# INTERAGENCY FOOD SAFETY ANALYTICS COLLABORATION (IFSAC)
# PUBLIC MEETING 2015

Tuesday, February 24, 2015, 8:30 a.m. – 5:00 p.m. EST
U.S. Department of Agriculture
South Building, Jefferson Auditorium
14th and Independence Avenue, S.W.
Washington, D.C. 20250
&
Via Live Webcasting
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## TRANSCRIPT

The U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and USDA's Food Safety and Inspection Service (FSIS) held a public meeting on Tuesday, February 24, 2015 to update stakeholders on the Interagency Food Safety Analytics Collaboration's (IFSAC) work to improve foodborne illness source attribution. Specifically, IFSAC provided updates on work to develop harmonized foodborne illness source attribution estimates, as well as other analyses IFSAC has undertaken since its formation in 2011.

Hyperlinks to each presentation slide set are available in the agenda below and also in the appropriate sections within this transcript.

**Final Meeting Agenda**

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| **8:00 – 8:30** | **Registration** |
| **8:30 – 8:55** | **Welcome and Introductions**<br>Mr. Al Almanza, Deputy Under Secretary, Office of Food Safety<br>Moderator: Greg DiNapoli, MA, Food Safety and Inspection Service (FSIS)<br><br>**Purpose of Meeting**<br>David Goldman, MD, MPH (FSIS)<br><br>**History and Overview of IFSAC**<br>Christopher Alvares, MS, BA (FSIS) |
| **8:55 – 9:55** | **Overview of Projects: Progress, Accomplishments, and Next Steps**<br>Cary Chen Parker, MPH (U.S. Food and Drug Administration (FDA))<br>Kristin Holt, DVM, MPH (FSIS)<br><br>**Question and Answer Period** |
| **9:55 – 10:10** | **Break** |
| **10:10 – 11:05** | **Estimating Foodborne Illness Source Attribution for Illnesses Caused by *Salmonella*, *Escherichia coli* O157 (*E. coli* O157), *Listeria monocytogenes (Lm)*, and *Campylobacter*: Part 1**<br><br>• Overview of Project Approach |

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| | Joanna Zablotsky Kufel, PhD, MPH (FSIS)<br>• Exploratory Analyses<br>Dana Cole, PhD, DVM (Centers for Disease Control and Prevention (CDC))<br><br>**Question and Answer Period** |
| **11:05 – 12:05** | **Estimating Foodborne Illness Source Attribution for Illnesses Caused by *Salmonella*, *E. coli* O157, *Lm*, and *Campylobacter*:** Part 2<br><br>• Methods and Model Results<br>Dana Cole, PhD, DVM (CDC)<br>• Assumptions, Strengths, Limitations, and Conclusions<br>Michael Bazaco, PhD, MS (FDA)<br><br>**Question and Answer Period** |
| **12:05 – 1:05** | **Lunch** |
| **1:05 – 2:05** | **Use and Application of Attribution Estimates by U.S. Federal Regulatory Agencies**<br>Christopher Alvares, MS, BA (FSIS) \| **Slides**<br>Sherri McGarry, MS (FDA) \| **Slides**<br><br>**IFSAC Strategic Vision and Directions for Future**<br>Patricia Griffin, MD (CDC)<br><br>**Question and Answer Period** |
| **2:05 – 2:20** | Break |
| **2:20 – 3:35** | **Discussion by Panel of Outside Experts**<br><br>• Sandra Eskin, JD, Director of Food Safety, The Pew Charitable Trusts<br>• Arie Havelaar, PhD, Chair, Foodborne Disease Burden Epidemiology Reference Group, World Health Organization (WHO); Professor, Emerging Pathogens Institute, University of Florida; Member of the Biohazards Panel of the European Food Safety Authority<br>• Craig Hedberg, PhD, MS, Professor, Division of Environmental Health Sciences, University of Minnesota School of Public Health<br>• Scott Hood, PhD, Director of Global Food Safety and Regulatory Affairs, General Mills<br>• Christopher Waldrop, MPH, Director of the Food Policy Institute, Consumer Federation of America<br>• Shelley Zansky, PhD, Director of the Emerging Infections Program within the Bureau of Communicable Disease Control, New York State Health Department<br><br>**Question and Answer Period** |
| **3:35 – 4:45** | **Public Comment Period** |
| **4:45 – 5:00** | **Closing Remarks** |

PROCEEDINGS

Recording Timestamp=00:05
Welcome and Introductions

GREG DINAPOLI: Welcome to the 2015 Interagency Food Safety Analytics Food Safety Analytics Collaboration Meeting.

Just a couple of housekeeping notes before we get started. I do want to let everyone know that this is being Webcast. We've got roughly 200 or so folks on the Webcast.

There's going to be a transcription that will be posted as well. Because it's being Webcast and then recorded, it usually takes about two weeks for it to be posted. It will be posted on the FSIS website and the IFSAC website as well.

You'll have your folder with you with all the agenda and the bios and the report itself, so I'm not going to go through all the bios right now, but you should have all that.

Food and beverage, they're not allowed in the auditorium, so if you need a cup of coffee or something the cafeteria is the place for that.

During the question and answer phases of the meeting, if you could clearly state your name and the organization you are with, we would appreciate that.

Our cafeteria is located in Wing-3, so it's just out this way. Because we only have an hour, we do encourage folks to use the cafeteria here in the building. If you'd like to go outside the building, that's fine, too, but just know that we've got an hour for lunch, and then when you come back Wing-4 Security is the way to come back.

For members of the media, if you have not signed in at the press table, please do so. Restrooms, they're in Wing-4, 5, and 6 corridors. And your nametags that you've got, please try not to lose those. It'll help you -- it'll help Security know that you're part of this public meeting so they won't stop you and question you.

For general questions and any other assistance, you can see Juanita Yates. Juanita is -- she's kind of running around in the back. She's in the back. And also Eddie Stoker.

And we've not received a request for sign language, so we do not have an Interpreter at this moment. So, I will now open the meeting and turn it over to USDA Office of Food Safety, Deputy Under Secretary Mr. Al Almanza. Thank you very much.

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AL AMANZA: Good morning, everyone. We're certainly pleased to host you all here today for today's important discussion. I want to certainly thank everybody for being here. American consumers enjoy one of the safest food supplies in the world, but we can't take that for granted. Everyone here today, I'm sure, recognizes that a lot of hard work goes into making sure our food is safe. While we have made a lot of progress in reducing foodborne illnesses, there's still a lot more work to be done. *Salmonella*, *E.*

*coli* O577, *Listeria monocytogenes*, and *Campylobacter* cause nearly two million cases of foodborne illnesses each year in the United States.

At USDA we are focused on addressing each of these pathogens and we are continually striving to develop better ways to keep these pathogens out of the products that we regulate.

In developing new strategies for improving food safety, our efforts are greatly facilitated if we understand the context in which we are working. Foodborne illness attribution provides a context and thus is essential to those efforts.

Better attribution estimates help us to develop improved strategies for preventing foodborne illness. They allow us to target our resources to those areas that are most in need of improvement and to identify those areas in which we are making the greatest progress.

As we all know, improving food safety involves a whole lot of collaboration. CDC, FDA, and FSIS have unique roles and jurisdictions, but they share a common goal of improving public health. IFSAC is proof that the Agencies can and do work together to make meaningful progress toward achieving that goal. Since its creation in 2011, IFSAC has organized a number of analytic projects that have been advanced -- or have advanced our understanding of foodborne illness and source attribution.

Thanks to the collaborative efforts embodied in IFSAC, our future work to ensure food safety will be better informed, better targeted, and more effective.

Thank you again for being here and thanks to everyone who has worked on this important project. Your efforts will undoubtedly lead to a safer food supply. Thank you.

GREG DINAPOLI: Thank you, Al. Going over the purpose of this meeting will be Dr. David Goldman. He is the Assistant Administrator for the Office of Public Health Science (OPHS) at FSIS.

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**Purpose of Meeting**

DAVID GOLDMAN: Good morning. Let me add my welcome from FSIS and on behalf of the IFSAC Steering Committee, I welcome you to this public meeting.

Slide 1 (Webcast Recording Slide 2 of 172)

It's important for us to engage with the public. In fact, it's so important that public engagement is in our Charter for IFSAC. And so for those who have been following us along, you'll know that we've hosted several webinars as a way to engage with the public. We've established an IFSAC web page hosted by the CDC and this is our second public meeting.

And so today's meeting is an effort to update you on some of the IFSAC projects and activities that have occurred since our last public meeting, and since some of those other webinars and other public engagements.

So, you will hear today progress on some of our projects. You'll hear, very importantly, the culmination of a major analytic project. And of course, we want to gather your feedback on those efforts as well as your suggestions for future activities in IFSAC.

Slide 2 (Webcast Recording Slide 3 of 172)
Before we move on to the agenda, I do want you to join me if you will in -- let's see -- if you can advance the slide for me -- join me in remembering one of the IFSAC family members who died just recently. Dr. Chuanfa Guo was a Statistician and Risk Assessor with the Food Safety and Inspection Service for better than ten years, and a member of IFSAC since its inception. He was a brilliant Statistician, a consummate professional, always helpful and cheerful. He always had a ready smile. Please join me for just a brief moment in remembering Chuanfa Guo.

(Pause.)

DAVID GOLDMAN: Thank you. Now I'll turn it back to Greg -- or shall we go directly to Chris?

GREG DINAPOLI: (Inaudible.)

DAVID GOLDMAN: Okay. Why don't we move on to Chris Alvares, who is another of the IFSAC Steering Committee members, and the current Chair of the IFSAC Steering Committee. He will make a presentation on the history of the IFSAC to set the stage for today's meeting. Chris?

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## History and Overview of IFSAC

Slide 1 (Webcast Recording Slide 5 of 172)
CHRISTOPHER ALVARES: Thank you, Dr. Goldman. Give me just a second to test out the -- okay, we're good to go.

Thanks again. Good morning, everyone. I'd like to start off the day talking a little bit about the history and background of IFSAC. We're here to present a variety of accomplishments, major work projects, and some of the activities we're doing in the area of communications.

But to start things off I think it would help to really give you an overview of what IFSAC is, how we've been operating, and to really set the stage for what you're going to hear about later today, and maybe also expand on or set the tone for some good discussions this afternoon.

We have a number of Q&A sessions planned. We'll hear from a number of panelists, and I think we really are looking forward to some feedback and some engagement here in the room as well as many of our folks who are online through the webcast.

Slide 2 (Webcast Recording Slide 6 of 172)
So, just as an introduction, IFSAC was really established in 2011 as a collaboration by three Agencies; CDC, FDA, and FSIS. It organized itself around a charter that just really describes the framework of how we operate.

We developed a strategic plan. This is really a five year plan that describes a number of our priorities, where we expected our work to be going over the course of five years, and really to describe how -- what directions we were going in.

