of foodborne illness and attributing those burdens to food types, but these metrics are essential. The last decade has shown the important role of cooperation and communication among public health officials, regulators, the food industry, and other allied stakeholders have had on ultimately improving food safety.

If it's not clear, AMI supports the efforts of IFSAC.

Thank you for your consideration, and we look forward to future collaborations.

But before I go off the record, I want to say AMI has

been working with similar groups like the gentlemen here today for the last couple months. Tremendous effort. We applaud you. If this is the next generation of food safety people, we might be in good hands.

Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Betsy.

Next is Manohar Furtado, with Life Technologies, Foster City, California.

MR. FURTADO: Good afternoon. My name is Manohar Furtado. I work for a company called Life Technologies. We are a biotechnology tools and reagents provider, and we sell materials into the life sciences base for breakthrough research in medical areas. We also have offerings that help with pathogen testing in foods, analysis of contamination in pharmaceutical products, animal diagnostics, and medical/clinical testing, as well as for forensic cases.

We appreciate the opportunity to share with IFSAC our thoughts on the use of rapid nucleic acid sequencing matters for pathogen detection, identification, and source attribution.

Life Technologies is a company that has been around for about 30 years, and we pride ourselves in providing

complete solutions. We have worked in the past with government agencies to put in place testing for things like anthrax, the H1N1 influenza testing, and more recently, helped solve the *E. coli* O104 outbreak in Europe by sequencing the entire pathogen.

Currently, a large proportion of the food testing is based on culture-based methods, biochemical characterization, and serotyping. One of the issues with many of these methods is they're as specific or discriminatory. There is a need for rapid methods of detection of bacterial, fungal, and viral pathogens similar to what's going on, for instance, in the molecular diagnostics base for human diagnostics, but the food industry is lagging behind as far as implementation of these methods go.

Increasing the use of molecular methods in a wider setting will definitely improve rapid detection, rapid response, and have a significant impact on the cost of foodborne illness in terms of lives as well as dollars by preventing outbreaks, by shortening the duration and spread. It's possible to multiplex these tests, so you can also work towards reducing cost.

As far as source attribution goes, there are a number of methods from PFGE to MLSD, SNP typing and NTR (ph)

panels that are used for identification in placing outbreaks. These methods are useful in addition to serotyping, of course; however, they interrogate a small proportion of the genome and a couple of publications recently comparing pulsed-field gel data with whole genome sequencing that definitely indicated the limitations.

So, definitely identification of strains requires not only the identification of the pathogen in a rapid method with a particular food type, but this has to be followed by a very reliable strain typing procedure that would be able to trace the food back to the source and determine the final contamination.

We believe that in the future there is going to be whole genome sequence using newly available next-generation sequencing formats that can be used effectively for strain typing in a cost effective manner and has the potential to replace current methodologies and to speed up the entire process. The 014 strain in Europe is a good example. It took 2 days to sequence the whole pathogen, and we had tests in place in about 10 days.

Whole genome sequencing typing, or WGST, we believe is the method of choice; however, in order to deal with the large quantities of data generated from these methods, industry and the food safety agencies worldwide should

develop global standards for sequence data formats to enable sharing. They should also develop easy-to-use bioinformatics tools that simplify interpretation and generate actionable information from genome sequence data.

Finally, sequence information for many of the less well-studied pathogens will be needed to populate reference databases. We believe that deployment of rapid molecular methods will greatly improve food safety and source attribution and that IFSAC team should adopt and disseminate these methods in their procedures.

Once again, I would like to thank the agencies involved for holding this important meeting, and Life Technologies looks forward to continuing discussions on this important issue.

(Applause.)

DR. DiNAPOLI: Thank you, Manohar.

Next is Nancy Donley, with STOP Foodborne Illness.

MS. DONLEY: Thank you very much. And I want to thank the agencies for holding this meeting today. However, I do feel compelled that I have to register a formal complaint, that this meeting was held simultaneously when another very important meeting was being held at the Commerce agency. And poor Dan Engeljohn is hearing this for the second time today; Tony Corbo, from Food & Water Watch, lodged the same

complaint at that meeting.

Both of these were very, very, very important meetings, and I felt like I had to opt in or opt out for one or the other. I chose both, so I didn't get a complete understanding of either one of the meetings. So, I encourage the agencies to look at calendars a little bit better in the future.