A number of these priorities and these initiatives that are described in the plan really represent cross-cutting initiatives, priority initiatives that are shared by all three Agencies.
And that's where we really think that the IFSAC collaboration has it strength, really in working and collaborating and sharing resources, and building upon the work that all three Agencies see as a major priority.

Although the work of IFSAC is primarily focused on analytics and work projects, you'll hear about one of our most significant ones today. There is a big component that we recognize that needs to be focused around communication and understanding of foodborne illness, understanding of attribution.

It is a complex subject, and so we've taken a number of steps to work on communications to ensure that the Agencies all have a common set of messages, a common set of understanding when we're talking to each of our constituents about this important topic.

Slide 3 (Webcast Recording Slide 7 of 172)
So, how is -- why is IFSAC important? As I mentioned, it's a real opportunity for the three Agencies to work together. Our ability to accomplish work by pooling resources is much greater than it would be if we were working independently.

We've brought together a number of scientists and a number of leaders from different disciplines to work on projects, to advance a lot of the work that's been going on really for many years, but I think what we've been able to accomplish in the last couple of years has been really significant as well.

The work that we undertake -- the projects are really meant to be complimentary. They're meant to build upon each other. I think you'll hear how that building has been going over the past couple of years.

We've talked a little bit in the past about food commodity schemes and you'll see how that's feeding into some of the work today. The accomplishments build upon each other and allow us to strengthen the overall work that we're doing.

Foodborne illness attribution is a complex subject and there's a lot of work that can be done, still needs to be done. There are a lot of unanswered questions. I think that the work we're talking about today will really move us further in that direction.

Slide 4 (Webcast Recording Slide 8 of 172)
I mentioned the IFSAC Charter. The Charter really describes the -- kind of the organization and the structure of IFSAC. At kind of the core of it is a Steering Committee. The Steering Committee is chaired by two representatives from each Agency. They rotate, or they can rotate, as needed by each Agency. The Steering Committee is chaired by one representative. That's me this year, but each year it rotates through the three Agencies.

The Steering Committee really kind of sets the direction of IFSAC; sets the priorities. The Committee also has a good understanding of the priorities of the individual Agencies themselves, so they're bringing the perspective of the three Agencies to IFSAC.

We're having dialogue about what's important to each Agency. How do we work together? How do we establish a common ground and work through our projects in this collaborative way and really meet the goals of all three Agencies.

One of the things we identified very early on was the need for a technical work group. A number of the really qualified and expert -- subject matter experts -- are really working on a lot of these projects in series or even in parallel, and so the Steering Committee organized the technical work, that this is a larger body of really statisticians, analysts, and epidemiologists, all the folks who are really contributing to these projects.

And so this technical work group really helps to work through a lot of the very specific details of projects. They (the technical workgroup) are one of our oversights or review bodies as projects are moving along, and they work very closely with the Steering Committee to provide updates, to address needs, and to turn the -- sort of the strategic vision of the Steering Committee-- into actionable projects and accomplishments.

Slide 5 (Webcast Recording Slide 9 of 172)
So, as I mentioned, the Steering Committee decides priorities, but the technical work group really takes those priorities and develops analytic proposals. Those proposals, if they're selected to move forward, are then developed further into project plans.

The project plans are really where we have a lot of detailed information. What is the goal of the project? Who's going to be working on it? That's where the Steering Committee has a role to really review resources and to commit resources from the three Agencies to these projects. It also defines timelines, milestones, and objectives.

One of the goals of IFSAC is really to have all of our projects culminate in some form of report or a manuscript, or some public-facing work product that we can share and that we can communicate outwardly as far as what we're accomplishing.

And so today is one example of that, but you'll hear in some of our other talks other ways that we've taken advantage of different forms of communication to share the work that we're doing.

Slide 6 (Webcast Recording Slide 10 of 172)
The strategic plan, I mentioned that it's a five year plan. It really describes where our priorities are as the three Agencies see -- where the three Agencies see our common ground.

We've identified four priority pathogens. Those are pathogens that we really feel are the most common in terms of cross-cutting priorities, in terms of their importance for a foodborne illness, because they're one of the most significant or the most significant group of pathogens in terms of the scope of illnesses, the severity of illnesses, and also the impacts that the Agencies can have in terms of interventions and control measures to try to reduce foodborne illness due to these pathogens.

The strategic plan has also identified a number of primary objectives. You can see them on the slide here, but I'll also maybe elaborate to say that we have these objectives defined in terms of different timeframes. We have some near- term goals, one to three year timeframes that we really were expecting to accomplish early on, and then we have some longer term, three to five year goals.

I think you'll see today that we're pretty well on track with a number of those short (near)-term goals. We're about halfway through our strategic plan and we're at a point where we really are starting to kind of shift our focus or work towards the more complex projects.

So, today is a very important milestone in the work that we're doing. We want to certainly continue that work and we'll talk about some future directions of this current line of work, but we're also looking to expand that and to go into more complex, more sophisticated areas of analysis as well.

Slide 7 (Webcast Recording Slide 11 of 172)
Although IFSAC is really, I think at the core of it, an analytic type of work group, a lot of our focus is on analysis projects and advancing the analytic accomplishments and the analytic contributions to foodborne illness, and particularly in the area of attribution. We recognize that it's (foodborne illness attribution) a complex subject and communications has to be a big part of what we do as Collaboration. Certainly it helps us coordinate across the three Agencies. It helps us communicate a shared vision, a shared set of objectives, but also helps us internally within the three Agencies identify, where we have common ground, and also where we have sort of our independent tracks that each Agency works on.

And finally, we want to make sure that what we accomplish through this collaboration is also shared publicly as well. We've done two public meetings -- well, at the end of today we'll have done two public meetings. We've also done webinars, we've organized publications, we've contributed or presented at scientific meetings, we've stood up a website so we have a web presence.

CDC has been hosting that, but we have a number of materials about IFSAC, the projects that we're doing. Our Charter, our strategic plan, are posted there for everyone to see, so it's a real point where you can see the projects that are ongoing. We try to keep that updated and let you know what new projects have been approved, what accomplishments we've had, what publications maybe are of particular note. It's a good resource for information as you go back and want to learn more about IFSAC.

Slide 8 (Webcast Recording Slide 12 of 172)
So, in terms of accomplishments, again, we've brought together an interdisciplinary and inter-Agency team of Analysts. They're working through a number of very challenging and very interesting projects. We've put together a framework that allows the three Agencies to work together to coordinate on priorities to determine what the IFSAC collaboration will be working on, work interactively, initiate projects, work through them to share resources. Everyone brings resources to these various projects, and you see we have 10 analysis projects that have been initiated. Four are completed.

We've also collaborated on a number of Agency-specific goals and initiatives. You hear a little bit about mention of the Egg Rule, some of the Agency's priority goals, and other types of Agency-specific priorities and measures that connect to IFSAC and the work we're doing.

And also the communications aspect -- we'll talk a bit more today about all the different ways we're trying to communicate the work that we're doing.

Slide 9 (Webcast Recording Slide 13 of 172)
So in summary, and to recap some of the earlier comments, I do want to reiterate that foodborne illness is a significant priority for all three Agencies, and you see that through this collaboration of IFSAC that we formed. It's a way for us to all work together towards the common goal of reducing foodborne illnesses.

We all have our own areas of that, our own focuses in terms of maybe commodities, pathogens, illnesses, but there's enough -- and there's a significant body of common ground and cross-cutting priorities that really make IFSAC a productive group, a successful group, and we really look forward today to being able to share what we've been doing, but also being able to hear from all of you here in the room and online. What more can we be doing? What questions do you have of the group? We have a group of panelists this afternoon that will also be sharing some perspectives from outside of the three Agencies on the subject of foodborne illness and attribution, and I think that will help really foster a dialogue and help us improve the communications, improve the transparency, and develop directions as we move forward and share more in the coming years. Thank you.

Recording timestamp=21:40

GREG DINAPOLI: Thank you, Chris. For the next hour we're going to move into the overview of projects, progress accomplishments, and next steps.

Before I introduce our folks here, I do want to mention that if you want to comment publicly right now during this meeting and you haven't signed up, you can please see Juanita Yates. She's in the back of the room right now and she'll get you in the queue for your name and to public comment.

So, I'd like to introduce Cary Chen Parker. Cary -- Ms. Parker is an Epidemiologist with FDA's CFSAN. Prior to coming to FDA, Cary completed a fellowship at CDC where she worked on surveillance of foodborne disease outbreaks.

And Kristin Holt -- Dr. Holt serves as FSIS's liaison to CDC. While serving in this position she facilitates communication between FSIS and CDC, and provided scientific and technical input on public health and food safety issues related to FSIS-regulated products.

So, at this moment Dr. Holt and Dr. Parker?

Recording timestamp=23:18

**Overview of Projects: Progress, Accomplishments, and Next Steps**

Slide 1 (Webcast Recording Slide 15 of 172)

CARY CHEN PARKER: Thank you, Greg. As Chris mentioned in his presentation, we've been engaged in a number of different projects to continue our efforts to improve our understanding and use of foodborne illness attribution.

Since IFSAC began in 2011, we've been working on a number of complimentary projects that address different facets of our attribution work. Now, Kristin and I would like to take some time and provide an overview of these projects, outline our progress, and describe next steps.

Slide 2 (Webcast Recording Slide 16 of 172)

So this is a very simplified outline of our presentation. We'd like to start by using the IFSAC Strategic Plan as a framework for discussing these analytic projects. Then, we'd like to conclude by highlighting our communication activities which were designed to engage with you, our stakeholders.

Slide 3 (Webcast Recording Slide 17 of 172)

The IFSAC Strategic Plan outlines our objectives, attribution analysis, and vision for communication efforts. It includes a variety of short and long term goals such as developing attribution estimates, improving data and methods for uncertainty, and engaging and communicating with stakeholders.

Our short term efforts range in the one to two year goal/range and long term is three to five years.

Slide 4 (Webcast Recording Slide 18 of 172)
I'd like to start by first describing projects that supported the short term goals. Since we're using a Strategic Plan as a framework, let me take a moment to orient you on how we've organized the presentation.

In blue font are the objectives of the Strategic Plan and underneath each goal or effort are the titles of the project or projects that supports the goal. I'll cover each goal and then in subsequent slides provide more details about each project.

The first short term goal or effort was to improve ways in which we categorize foods. The second short term goal was to examine the different types of uncertainties that come with estimating attribution fractions and we have two projects that serve that purpose.

Slide 5 (Webcast Recording Slide 19 of 172)
The third short term goal was to determine gaps in the data and identify solutions to improve these attribution estimates. There were two projects that supported these efforts.

And finally, the fourth short term goal was to develop for the first time a single approach to produce harmonized attribution estimates from outbreak data for these four IFSAC priority pathogens.

Slide 6 (Webcast Recording Slide 20 of 172)
Now that I've outlined the Strategic Plan framework, I will describe each project in more detail. At the top of the slide you'll see the specific Strategic Plan or goal in blue font, and the green font, again, is the project title.