That said, I would like to put on this particular meeting is that I think the time has really come to focus on the tip on the base of the iceberg, if you will. What we've been hearing a lot about is focusing on the tip of the iceberg, and those are the foods that are attributed in foodborne illness outbreaks. The vast majority of foodborne illnesses, though, are from unknown foods, and because they're more difficult to trace, it's alluring to focus on the low-hanging fruit, that are represented by foodborne illness outbreaks.

Moving forward, we do need to think further and broader than current practice. In other words, be more proactive than reactive. We need a better understanding, for instance, of pathogen etiology. We also need better methods of controlling and eliminating pathogens in animal reservoirs. And we need to have a better understanding of how foods get contaminated in the first place.

Now, I am not a scientist, I will be the first to tell you, who has the answers to these concerns and questions, or even the best way to go about getting them, but I do just want to reinforce that it is the time to get a better handle on what the base of the foodborne illness iceberg is composed of, and that time is now.

As a representative of a consumer organization that represents foodborne illness victims and their families, I can't drive this home nearly hard enough. Suffering or dying from a foodborne illness is horrifying enough, but it's magnified exponentially when the source, the actual food, is unknown.

Thank you.

MR. DiNAPOLI: Thank you, Nancy.

That concludes the Public Comment Period. And at this point, I'm going to invite Dr. Goldman for closing remarks.

CLOSING REMARKS

3:45 - 4:00 p.m.

DR. GOLDMAN: Thank you very much, Greg. And thanks to those of you who contributed to the public comment just now.

This is an unenviable task for anybody who has had to try to summarize a meeting, but I'll grant you a sigh of relief. I'm not going to go through the agenda. I'm not

going to go through each point that was made. This was a very complex meeting on a complex issue, and as was noted earlier, you will have access to all the presentations and to the transcript of the meeting in the near future. So, again, I'm not going to go through that.

I do want to start out thanking the group from Chadds Ford, Pennsylvania. I got to meet them at the break this morning, and I'm impressed not only with their scientific understanding of a very important issue, but their advocacy. They spent part of the day today meeting with their congressional representative. So, I encourage them to continue their civic activities, as well as their scientific undertaking. So, help me thank the group from Chadds Ford.

(Applause.)

DR. GOLDMAN: I wanted to just mention, from the FSIS point of view, how important attribution is by briefly illustrating a situation that we encountered and then some actions we undertook about 5 or 6 years ago as a way to show you that attribution really is important to the regulatory agencies, and in particular, important to the regulatory agencies who do need to work with their industry partners to ensure that food is produced safely.

Back in 2005, the agency's data on *Salmonella* in

broilers showed that 16.3 percent of the broiler carcasses that were sampled were positive for *Salmonella*. This was at the time when FoodNet was reporting to us that the human race of salmonellosis had not budged since the beginning of FoodNet. And it was a cause of great concern for all the partners in FoodNet, but, in particular, the regulatory agencies. And, of course, at that point we knew that some salmonellosis is attributable to consumption of chicken. We didn't have a very good understanding of the percentage of salmonellosis that was attributable to chicken, and we still don't have a real clear idea, although I think we have a better idea. But, as a result of this rather alarming percent positive rate in the sampling that we do -- and I should very clearly say this is not random sampling, and it's a complex sampling scheme, I won't go to explain that at this point -- but because of our alarm at that very high rate of *Salmonella* on the broiler carcasses that we sampled in that year, we undertook some policy changes in cooperation with the industry that produces broilers for consumption in this country and for export. And over a period of several years and to date, that percent positive figure has decreased by almost two-thirds.

Now, at the same time, for those of you who pay attention to the FoodNet annual report, human salmonellosis

has not changed, it is virtually unchanged over the period really since the beginning of FoodNet.

So, that little vignette tells us and should illustrate for all of you how difficult attribution is and how important it is to understand what your target is when you start aiming downstream.

I won't say that we are concerned that we launched the program that we did. We certainly believe, and it's laid out in the HACCP rule, that prevention of contamination of any of the meat products that we regulate is an important contributor to decreases in illness. We now know, of course, that there's not a straight line between product contamination and illnesses.

So, I just wanted to share that as an example of something of a case in which attribution information in the future will very much help our agency in moving forward.

I did one of these unsystematic word mapping exercises during the day today. You know, you've seen these little graphical depictions of the words that are used in a given venue, and I just wanted to share some of the words, sort of the positive and the negative.