So the title here is "Improve the Food Categories Used to Estimate Attribution." In this project we wanted to improve the food categories used to estimate attribution by expanding upon the previously used food categorization scheme so that we could include more specific food categories, and also provide categories that are more useful for regulatory Agencies and stakeholders.

Slide 7 (Webcast Recording Slide 21 of 172)
I'm going to step back a little bit and provide you some background information. Prior to the formation of IFSAC, CDC developed a food categorization scheme with input from both FSIS and FDA.

There were 17 food categories in this old scheme (in the blue boxes). They were used to classify over 2,000 foods that were implicated in outbreaks between 1998 and 2008, and you'll see the citation for the Painter paper there.
So, if we walk through here, let's start at the top. There are three major food categories: aquatic, land, and plant. If we go under the plant category, there is produce, and under produce, vegetables will lead us to leafy vegetables. It's still a very broad category.

Slide 8 (Webcast Recording Slide 22 of 172)

Our method was to increase the accuracy and utility of the food categories. The methods aim to build on earlier commoditization schemes and create a scheme to better reflect FDA and FSIS regulatory classification of foods, and with IFSAC, in our work, ensure that scientists throughout FDA and FSIS had input into the scheme and understood how they applied to outbreak data in use in attribution studies.

Another goal in our methods was to reflect production practices in [post] harvest handling systems. Although we recognize that not all practices are captured in our new scheme, we are hoping to improve upon them in the future. It is a step wise progression. We're also hoping with the methods, new methods, to accurately reflect botanical categories.

Slide 9 (Webcast Recording Slide 23 of 172)
So this is the results. This is our new scheme that was developed. We've been using it for attribution studies and outbreak summaries since 2011.

After the new categorization scheme was determined, IFSAC assigned all applicable food items in the CDC outbreak surveillance database to these new categories. Additionally, the IFSAC team developed a food glossary with examples of foods for each food category. The revised scheme has six distinct levels to which foods can be assigned, depending upon the type of food.

First, foods are assigned to one of four major food groups: land animals, aquatic animals, plants, and other. Food groups include previously -- include increasingly specific food categories.

So if we stick with our previous example of a leafy produce from the previous Painter scheme and then contrast it with this new IFSAC scheme, this is where the leafy produce would fall. So if you follow me, up in plants and then coming down to produce, under vegetables, and then seeded vegetables -- I'm sorry, and vegetable row crops -- then there are -- the lowest categories are stem, leafy, or flowers, flowering plants.

Slide 10 (Webcast Recording Slide 24 of 172)
As you recall that one of our goals was to reflect production practices and post-harvest handling systems, here are sub-categories that reflect processing.

I'll walk you through the seeded vegetable column. As you know, food commodities in the seeded vegetable group may be processed in a variety of ways, such as sundried tomatoes, frozen corn, or canned pumpkin.

Slide 11 (Webcast Recording Slide 25 of 172)
The new food categorization scheme was shared during a June 2013 webinar and it's available on our activities and events web page. There you'll find the recording of the webinar, a transcript, and slides.

In the next steps we're hoping to integrate the new categories and food assignment rules into routine foodborne disease outbreak surveillance system data collection and reporting activities.

Slide 12 (Webcast Recording Slide 26 of 172)
The next project is determining representativeness of outbreak data. We wanted to compare the characteristics of ill food -- ill people and foods linked to outbreaks of our four priority pathogens, with those associated with sporadic or non-outbreak illnesses and foods consumed by the general population, to determine whether outbreak illnesses are actually representative of sporadic illnesses.

Slide 13 (Webcast Recording Slide 27 of 172)
We accomplish that by using two types of analyses. The FoodNet Sub-Project and the NHANES, the National Health and Nutrition Examination Survey Sub-Project.

In the FoodNet Sub-Project, we compared epidemiological features of outbreak and non-outbreak illnesses ascertained in FoodNet and in the NHANES study we compared the distribution of foods associated with foodborne outbreaks, the distribution of foods eaten by the NHANES participants.

Slide 14 (Webcast Recording Slide 28 of 172)
I'll walk through each of the sub-projects a little bit more. We used data from FoodNet which stands for the Foodborne Diseases Active Surveillance Network. FoodNet conducts surveillance for a number of enteric infections diagnosed by laboratory testing of patient samples.

FoodNet is a collaborative program among ten state health departments and federal agencies. Their surveillance area includes 15% of the U.S. population, or about 48 million persons.

We compared the characteristics of illnesses associated with foodborne outbreaks with those that are not linked to foodborne outbreaks, which we call sporadic illnesses. The fact is that most foodborne illnesses do occur as individual sporadic cases, not otherwise connected or recognized as part of an outbreak. However, most information about food sources is derived from outbreak and outbreak investigations.

To conduct this analysis we used FoodNet data because these data provide information on both sporadic and outbreak cases.

FoodNet is designed to actively identify sporadic illnesses, some of the illnesses in FoodNet are eventually identified as having been associated with outbreaks.

The assumption was this, if outbreak and sporadic cases are similar in terms of person, place, and time, then it is more plausible that attribution estimates derived from outbreak data could be reasonably applicable to the general population.

Slide 15 (Webcast Recording Slide 29 of 172)
And here are the results. For -- again, to reiterate, in general, outbreak cases closely resemble sporadic cases for three of the four pathogens that were examined; *E. coli*, *Listeria monocytogenes*, and *Campylobacter*.

Although *Campylobacter* sporadic illnesses are similar to outbreak illnesses, there are very few -- a very small number of outbreak illnesses available for comparison, which limits some of the conclusions that can be drawn.

For *Salmonella*, outbreak cases resemble sporadic cases in older children and adults, but there is important difference when you look at infants and young children age three or less. The study reminds us that *Salmonella* infections in the very young can come from other sources in the environment besides foods that can cause outbreaks.

Slide 16 (Webcast Recording Slide 30 of 172)

Our conclusions here are that we found that it's important -- that these findings are important because they indicate, with the exception of *Salmonella* illnesses among children three or less, it may be appropriate to use outbreak data to estimate which foods may be associated with sporadic illnesses in the population.

We communicated our findings during an IFSAC webinar on January 10th, 2014, and again, if you check our IFSAC website you'll be able to find all the materials from the webinar there. Our next step is to develop a manuscript.

Slide 17 (Webcast Recording Slide 31 of 172)
Now on to the NHANES Sub-Project. The National Health and Nutrition Examination Survey, NHANES, is a survey research program designed to assess the health and nutritional status of adults and children in the United States, and to track changes over time, and one of the many surveys collects information about the foods that we eat.

The NHANES program began in the early 1960's and examines a nationally representative sample of about 5,000 persons each year. Our methodologies in this project was to compare the distribution of foods associated with foodborne outbreaks and the distribution of foods eaten by NHANES participants, and then to link all those foods implicated in outbreaks to foods consumed by those participants. Here our analyses are continuing.

Slide 18 (Webcast Recording Slide 32 of 172)
Another project that we embarked on was a collaboration with IRAC, or the Interagency Risk Assessment Consortium. We established this external collaboration to identify opportunities to leverage methods across different analytic disciplines.

Our approach in this was to conduct joint seminar series and capstone workshops. We discussed ways to improve the quality of information that regulatory agencies use for risk-based decision making, and discuss ways that IFSAC, with our epidemiological methods, can inform risk assessors.

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The outcomes from this collaboration included us providing data on epidemiological methods for identifying risk factors and other influences of the population's health, and the IRAC group sharing with us risk assessment methods for estimating the likelihood that illnesses result from a specific hazard.

Based on this collaborative exchange, IFSAC and IRAC participants identified ways to benefit from both methods in the future.

I'd like to pause here and turn it over to my colleague, Kristin Holt. She'll talk a little bit more about other types of projects in the short term, and also in the long term, and finish off with giving you more details about communication activities.

Recording Timestamp=38:04

Slide 20 (Webcast Recording Slide 35 or 172)
KRISTIN HOLT: Thank you, Cary, and good morning.

So, I'm going to shift you to a project that supports a strategic plan Short Term Effort #3, which is to determine gaps and identify solutions to improve foodborne illness source attribution estimates.
So, for this IFSAC project, the project team was focused on evaluating a pathogen subtype model to better estimate the number of *Salmonella* illnesses associated with different food sources using the Hald model.

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And so for background, I think many of you probably are familiar with the Hald model, and we talked about that activity during our first public meeting. So the Hald model, which was developed by Tina Hald from the Technical University of Denmark, links the number of reported foodborne illnesses caused by *Salmonella* to levels of contamination in food reservoirs in the amount of each food consumed.
But the model also includes two other factors assumed to influence the number of illnesses, and one is called -- I guess, a category of the food source factors, which try to capture those relative differences among food reservoirs that might influence their ability to transmit *Salmonella*. So just differences in processing or preparation practices.

And the other factors are the pathogen factors which capture the relative difference between *Salmonella* subtypes that influence their ability to cause a disease, such as pathogenicity or survival in food.

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And to move to our IFSAC project, our objective was to expand a U.S. model previously used to attribute illnesses to FSIS regulated food products by incorporating date from FDA regulated food sources of *Salmonella* and exploring whether the model can provide reasonable estimates of foodborne illness source attribution to evaluate the relationship between food contamination, consumption, and human illness, and estimate the percentage of illnesses attributable to food contamination before the point of food preparation and service.

And if you look at the Guo et al publication, which was led by our esteemed colleague, Dr. Guo, that was our first U.S. attempt to adapt the Hald model in the United States. And that is available in Foodborne Pathogens and Disease.

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And so for this project these are our methods -- to include data from additional food products such as seafood, herbs, and produce, and include shell eggs in the model using three different contamination scenarios, and assess model results under each scenario.
And in our first model adaptation, we had a lot of difficulty with the shell egg data because we had an older, very small data set, so this actually took us, you know, further along in our effort.
And then also, a part of the method is to update the model to improve model performance…

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…and our progress so far is that we have a report outlining the model and results in development, so we basically have the project completed. And our next steps are to determine how to use the model to assess changes over time, improve date collection and incorporate more specific pathogen subtyping data in future models.

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Now I'm going to shift you to -- back to the strategic plan -- and talk about some of the projects that fit under a category that we call long term effort. So Cary went through short term efforts and covered that the Hald model also touches on short term effort.

So, I'm going to hit on two long term effort categories. The first is to develop foodborne illness attribution models using a variety of data sources. And, of course, just from you hearing me talk about our adaptation of the Hald model, we talked about using new data sources.

Also, another project I'm going to talk about in more detail is the Baseline Estimate of the Proportion of Foodborne *Salmonella enterica* subtype Enteritidis, or SE, Illnesses, that can be attributed to shell eggs and other common sources.

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And the second long term category is to determine most appropriate methods -- determine the most appropriate methods for generating both blended and harmonized food source attribution estimates. And so here are two projects that support this long term effort, and one is the SE project that I just mentioned and I'm going to talk about in more detail, and then another project estimating foodborne illness source attribution for illnesses caused by *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, and *Campylobacter*, which we're going to cover in very much detail at this meeting.

Slide 27 (Webcast Recording Slide 42 of 172)
So the SE project supports long term effort number one to develop foodborne illness source attribution models using a variety of data sources, and long term effort two to determine the most appropriate methods for generating both blended and harmonized food source attribution estimates.

It's for this project -- and the long name, I guess, is the Baseline Estimate of the Proportion of Foodborne *Salmonella enterica* subtype Enteritidis (SE) Illnesses, that can be attributed to shell eggs and other common sources, and I'm going to use a little shorter title in the next few slides.

Slide 28 (Webcast Recording Slide 43 of 172)
So, for background, I think you need to remember that CDC and FDA have partnered since 2010 on a Department of Health and Human Services Agency priority goal to reduce SE infections. So what's new, and you know that 2010 predates IFSAC -- what's new is us getting together and leveraging IFSAC analytical abilities.

So for this project there was a goal focused on reducing infections associated with shell eggs, and it relates to the FDA final egg rule issued in 2010, and you can find more details on the performance.gov site.

So, for background -- continuing -- we know that attribution estimates vary by the data source and the method, so if you look at a 2010 -- excuse me, a 2002 a FoodNet case-control study of sporadic illnesses, those nonoutbreak illnesses, you noted that small proportion of illnesses were attributed to shell eggs, but if you look at the outbreak data, you see a high proportion of illnesses attributed to shell eggs.

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So for this IFSAC project the objective was to develop estimates of the percentage of illnesses attributed to shell egg -- attributable to shell eggs before the egg rule -- and FDA chose a 2007 to 2009 baseline period for this project, and the method was to produce the baseline estimates of the proportion of the

SE illnesses attributed to the shell eggs by using mathematical models and incorporated data from the foodborne disease outbreak investigations, and from a 2002 case-control study of sporadic or non-outbreak illnesses.

So, the "and" is underlined because basically if you remember the term "blended" was in that IFSAC strategic plan effort, so this is a blending approach.

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So, the results -- the baseline attribution of SE foodborne illnesses for the period of 2007 to 2009 was arrived at, and the attribution fraction with its 95% confidence interval is here showing shell eggs at 40%.

And the next steps -- to propose a method to estimate attribution for recent sources of SE using the newer data. So we're going to keep this project going along.

Slide 31 (Webcast Recording Slide 46 of 172)
And now I'm going to talk about the last project estimating foodborne illness source attribution for illnesses caused by *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, and *Campylobacter*, and it supports several strategic plan efforts, two short term and one long term.

The first short term is "examine uncertainties associated with current foodborne illness source attribution estimates," and the next is, "use estimates from outbreak based foodborne illness source attribution," and the long term effort is to develop -- excuse me -- to determine the most appropriate methods for generating both blended and harmonized food source attribution estimates. And this one is more focused on the harmonized part.

Slide 32 (Webcast Recording Slide 47 of 172)
And the objectives for this project are to identify appropriate methods to estimate percentages of illnesses caused by the priority pathogens attributable to food categories in the new categorization scheme using outbreak data, and Cary shared with you that new categorization scheme.

Develop Tri-Agency outbreak derived attribution fractions using a refined simple food methodology with quantified uncertainty, and to provide harmonized source attribution estimates by developing a single robust method to produce estimates that all three agencies may use in their food safety activities.

Slide 33 (Webcast Recording Slide 48 of 172)
And so I'm not really going to tell you too much about this project because the next speaker will cover this with more details on the methods, results, and conclusions.

Slide 34 (Webcast Recording Slide 49 of 172)
So I'm going to end with a couple of slides touching on communications, and somewhat recapping what Chris Alvares shared with you earlier. I just want to capture here in this talk, you know, accomplishments and future directions.

So, in 2011 we had the Charter signed and we approached the FDA Risk Communication Advisory Committee for feedback. In 2012 we had the development and implementation of our IFSAC strategic plan, and we had our first public meeting to introduce you to IFSAC, talk about the development of that

strategic plan, and to solicit public input on opportunities and challenges to improve foodborne attribution efforts in the U.S.

In 2013 we had our first webinar on improving the categories used to classify foods implicated in outbreaks, and I hope many of you were able to join that webinar.

Slide 35 (Webcast Recording Slide 50 of 172)
In 2014 we had our second webinar, Are Outbreak Illnesses Representative of Sporadic Illnesses?, and we also launched the web page. So if you haven't visited our IFSAC site, please do. We have the webinars there and a lot of other great information for you to look at.

In 2015 -- I guess we're here having our second public meeting, which we see as an opportunity for IFSAC, the public, and our food safety partners to discuss IFSAC's work and overall federal efforts to improve estimates of foodborne illness source attribution, and engage stakeholders and solicit feedback for plans for future IFSAC projects, and we plan to continue our communication efforts through various avenues as analytic projects progress and the results become available.

Slide 36 (Webcast Recording Slide 51 of 172)
Thank you.

Recording timestamp=49:15
Question and Answer Period

GREG DINAPOLI: Thank you, Dr. Holt. At this moment I'd like to invite all the working group members to the panel for the question and answer. At this moment if you'd like to ask a question, please use the --

YUANITA YATES: Testing --

GREG DINAPOLI: -- use the microphone in the aisle there.

BARBARA KOWALCYK: Okay.

GREG DINAPOLI: If you could just identify yourself and who you're with?

BARBARA KOWALCYK: Sure. Barbara Kowalcyk, RTI international. So, I had a question about the first project that you mentioned, Kristen, regarding using data from outbreaks in the 2002 case-control study of sporadic illnesses.

Are the methods going to be presented later in the meeting, and if not, could you comment on the methods that you used a little bit more in detail, or is there a citation where it's going to be published?

DANA COLE: Is this one? Oh, thank you. We're not -- our focus in this meeting is on the last project that she didn't give a lot of details on, but I'm happy to talk to you about that particular project.
So, the one with the -- that we used the results of the 2002 case-control study of SE -- we do have one methods paper that was recently published online in *Epidemiology and Infections*, and that describes a new approach for analyzing that case controlled study data.

We used -- rather than using a more traditional logistic regression, we applied a random forest method to estimate population attributable fractions from the case-control study, so it was a better method that accounted for the hierarchical structure of the questionnaire data a bit better than a logistic regression did. So, as I mentioned, that just recently came out online –

BARBARA KOWALCYK: Okay.

DANA COLE: -- a publication -- and then that -- the results from that analysis of the sporadic cases were then blended with the results that we obtained from outbreaks -- examining outbreaks that occurred from 2002 to 2009. That paper describing the blending method, we don't have out yet. We are still working on the manuscript development.

BARBARA KOWALCYK: Okay. When do you anticipate that that would be out, or are the methods that you used for blending going to be presented?

DANA COLE: Pardon? Oh, are they going to be presented? Not today. Um -- I'm trying to think. I thought we -- no, I guess we haven't. We presented it to some in some forums, but I guess not on a webinar yet.

But we -- they're fairly straightforward, just off the -- you know, for purposes of answering the question, we just put the results in a distribution and then sampled from each distribution, the outbreak distribution and the sporadic case distribution, and then just took an average of what came out of the blending of those two distributions.

But we hope that we can get those -- the blending results out there fairly shortly because it's a method that we think sort of leverages the data you get from both sporadic cases and outbreak cases, and we'd like to present that.

BARBARA KOWALCYK: Okay. Thank you.

GREG DINAPOLI: Any other questions from the audience?
(No audible response.)

DANA COLE: While we wait to see if there are other questions from online, I was told I should introduce myself. Sorry. I know Barbara and I know she knows who I am so I didn't introduce myself, but I'm Dana Cole. I'm from CDC. I'm the Lead of the Analytics Team in Enteric Diseases Epidemiology Branch and one of the Technical Leads from CDC to the Interagency Food Safety Analytics Collaboration.

GREG DINAPOLI: Joanna, would you like to introduce yourself or would you like me to? I can do that if you'd like.

JOANNA ZABLOTSKY KUFEL: Do you want -- well, I guess you weren't introduced, so I'm Joanna Zablotsky Kufel. I am with FSIS and the Office of Food -- sorry -- Office of Data Integration and Food Protection, and I'm also one of the technical members of their staff.

MIKE HOEKSTRA: Mike Hoekstra. I'm a longtime employee of CDC working with foodborne illness. I'm a Mathematical Statistician. I've been working with Technical Workgroup since its inception.

MICHAEL BAZACO: My name is Michael Bazaco. I'm with the FDA Center for Food Safety and Applied Nutrition, Office of Analytics and Outreach. I'm an Epidemiologist and one of the FDA Technical Leads on IFSAC.

GREG DINAPOLI: All right. Thank you. It seems like we've got some questions and I think we're going to try to get some questions -- no questions from folks on the webinar?

CARY CHEN PARKER: I'm playing double duty today, but nope, no questions of webcasting folks yet.

GREG DINAPOLI: Thank you, Cary.

CARY CHEN PARKER: Uh-huh.

GREG DINAPOLI: Please, go ahead.

CAROLINE SMITH DEWALL: Thanks. Caroline Smith Dewaal, Center for Science and the Public Interest. I'm interested in your new work on food categorization, and especially how it's going to align with the data coming in from the states. So, for example, are you going to be training people on what are tubers and on some of the more esoteric categories that you use to regulate meat products, for example? And I ask this because in fact we've dug into that data pretty deeply and it seems aspirational that you're going to get meaningful data coming up from the state and local Health Departments that's going to feed into those categories.

So, I'm just wondering what type of training -- or are you thinking you're going to do the categorization at CDC rather than waiting for it to be reported up from the sates? That you'll be assigning those categories?

I'm just wondering, and I'll just share with you an experience we had. We did a deep dive into the meat data and instead of taking -- instead of applying categories we let the data communicate categories up to us.
This is data coming in from state and local Health Departments, and we found categories like barbeque being really important, and we couldn't tell whether it was barbeque beef or barbeque pork necessarily, but the barbeque itself became an important category.

So, again, the people collecting the data at the state and local level are going to be essential to the success of your new scheme.

DANA COLE: I'll take that question, too, since CDC is collecting that data. You hit on some very important issues, of course, with regard to collecting the data and reporting the data, and the short answer to the one question about who is going to be categorizing the foods, you're right, there is -- you're highlighting the barbeque issue is a great highlight as to the different ways you can look at the foods themselves and decide how to categorize them.

And for that reason, we really want to standardize, to the best we can, the way foods are categorized, so that it's transparent. So for that reason we are not asking -- there's a couple of reasons, but the first reason is that we are not asking the states to go ahead and categorize their own foods. We want rather the states to collect and report as much of the data about the foods causing the outbreak as they can.