So, on the negative side -- I categorized these as negative, but you can decide for yourself -- I heard the word "complexity" used quite a bit. I heard the word

"uncertainty" said repeatedly. We talked about limitations. There were concerns about data quality that were raised. One of the commenters just now talked about misattribution as a concern.

On the other side, on the positive side, if you will, I heard the terms "transparency" used, "coordination," "shared" or "common" approaches, and communications.

And I want to transition now to the issue of communications. I thought Dana Pitts did a really excellent job of sharing with you the concerns we've had about how to communicate this issue, and so we'll be interested, in particular, on your feedback about her presentation and her question about whether or not this should be a project unto itself within IFSAC.

But essentially what we've done today is sort of pull the curtain back on what for many has been sort of a black box of activities that the federal agencies have undertaken over the years. A lot of you, as I mentioned at the beginning, are insiders. You know this issue, and you understand it pretty well, but there are others who are not as familiar. And we thought it was very important, as part of our obligation, to be transparent, to share with you, not only what we're doing, but how we're approaching this. And we really do earnestly and honestly want your feedback

on that, so please do that.

The other point that was raised a couple of times today was, although we are proud of the fact that in the Strategic Plan we talk about having our products peer-reviewed and published in scientific journals, we know that can't be the only solution in terms of communicating the results of our efforts, and so this meeting was important, at least, in part, for that purpose, to share with you what we plan to do.

Today was a combination of sharing our strategy and some of our strategic and tactical, some of our actual operations and projects. I think we have raised expectations here among you attending that we will report to you periodically; I think we all acknowledge that. The Steering Committee has not -- we haven't decided how we want to do that, but it's pretty clear from the comments and from your participation here that we are obliged to periodically report to the public on our efforts. I heard an annual report as a suggestion, I think by Chris Waldrop.

So, we will take all of that in terms of our interaction with the public and with you, who are very interested in this particular issue, under advisement. We will have some further discussions of the Steering Committee after this meeting. Some of you will be

participating in a Pew event tomorrow, and there will be further discussion there about this issue, and particularly about communications.

Sort of in summary, I think what I heard was that overall we're on the right track. We heard appreciation for the fact that we held this meeting, that we were willing to tell you what we know and, as importantly, what we don't know or don't yet know. We did hear some very specific suggestions for data sources that we might incorporate into our estimation as well as different analytic methods to consider in the work that we do, so we appreciate that input.

I want to end by thanking a few people, but I first want to recognize our Steering Committee members. So can I ask the Steering Committee members to stand up so that you see who represents the various agencies?

(Steering Committee members stand.)

DR. GOLDMAN: So, as Chris pointed out earlier on, there are two members from each agency represented. We have a rotating chairpersonship. And FDA will be up next, so thank you to my fellow Steering Committee members.

And next, I want to recognize the Technical Working Group, as Chris Braden pointed out also earlier. This is where the work gets done. We have many of the Technical

Working Group members here. In particular, I want to recognize Joanna Zablotsky Kufel and Neal Golden and Kristin Holt, who are the FSIS representatives to the Technical Working Group, and, in particular, because they helped to put on this meeting, as well as our colleagues from the Office of Public Affairs and Consumer Education, Greg DiNapoli and others here on the front row that weren't recognized earlier. But could I ask the Technical Working Group members to stand up? You have to see this force here.

(Technical Working Group members stand.)

DR. GOLDMAN: So, there are maybe 12 or so of the Technical Working Group members here, and there are at least that many others who aren't here today who participate. And, again, this is where the work gets done, and we really appreciate their efforts.

I think with that, I want to close by again thanking you for being here, for hanging in here for a full day. And please let us know when we should get back together with you again and share our progress on the projects you heard outlined today as well as the projects that are going to be approved and undertaken in the next year.

Thank you again.

(Applause.)

(Whereupon, at 3:34 p.m., the "Foodborne Illness Source Attribution Public Meeting" was adjourned.)

CERTIFICATE OF NOTARY PUBLIC

I, NATASHA KORNILOVA, the officer before whom the foregoing hearing was taken, do hereby certify that the testimony appearing in the foregoing hearing was taken by me in audio recording and thereafter reduced to typewriting under my supervision; that said transcription is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

_____

NATASHA KORNILOVA

Notary Public in and for the

District of Columbia