And that's -- we are wanting to discuss that with them further, particularly when it comes to, say, complex foods, as you know -- those foods that have ingredients they don't know what was a contaminating ingredient -- so they have a food that they report with multiple ingredients.

We would like to know as much about those ingredients, for example, as well as the contaminating food that they implicated, so we are not stressing to the Public Health Departments that they need to be categorizing the foods, we just want their raw data -- as much data.

So the other question about the processing categories, that's a little different. As you know from looking at the data, we do need to -- we do have processing categories that are very sort of well informed by the regulatory Agencies, but may not be so obvious to the -- to the Public Health Epidemiologist collecting data.

So there we do need -- and that was part of the next steps. Part of that slide is that we need to come up with very clear definitions and provide access to the states so they understand those definitions and opportunities to collect the data, first of all -- collect the processing category data to the best that they can and report that into the -- because if you don't make it available and with standard definitions, of course you're not going to get that data back out of the system.

So we are in the process of creating those definitions and sharing those definitions with the states, and making the process of reporting -- make it easy for them to report those categories.

But, again, getting back to my point that we want to really standardize as much as possible how those foods are categorized to the different food categories, we have, in IFSAC -- that was another big effort that we have accomplished. As well as creating the new food categorization scheme, we've come up through the work group -- the three Agencies -- a set of standard rules.

Again, so when you're confronted with barbeque beef, we have a set of rules that we say, "If it says this, then this is how we're going to categorize it." And again, that allows a better transparency and standardization as far as this is -- you know, "You can categorize it differently or make a different decision, but this is how we have decided as the three Agencies as the best way to handle this data for now as we seek to improve that data."

CAROLINE SMITH DEWAAL: Thanks for that explanation. I would just caution, as you move forward on this, that you may be discarding a large amount of valuable data because it doesn't fit your new categorization scheme.

And given the trends that we're seeing in outbreak reporting data coming up from the states, which I'll talk about briefly this afternoon in the public comment period -- but I know you're aware of them. I mean, I'm not sure we can afford to throw out valuable data, so I would just caution as you move forward on this that imposing a scheme sometimes may make it be less valuable data than you would if you used -- if you accept the data that's coming up.

But, it's very interesting work. Thanks for sharing.

GREG DINAPOLI: Thank You, Caroline. Go ahead.

CRAIG HEDBERG: So, I'm Craig Hedberg from the University of Minnesota. I get to be on a panel this afternoon, so I could have saved my comments for then, but if we have time I want to make two slightly unrelated comments, one on sort of the botanical characterization of -- improving the botanical characterization of foods.

Seeded vegetables are actually fruits, and from the standpoint of how the fruit becomes contaminated, there could be some common pathways that are important for us to take in mind.

So, as we sort of cut and paste and put things back together, I think we need to sort of have in mind, you know, where some of these pathways may link, even though, you know, in the kitchen we call it a vegetable, but botanically it's actually a fruit.

The other question I have is relating to the *Salmonella Enteritidis* the blending case control study data from the 2002 case-control study with the outbreak data which is sort of later on in time.

You know, one of the things that's interesting about foodborne diseases is it's a constantly moving target, and so, you know, the risk profile that existed during the case-control study may be a little bit different from the risk profile that existed during the later outbreak periods.

And so, I guess one of the challenges and questions I have going forward is, you know, if it's not possible to get credible case-control study data of sporadic cases going forward, what are the opportunities to actually systematically track food history data coming in from sporadic cases all around us to try to estimate some of those exposure fractions in a more contemporaneous timeframe with the outbreak data?

GREG DINAPOLI: Thank you. If you could please identify -- I'm not sure if you identified whom you're with?

CRAIG HEDBERG: Yeah. I'm with the University of Minnesota, School of Public Health.

GREG DINAPOLI: And your name?

CRAIG HEDBERG: Craig Hedberg.

GREG DINAPOLI: Thank you.

DANA COLE: Yes. You're right. We had to assume that the exposure profiles of 2002 sporadic cases were unchanged during the entire study period that we were using the outbreak data to inform the outbreak attribution estimates.

And so we used data from the outbreak side going -- to include 2002 -- to make sure that we are at least, you know, inclusive of the time period the data was collected for the sporadic case-control study through 2009, which is the end of our FDA baseline period for estimating attribution estimates.

And you're right, we need to go forward now and figure out, you know, what those case exposure profiles may look like today. So, recently FOODNET -- and I don't want to jump ahead in our agenda too much because we're talking a little bit more about this I think later in the meeting, but FOODNET -- the foodborne disease active surveillance system that was described earlier today has started collecting

exposure data on a subset of their cases, just so that we can have some data coming in on exposures -- exposure profiles for sporadic cases to help us inform our models and determine if we are getting a signal that the exposure profile among cases is shifting since we have done a case-control study of those cases earlier in the decade.

GREG DINAPOLI: Any other questions?

BARBARA KOWALCYK: Oh, sorry. Barbara Kowalcyk, RTI International. The other question I had particularly I think for you, Dana, is in the FOODNET subproject, one of the conclusions was that -- with the exception of *Salmonella* for children under the age of three -- outbreak data was a good surrogate. And I was interested to -- *Campylobacter* did seem to be different, and I was wondering why you had not -- why you felt that it was acceptable for Campy.

DANA COLE: All right. I was going to give someone else an opportunity. You're right. I mean, the *Salmonella*, we definitely saw that difference and could characterize that.

The problem we had with *Campylobacter*, which was a bullet point on the side that may have been missed, but that the problem, as you probably know with *Campylobacter* illnesses is that there is a -- so many more -- that are sporadic in detecting - a *Campylobacter* outbreak is difficult, and so the sort of ratio of sporadic illnesses to outbreak illnesses in the case of *Campylobacter* is much larger than, say, it is for *Salmonella* and *E. coli*, and some of those others.

So, although we didn't have statistical evidence that there were differences, we couldn't rule out the fact that we had just a small number of case -- outbreak cases from which to compare to the sporadic cases relatively for *Campylobacter*.

So, you know, this study -- this FOODNET study was really looking for, you know, signals in the data, you know, statistically, that would point to fundamental differences. And so, as you'll see with our other projects, you know, data scarcity and having a body of data that's strong enough that when you compare two groups, that you can detect that signal.

So we did not see a signal for *Campylobacter*, but we can't rule out the possibility that there's just so few outbreak cases we don't have a good body of data on the outbreak side for *Campylobacter*.

GREG DINAPOLI: Thank you, Diana. Any -- no questions?
(No audible response.)

GREG DINAPOLI: The working group members, would you like to -- we're a little early, but is there any final comments or remarks? Joanna or –

MIKE HOEKSTRA: Yeah. I'd like to make one additional comment to Caroline Smith Dewaal.
In her comments she suggested in part, or gave an appearance that in essence the analyses that we present are based on a fixed choice.

And I'd like to go back to Dana's statement about how we thrive on the raw data because, in fact, we would consider matching the raw data with what we feel is a credible and epidemiologically sensible, and public health valuable, classification of foods, and we can do that in many ways, so that in fact, the analyses that we show -- the number 952 will come up today.

But, in fact, behind that is the entire database and the entire body of information that we pick up through surveillance, and thus, we can address the pork/beef question, at least in a naïve fashion, by saying, "What if it was all beef? What if it was all pork? What if there is some chicken in there?" So, we don't throw away data. We try to use the data to the best of our ability to create a credible picture of foodborne illness. But in fact, we reuse and scenario analyze data to a great extent, indeed to a greater and greater extent as our computing capacity and analytic engine gets larger and more capable.

GREG DINAPOLI: You're nodding your head, Caroline.

CAROLINE SMITH DEWAAL: No, thank you. Nothing –

GREG DINAPOLI: Good. Good. Thank you, Michael. If that's it, we'll wrap up this session and we'll take about ten minutes, 15 minutes. Say back here at 10:00 o'clock.
(Recess.)
(Off the record.)

Recording Timestamp=01:11:31
GREG DINAPOLI: At this moment I'd like to welcome our two panelists, and then the working group members will do their question and answer.

I'd like to introduce Dr. Joanna Zablotsky Kufel. Joanna has received her Master's in Public Health in Environmental Public Health and Health Policy and Management, from Johns Hopkins School of Public Health in 2003, and her PhD from the Johns Hopkins School of Public Health, Department of Health Policy and Management.

Did everyone get that? A lot of Public Health Management -- sorry -- in 2009. She also earned a Risk Sciences and Public Policy Certificate and her career started here at FSIS as a Food Safety Fellow, where she helped develop performance measures for FSIS strategic planning activities and evaluating the effectiveness of Agency policy.

I'm going to introduce as well Dr. Dana Cole. Dana is a large animal Veterinarian and Doctoral Epidemiologist responsible for the direction of the Analytics team within the Enteric Diseases Epidemiology Branch at CDC.

Dana leads efforts to attribute enteric illnesses to their sources. Dana worked in the Georgia Division of Public Health, the University of Georgia, before coming to the CDC.

Joanna and Dana? I guess Joanna first.

Recording Timestamp=01:13:28

**Estimating Foodborne Illness Source Attribution for Illnesses Caused by *Salmonella*, *Escherichia coli* O157 (*E. coli* O157), *Listeria monocytogenes (Lm)*, and *Campylobacter*: Part 1**

Slide 1 (Webcast Recording Slide 52 of 172)

JOANNA ZABLOTSKY KUFEL: All right. So welcome everybody. Thank you again for coming today. My name is Joanna Zablotsky Kufel and I'm with the Office of Data Integration and Food Protection here within FSIS, and I'm going to be starting us off on a set of three talks.

So I'm going to start, Dana will take up the middle, and then Dr. Michael Bazaco will finish today for this set of talks.

So we're going to be talking about a new project that we recently completed within IFSAC that we're all pretty excited about. It's been a lot of work and a lot of collaboration and a lot of effort, and so we're excited to be sharing it publicly and to talk about what we did.

Slide 4 (Webcast Recording Slide 54 of 172)
So, an outline of my talk, moving forward, is just basically the purpose, background, the data sources, the selection model inputs, comparison to Painter -- because people probably are wondering how this relates -- how our work relates to what Dr. Painter did, and then some conclusions.

Slide 5 (Webcast Recording Slide 55 of 172)
So, the purpose of the effort that we embarked upon is to provide a harmonized source estimate by developing a single, robust, method to estimate source attribution for the four key pathogens and -- so that we can use them -- the three regulatory Agencies -- or sorry, the two regulatory Agencies and CDC can use them in their food safety efforts.

Slide 6 (Webcast Recording Slide 56 of 172)
So, I want to start by talking about the fact that we selected these four priority pathogens. We are focusing today and in this work on *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, and *Campylobacter*, and we picked those pathogens because of the frequency and severity of illnesses that they cause, and also that fact that targeted interventions can and have been effective in reducing the burden of illness and also the rates of contamination on product.

Slide 7 (Webcast Recording Slide 57 of 172)
So, I want to start today by talking a little bit about where we came from so that you can also sort of see what informed where we went. Cary and Kristin talked about a number of projects that IFSAC has done already and I also want to stress, as they did, that this was an iterative and collaborative process in the sense that we developed a number of projects whose findings would support the other projects that we're working on, so we wanted to try and make it as informed of an effort as possible.

So, Cary and Kristin mentioned the first phase of this work for estimating attribution -- harmonized attribution fractions -- so I'm just going to go into a little bit more detail about what we did and how that work informs what we've got in this project.

But, just so -- a little bit of background. The objective of the first phase of this project was to determine the best approach to estimate source attribution using outbreak surveillance data while exploring uncertainties and variability associated with computing attribution estimates using outbreak data.

And so we took essentially two approaches to this. One is we developed an approach, if you will -- a set of methods to estimate attribution, and we also conducted a literature review because we recognized that a lot of other work has been done and we wanted to make sure we are as well informed as we could be about what other efforts have found.

Slide 8 (Webcast Recording Slide 58 of 172)
So, the first phase was a modeling approach, so we determined the data sources and the food categories. So the food categories are the ones that Dr. Cole and Cary and Kristin mentioned earlier, so that was an IFSAC project. Again, we had a webinar on it.

I won't go into detail about it because Cary did a nice job doing that earlier, but the data source is something that we haven't maybe talked quite as much about. This is the CDC FDOSS data; those in the room are probably -- and on the web -- are probably pretty familiar with it.

We, in this first effort, used data through 2010 because that was what was available to us, and we used the food categorization scheme.

We defined inclusion and exclusion criteria, and we explored measures for estimating attributions, so we looked at different things like, should we use illness counts from outbreaks or should we use outbreak counts? So that's just one of the decisions that we had to make and I'll go more into that as I keep going with my talk.

Slide 9 (Webcast Recording Slide 59 of 172)
So, in terms of the literature review, we had a number of data sources that we used. PubMed, Web Science, and EmBase. We considered over 125 publications and 65 outbreak abstracts that covered the pathogens that I mentioned, as well as looking at multi-pathogen papers to make sure we kind of -- we covered the breadth of the available literature, and then we developed standard tables and we used that to summarize the information that we gathered by pathogen.

Slide 10 (Webcast Recording Slide 60 of 172)
So, let me talk a little bit about the results and findings that we came away with for Phase I. So, the analysis revealed the attribution estimates derived from outbreak data can vary on a -- based on a number of things.

The unit of analysis, though, as I mentioned -- outbreak counts versus outbreak illnesses -- the food classification scheme -- that's going to trip me up all day -- that are used to categorize foods. So, obviously as was mentioned, Dr. Painter had developed a classification scheme and we've also developed one, and so the one that you use obviously changes what estimates you can arrive at. The time period of analysis -- how many years of data were working with -- and the amount of missing data -- and the number of foods with unknown contaminated ingredients.

Slide 11 (Webcast Recording Slide 61 of 172)
So, what we found was that the attribution estimates that you can calculate from outbreak data are different than the estimates that you can calculate from using other surveillance data and other sources -- other methods.

One of the other major findings was that -- what we really found was that what had been done before and what IFSAC had done already was probably not quite as sophisticated as it needed to be to get to the result that we wanted as a tri-Agency group.

So we wanted to develop this tri-agency fractions -- so we realized a more complex method would be needed. We would need to be able to smooth a variation that we identified in the first pass of this, we

needed to be able to account for factors associated with outbreak size -- so very large outbreaks -- and we needed to develop uncertainty parameters because that was not something we did in the first pass. So this is really the foundation -- serves as a foundation for the work that we're going to be presenting today.

Slide 12 (Webcast Recording Slide 62 of 172)
So, I also again wanted to quickly touch upon the other two projects that were really influential in shaping the work that went into the project today.

The food category effort that I'm not going to, again, belabor, because it's been mentioned -- but also the project that was discussed a little bit earlier in terms of the assessment of whether outbreak data is representative of sporadic illnesses.

Slide 13 (Webcast Recording Slide 63 of 172)
So, let me start talking about Phase II.

Slide 14 (Webcast Recording Slide 64 of 172)
So, again, we use the same data source here. FDOSS data is collected by the states and provided voluntarily to CDC, and there's a number of issues of course with that, most of which have already been discussed today and we're happy to talk more about those moving forward.

Slide 15 (Webcast Recording Slide 65 of 172)
So, next I want to talk about the selection and model input. We considered a variety of different model inputs. In terms of simple versus complex foods, suspected versus confirmed etiology, and outbreak illnesses versus outbreak counts -- and I'll walk through all of these.

Slide 16 (Webcast Recording Slide 66 of 172)
So, simple versus complex foods -- the way that we typically try and think about simple foods in a very simple way is that a simple food is something as simple and straightforward as a chicken breast. When you talk about complex foods, you start getting in to more complicated foods in terms of, let's say, a chicken salad sandwich.

So, a chicken breast is just a chicken breast. A chicken salad sandwich has chicken, has mayo, has probably some vegetables, maybe some walnuts, maybe some grapes, and bread and lettuce and cheese and a number of other ingredients, so it becomes much more complicated to know exactly what the food item in the overall product, or the complex food, caused the illness. It also makes it harder to tease out a number of other things.

Slide 17 (Webcast Recording Slide 67 of 172)
So -- sorry, advance the slide. There are a number of strengths and limitations for using simple versus complex foods. In terms of the simple food attribution, we gain some strength in the fact that the -- we can clearly identify which food category was contaminated.
So, based on the data and the data set, the FDOSS data, we know that it was the chicken, let's say, that was contaminated. And it's much easier to delineate regulatory authority for outbreak associated foods because, again, it's -- if it's the chicken, it's pretty obvious that its FSIS -- if it's leafy greens, it's pretty obvious that it's FDA.

There are, of course, some limitations though by using simple foods only. We do lose approximately half the outbreaks in the analysis, and we also lose data about what foods are typically consumed as a part of a complex food diet. Most of us don't just eat chicken breast and -- in one meal -- and then have a steak for dinner, and then some cereal for breakfast without milk. So, most of us don't eat in a very simple way, and so that makes it a little bit more complicated.

Slide 18 (Webcast Recording Slide 68 of 172)
In terms of complex foods, of course the strength here is that all of the food that's in the database gets included in the analysis, but we do lose some accuracy in terms of assigning foods to categories, and also, there's no formal interagency agreement on how to do a complex food methodology.
There's obviously been work published in the literature about it, but from a FSIS, FDA and CDC perspective, there isn't one agreed upon approach, but, as you'll see, that's one of the next things that we're looking to do for IFSAC.

Slide 19 (Webcast Recording Slide 69 of 172)
So, the next piece of this is confirmed versus suspected etiology. So, for each bacterial agent there are laboratory and clinical guidelines for confirming an etiology.
If at least one etiology was laboratory confirmed, the outbreak was considered to have confirmed etiology. *[Editorial note:* Information on Slide 19 contained an error at the time of the public meeting and in the live webcast recording. In the posted presentation slide set, Slide 19 has been edited post-meeting to reflect the correct definition of "etiology confirmed": "If at least two outbreak illnesses are laboratory- confirmed, the outbreak is considered to have a confirmed etiology."]

If no etiology was laboratory confirmed, but an etiology was reported based on a clinical of epidemiological feature, the outbreak was considered to have a suspect etiology, and that's just for definition purposes.

Slide 20 (Webcast Recording Slide 70 of 172)
So, again, there are strengths and limitations to both of these approaches. By using just confirmed etiology, we ensure that the inclusion -- excuse me -- we ensure we're including only outbreaks that are definitively associated with particular pathogens, so we know that *Salmonella* illness was actually a *Salmonella* illness, but we lose outbreak data for analysis by going with this approach.

If we were to use confirmed and suspected etiology, we maximize use of the available data, but there are concerns -- or sorry – but concerns with using the suspected etiology is reduced with the four pathogens that we're talking about here.

So, there's a greater concern with pathogens like norovirus, where most of the cases maybe are not confirmed, but are suspected, but that's not as much the case with these four pathogens. But the limitations are that we have increased uncertainty.

Slide 21 (Webcast Recording Slide 71 of 172)
So, IFSAC, in addition to reviewing the literature -- as I said, we conducted a quantitative assessment in the first phase that I mentioned to determine what would be lost if we used only confirmed outbreaks in this analysis, and what we found was that confirmed outbreaks for these pathogens consist of about 90% of the data, so the vast majority of the data was actually -- the outbreaks are confirmed.

And previous analyses by Painter et al utilized both confirmed and suspected etiologies to estimate attribution, so there's a framework and a basis in literature for this approach. So, given all of that, we decided with this effort, in Phase II, to use both confirmed and suspected etiology.

Slide 22 (Webcast Recording Slide 72 of 172)
So, outbreak illnesses versus outbreak counts -- so, again, outbreak illnesses are the number of illnesses within each outbreak, so cases of illness within an outbreak, which can vary, obviously, depending on the size of the outbreak. If it's a very small outbreak, it could be three, four, five, six, seven cases, but in very large outbreaks, that could rise to 1,500 cases or something to that effect.

And there's an assumption here that's being made about the probabilities that exist for these -- for using each one of these things. So, for outbreak illnesses, the probability that a food commodity will cause illness varies across the different commodities as opposed to using illness counts -- or sorry, outbreak counts -- where each food commodity has the same probability of causing illness in the population.

So, for example, if there's a ground chicken outbreak, it may cause the same -- it may cause just one outbreak, but many, many more people may get sick because of that contaminated raw chicken because it's getting spread further across the population and into the food supply, as opposed to something like a chicken carcass that is a single -- if not going to get necessarily as distributed within the population for the food supply.

Slide 23 (Webcast Recording Slide 73 of 172)
So, again, each of these approaches have strengths and weaknesses or limitations using outbreak illnesses. Using outbreak illnesses enables better assignment of illnesses to commodities, but small outbreaks are potentially underrepresented in the data as they are less likely to be detected and investigated, and there is a potential bias towards large outbreaks here as well, because larger outbreaks are easier to detect.

In terms of outbreak counts, the strengths are that the use has the potential to reduce the influence of these very large outbreaks on the resulting attribution estimates, but it eliminates the possibility of investigating the relationship between outbreak size and other variables, including implicated food -- setting among other variables.

Slide 24 (Webcast Recording Slide 74 of 172)
So, IFSAC decided to use illness counts based on that assessment, which enables better assignment to illnesses -- of illnesses to commodities -- minimizes the impact of large outbreaks, and also allows for future IFSAC efforts to incorporate complex foods into attribution estimates. And as I mentioned, it was alluded to earlier, and then Dr. Griffin is going to be talking about that later on today as a future IFSAC project.

Slide 25 (Webcast Recording Slide 75 of 172)
So, again, we just wanted to draw a bit of comparison between the work we're doing here and presenting here today, and the work that's been done by others, specifically, Dr. Painter at CDC.

So the work is different from what Dr. Painter did. It was informed by, but it's different. So IFSAC uses simple foods, whereas the Painter work uses complex foods.

We are using newer data. Again, that's because it's available to us to a large extent. We're using data through 2012, whereas Painter used data through 2008.

We have different categorization schemes. It ends up that we both have 17 food commodities -- or food categories -- but as you'll see probably from Dr. Cole's talk this afternoon, or later today, that the 17 commodities that IFSAC developed actually started with about 40 commodities, and then were narrowed for the purposes of analysis, whereas the Painter scheme that was developed, it was 17 terminal commodities.

In terms of study outcomes, IFSAC looked at the percent of illness attribution as the outcome, whereas Painter did a bit of a burden estimate in terms of looking at the number of illnesses, hospitalizations, and deaths.

And then, as we've already said, the number of pathogens that were considered in the analysis, we in IFSAC only used these four priority pathogens, whereas Painter used 36 agents.

Slide 26 (Webcast Recording Slide 76 of 172)
So, just a summary of the decisions that we used, we are using CDC FDOSS data from 1998 through 2012. We used the four priority pathogens, simple food attribution approach, confirmed versus suspected etiology, and outbreak illness as a unit of measure.

So, I'm going to stop here and turn the talk over to Dr. Dana Cole to talk about exploratory analyses, and then after this part of Dana's talk, we'll stop and take questions from the audience.

Recording Timestamp=01:31:02

Slide 29(Webcast Recording Slide 78 of 172)
DANA COLE: Okay. I'm going to go over at this time the exploratory analyses that informed our model development because, as Joanna indicated, in our first phase we realized that we wanted to do a -- calculate the attribution estimates using a more sophisticated modeling approach, and when you make that decision you need to do a series of exploratory analyses to determine the distribution of the underlying data and make decisions then on how you're going to approach a model.
So I'm going to walk through first the exploratory analyses. We'll break for a question and answer period and then we'll come back and I'll talk about the method and model results, and then we'll follow up with Dr. Bazaco talking about the assumptions and the strengths and limitations and conclusions based on our modeling decisions.

Slide 30 (Webcast Recording Slide 79 of 172)
So, first our exploratory analyses -- so as you heard from Joanna, we were looking really at three sources of data variability that we wanted to explore in detail to make our decisions about how to develop the model.

So we looked at outbreak size variability because, as she said, our choice of using outbreak illnesses, or the number of illnesses associated with outbreaks, as our unit of measure, and calculation of attribution estimates meant that we needed to look at size of sources of variability across outbreak size.
We also wanted to look at the variability across the different food categories and make decisions about the food categories to be included in our analysis, and we had to ultimately decide on the years that -- and how to treat the data across the different years of our database.

So, the first exploratory analysis, our outbreak size variability, again, remember our goal was to estimate attribution percentages based on the number of illnesses, but if -- you can see from this graphic that I have up here that the distribution of outbreak -- the number of illnesses associated with each outbreak was not a normal distribution.

So, if I can use a pointer -- so across the "x" axis is the different food categories included in the analysis, and then each point represents the number of illnesses associated with an outbreak assigned to one of those food categories.

So you can see that it's a -- most -- the number of illnesses are clustered down here at the bottom of the graphic, but then we have these very large outbreaks scattered above indicating that the variability associated with the outbreak size was not a normal distribution.

And so, to limit some of the effect of these very -- these larger outbreaks, and approximate a normal distribution, we chose to log transform the outbreak size so that we could approximate a normal distribution. That's much easier if you can approximate a normal distribution for modeling.

Slide 31 (Webcast Recording Slide 80 of 172)
So, I'll walk you through these very pretty graphics. So we've already decided now that we need to log transform outbreak size, but there's more to outbreak size than just sort of making it a normal distribution. We also sought -- we knew that there are a number of variables that are associated with the size of an outbreak.

So, for example, looking at this graphic here, we have each of our pathogens on the horizontal axis, so going vertically you see the distribution of the outbreak size going vertically.

And so our first variable up here at the top is, for example, whether the outbreak was multi-state or not. So, we -- if you look at the first line here, this point is the average outbreak size across all multi-state or single state outbreaks.

And what we mean by multi-state outbreaks is the outbreak itself had exposures occurring in more than one state, versus a single-state outbreak where the outbreak -- all of the illnesses were caused by an exposure that -- in a single state and was not distributed widely across states or across the country. So, as you would expect when you look at outbreak size, going across here -- across all our different pathogens -- the average across -- the middle term is the average outbreak size by whether it was multi-state or single-state. So you can see that they start to diverge.

So, the focus is on the circled area here where you can see that as the -- as outbreaks associated with multi-state distribution -- as you might expect -- tend to be -- have a much larger average size. And if you look at the far right, then that is the distribution of all the outbreaks and the outbreak size of all the distribution.

So you can see how the distribution fans out quite dramatically on the far side, again characterizing the high level of variability that we have in outbreak size across our variables.

So, again, the other factor that we saw here in the middle row is the setting of food preparation, so if you look at our different food preparation settings -- so there is -- of course, if you have a multi-state

outbreak, you tend to have a variety of food preparation settings, so one of our categories is multiple food preparation settings.

We also have those food preparation settings where the food was prepared in the private home, and then we have a food preparation setting of a restaurant.

Again, you can see, if you look at this middle graph, that the average outbreak size varies according to how -- where the food was prepared -- and so we knew that we needed to account for that also in our model, the setting of food preparation.

And then finally, down here is our food categories themselves. Joanna spoke to the fact that we hypothesize and understand that outbreak size is going to vary by the food category itself, and in fact explore that data and see that -- if you look again across our pathogens paying attention to the average outbreak size associated with each food category, you see quite a spread here in the middle.
And then when you see the whole distribution outbreak sizes, you can see it's quite variable, again, making us realize that even for all four of our pathogens under study, we needed to consider these three variables.

And again, if you look at -- across each pathogen -- you can see the outbreak size tends to vary somewhat across each pathogen, so we knew we needed to take into account all these variables in our model when we are estimating attribution percentages.

Slide 32 (Webcast Recording Slide 81 of 172)
So our results and decision from our first exploratory analysis of outbreak size -- first, we needed to log transform our observed number of illnesses so that we had an approximate normal distribution of illnesses from which to model.

Then we found that there were four factors, as I highlighted, that were significantly associated with outbreak size. We understood the pathogen was one variable, the setting of food preparation was another, whether the exposures to the contaminated food occurred in a single state or distributed across multiple states, and the food category itself that caused the outbreak all contributed to variability in the outbreak size.

So we concluded that we needed to consider all these when we started model building to estimate attribution percentages.

Slide 33 (Webcast Recording Slide 82 of 172)
The second exploratory analysis had to do with the food categories that we were going to generate attribution estimates for. So you've seen this food categorization scheme earlier today and you can see the high number of food categories that we now have available to assign foods to specific categories. However, in order to generate estimates for these food categories, you need to have enough outbreaks in each box to generate -- to have the data that you need to generate an estimate -- and we quickly found, again in part because we're limiting our analysis to the four priority pathogens -- then we started to look at the distribution of the outbreaks across our various food categories -- we didn't have enough data to generate attribution estimates for every single food category that we had in our food categorization scheme for these four pathogens.

So our goal then was to maximize the number of food categories that we generate attribution percentages for, but also maximize the amount of data that we had in each category to inform the estimate.

Slide 34 (Webcast Recording Slide 83 of 172)
So, the first step then was to go look at the food categorization scheme and go to the lowest level, if you will, that we could where we had outbreaks and illnesses in each of the boxes. And so that brought us to this level, where we have -- we've just -- for the lower subcategories we just aggregated them up to their parent category for purposes of analysis.

So you can see that we don't have nearly the number of categories, but yet, again, with our -- just generating attribution estimates for four pathogens, we needed to aggregate even more so that we could maximize again the number of outbreaks and illnesses that we had in each category for purposes of modeling.

So we took another step, then, and decided that -- to aggregate further -- so, for example, this box -- the other meat and other poultry categories are aggregated or combined into another -- an "other meat and poultry" category.

By the same token, in the aquatic animals, we combined those outbreaks that were attributed to shellfish with those that were attributed to other aquatic animals for an "other seafood" category. And finally, we took in the plant food group -- we took the nuts and seeds category and combined it with fungi, herbs, and root underground categories into a combined "other produce" category, so that is how we got from 40 categories to the 17 that we used in our analysis.

We might have to replace the battery. Did I go too far? Is that right? Yeah, that's right. Okay.

Slide 35 (Webcast Recording Slide 84 of 172)
So the other component of our exploratory analysis was the years to include in the analysis itself. So our goal in generating these attribution estimates is we wanted to have the attribution estimates that reflected the most recent years of data.

So we wanted the most current and most recent attribution estimates that we had available, but we also recognized that outbreak data, by its nature, is very variable from year to year, so we needed to use -- while our goal was to minimize the number of years of data so that we could have the most current estimates, we recognized that we needed to include enough years that we could feel confident that we had smoothed the variability some.

So this is just an example of one of the exploratory analyses we did looking at the data -- to look at the variability -- depending if you used three years of data or five years of data or seven years of data to inform your estimate.

So these are three year averages versus five year averages, versus seven year averages, and you can see that just looking at this, the three year average, the blue line, shows you a lot of variability, such that the time period of your analysis is really going to have an impact on your actual estimated percentages. But the five year and seven years show a lot more stability, a lot more smoothness in the estimate, so we knew that we could choose five or seven years as our time period of analysis and have reasonable stability to our estimates.

Next slide. Yeah. I'm having trouble with this. Thank you.

Slide 36 (Webcast Recording Slide 85 of 172)
However, when you look at the outbreaks as they are distributed across the time -- entire time period -- we noted that if we were to truncate the data -- in other words, we were only to use say five years or seven years of data to generate our illnesses -- that there were years where an entire food category had no outbreaks attributed to it. So this table shows those in blue. So every blue category had no outbreaks attributed to it during that year.

And so, we realized that simply using the data that had occurred in the most recent five or seven year timeframe would exclude categories that we felt had been attributed to foodborne illness in the past, and so we didn't feel comfortable entirely ruling that data out because in some cases some food categories are less commonly implicated than others, but that doesn't necessarily translate to zero foodborne disease risk.

So, we decided that while we wanted to emphasize the most recent five to seven year time period, we didn't want to just truncate the data and ignore all the data that occurred before then, that we actually wanted to somehow weight the data, such that the most recent time period would be responsible for most of the data informing the estimates, but we didn't ignore the data that occurred prior to that, and I'll walk you through that in the next slide.

Slide 37 (Webcast Recording Slide 86 of 172)
So, our conclusions for our exploratory -- our third exploratory analysis -- was that because, again, our goal was to limit how the shortest time period, the most up to date attribution estimates -- and since five versus seven years both resulted in fairly smooth, stable estimates, we decided to choose five years as our period where we were going to fully weight the data and give the data that occurred in that most recent five year time period full weight to our attribution estimates, and did not -- but then when we thought about excluding data, we did not decide to exclude the data because, again, if we did that we would exclude entire food categories or have food categories that only had one year of data available to model.

And furthermore, if we excluded these categories, these categories were more likely to be FDA regulated food categories, and again, we didn't feel that these categories represented zero risk, as would be suggested if we just ignored all the data prior to the five years.

So, our decision was we are going to use all the years of data, but again, we're going to give full weight to the data in the most recent time period -- so 2008 to 2012 -- and discount the weight of the data for years occurring prior to 2008.

Slide 38 (Webcast Recording Slide 87 of 172)
Thank you. So this shows our approach to discounting. So the top graphic shows each year of data and the possible weights that you would apply to that data.

So, what we have here is -- for the most recent five year time period we have what we call a shelf. So all of the data reported during that five years gets full weight, so you can see from the y axis it has a "1." So, full data. We're not discounting that data for the most recent five years.

But then through the process of examining the data and establishing our priorities for how we thought we wanted to weight the data, we sought an exponential decay function that would give at least 50% of the information that informed the actual attribution percentage to the most recent five year period. So we wanted that most recent five year period to drive at least 50% of the data, so that we mean everything reported before that could be no more weight to the total estimation -- model estimation -- than 50%.

And we had a second goal, again, that data older than ten years -- because we had 15 years of data in our study -- data older than 10 years, we didn't feel we wanted to give more than 8% weight -- so less than 8% weight to anything over 10 years old.

Again, we don't want to completely ignore that data, but we don't want it to have an undue influence on our estimates.

So, you can see that we explored a variety of exponential functions that would -- to inform our discounting scheme -- and the one that fit the criteria of at least 50% weight to the most recent five year period, and 50% weight to data older than that, with less than 8% for anything over ten years, was this exponential decay function in 0.7.

As you can see when you look at the weight given to each five year time period, our most recent time period actually got 67% of the weight, so more than 50%, but our older -- data older than ten years, was only 5% of the weight, and then leaving 28% of the total weight to that middle time period. And that was the function, again, that satisfied all our criteria.

If you look at the data weights for these other functions that we explored, they didn't meet our criteria, so we ultimately chose the 0.7 one -- exponential decay function.

So, that's our exploratory analysis. Again, we want to break now for a question and answer period. We've put a lot out there as far as our explorations and our data analysis that we wanted to give you the opportunity while the questions are still fresh in your mind to ask us some questions about it before we go into the model results and the rest of the modeling effort.

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Question and Answer Period

GREG DINAPOLI: We can start with the -- if there are any questions from the audience?
(No audible response.)

DANA COLE: They just want to move on to the model.

GREG DINAPOLI: They do.

DANA COLE: Just get to the meat of it, right?

GERG DINAPOLI: Is there anything the panelists would like to say to get things started? Caroline, I think is going to get us started.

CAROLINE SMITH DEWAAL: I seem to be a long way from the microphone. The -- so, Dana, what I'm seeing, and this is a lot of data, and I would love to have these slide sets so we can study them in a little more depth.

What I'm wondering, though -- for example, I saw on the seafood line that you have years and years where you have no data, and that's not consistent with what we're seeing. I mean, we see seafood data coming in every year, so what data are you excluding?

DANA COLE: I think the important point is these are just the four priority pathogens.

CAROLINE SMITH DEWAAL: Okay.

DANA COLE: It's not the entire outbreak data set.

CAROLINE SMITH DEWAAL: Okay. Right.

DANA COLE: There's a lot of other causes of seafood outbreaks that we don't have here in our analysis because we just focused on *Salmonella*, *E. coli* 0157, *Campylobacter*, and *Listeria*.

CAROLINE SMITH DEWAAL: That totally explains it.

DANA COLE: Yeah.

CAROLINE SMITH DEWAAL: So –

DANA COLE: No Vibrio in this analysis.

CAROLINE SMITH DEWAAL: And no Vibrios are in there?

DANA COLE: No Vibrios

CAROLINE SMITH DEWAAL: Okay.

GREG DINAPOLI: Cary, any questions from –

CARY CHEN PARKER: No.

GREG DINAPOLI: No? Panelists, any -- especially from Dr. Batz, Dr. Golden -- they're both new up here, so.

MIKE HOEKSTRA: I'll go ahead and try and add my own flesh out, which is that in essence one of the things you're probably thinking as you try and absorb all of these slides is that, wow, they made a lot of decisions.

And, indeed, that was the process, and you can go and ask to what extent was science able to drive those decisions? To what extent was the active areas of quantitation and other problems in public health able to drive that decision making process? To what extent were factors of personal belief, and so on, or the literature, at play in those decisions?

And it would be hard to summarize that across the board, and yet, we spent a lot of time basically debating precisely these points, and in some sense we hope that -- to use the modern phrase -- the wisdom of crowds -- insofar as we are a crowd or connected to a crowd -- was able to inform that decision making process because it's a legitimate question.

How did you get where you are? We're trying to put that out there. We made every effort to consider, in essence, the consequences, and both in terms of qualitative and quantitative investigation, the consequences of our decision making.

GREG DINAPOLI: Thank you very much. Anyone? Any questions?

BETSY BOOREN: Good morning. Betsy Booren, North American Meat Institute.

I appreciated your analysis on the weightedness of looking at the data, and I think that's really critical. Have you started to dig in to the different main topic areas? Like meat and poultry would have a different risk perhaps for STEC or *Listeria*, as would produce, and I'd be interested in seeing -- or I would imagine the regulators -- would be interested to see how that weighted aspect in those specific foods may drive the policy.

DANA COLE: Some of that -- at least not -- the answer to the question about driving policy -- but some of the effect of the weighting you'll see -- of the discount weighting you'll see as we get to the model results.

CHRISTOPHER BRADEN: My name is Chris Braden from the Centers for Disease Control and I was part of the decision making, but I just want to -- that's why I want for you to --
I wanted to emphasize one thing that I thought was very interesting in the decision process, and I didn't pay a lot of credence to outbreak counts as a measure in doing the -- this attribution estimate -- until we really got into the argument as to the pros and cons of using outbreak counts versus numbers of illnesses.

And what we ended up doing, because outbreak counts could have such a bias introduced by very large outbreaks, is introducing these terms that basically smoothed the distribution of outbreak size.
But if you -- I was wondering if you could comment on the model, because what you want to do -- I'm sorry, this keeps going down -- what you want to do is you want to be able to have enough variability in the outbreak size to account for what is logical epidemiologic thinking about the fact that some foods and some pathogens are more likely to account for larger outbreaks, which would also probably be true for their risk for sporadic cases.

Therefore, they should have a higher weight, epidemiologically speaking, and at least as far as my logic is concerned, whereas if you just averaged them all to where you would have basically a constant outbreak size, you would be basically then equivalent to modeling outbreak count because every outbreak would be the same size.

So, how well do we think we did in getting to that balance between a -- you know, a very smooth distribution -- say, for an average overall -- versus accounting for what should be, epidemiologically speaking, a logical distribution of outbreak sizes that accounts for that greater risk for some foods and pathogens?

MIKE HOEKSTRA: We think we did alright. In general, our view was that if you go the outbreak count route, then in some sense you are trying to characterize system failure in the sense that an outbreak in and of itself is a kind of an event.

And what we were actually hoping to do is to extrapolate our numbers out to a larger population, and that indeed illnesses is the right measure, independent of the fact that illnesses are reported in an uncertain fashion.

The fact that the log transformation basically produced pretty close to normal distributions on log outbreak size is quite reassuring, because that basically says that using means has some meaning. You're measuring a real thing.

And yet, we were also able, in working with log transformed illnesses, to still isolate the very large outbreaks and examine their influence on our final estimates.

So, in fact, we thought the epidemiologic problem is linked to outbreak illnesses as they're reported, admittedly with uncertainty, and that the log transformation allows us to get a look at factors at play in terms of outbreak size, the number of illnesses, as they relate to pathogen, to multi state, single state, to mode of preparation, to commodity, and that indeed -- that picture provides the best link to the foodborne illness problem.

GREG DINAPOLI: Thank you, Michael. Thank you, Dr. Braden, for your contribution. Anyone else on the panel who would like to --

MICHAEL BATZ: Sure. It's Batz --

GREG DINAPOLI: Okay.

MICHAEL BATZ: It's Mr. Michael Batz. I don't want to overstate my credibility here, but I wanted to build on that a little bit, but first I think Caroline should ask all the questions, and you shouldn't be asking all of these tough questions of us up there, but -- no, but I think the difficulty that we faced with this question, as of all of them, is that it's not easy to define a clear hypothesis or an easy test to say, what is the right thing?

So we end up in a bit of a Goldilocks scenario where we have good arguments in favor of why outbreak counts are a reasonable measure, and we have other arguments for why outbreak illnesses matter, but then each of them also have built on top that, limitations.

And so then we end up somewhere in the middle because we can't agree that either one of them is right, and I think what the presentations that we've had this morning hopefully start to lay out is that we've had to make a more sophisticated model based on the fact that we were seeing these patterns -- that we were seeing that it did matter which one of those we chose.

So it became more a matter of saying, "Well, we can't choose either one of them. We need to try to deal with this problem head on by creating more sophisticated models." And I think some of that is the log transformation stuff, and some of that is the model that we'll be talking about I think in the next session.

But hopefully it starts to explain why the -- why we've had to make some of these Goldilocks type decisions along the way that reflect our best judgment, but that nevertheless reflect judgment and not a clear, you know, line in the sand that we said, "This is definitely the right way to do things."

All these things, I think, require judgment, and I think -- you know, hopefully peer review will tell us, you know, how well we've done at making those judgments and done our duty to make sure that not only are the estimates more robust and more useful than before, but that the vigor that we applied, you know, bears that level of scrutiny well.

GREG DINAPOLI: I've got two questions now. If you could state your name and who you're with?

KAREN HOELZER: Karen Hoelzer with the Pew Charitable Trust. I was wondering if you could explore a little bit more how you discounted all the outbreaks. In particular, where do the 8% weighting for outbreak data more than ten years ago come from?

And I may have read one of your figures incorrectly, but it looked like the smoothing line was actually better for five years of data than for seven years of data. If that is the case, could you explain why you think that might be the case?

DANA COLE: So that was just an example, so it didn't show overall -- that was just *E. coli* O157 and meat. So, again, depending on the seven year -- what happened in the seven years, it may or may not have been. But overall, across all our analyses for all the pathogens across time, five years, again, gave us enough -- gave us that smoothness that we wanted, that sort of stability that we were looking for across all the pathogens, and also was the least amount of time to give us the most current attribution estimate possible. And I forgot your first question, sorry.

KAREN HOELZER: The 8% for older data, where do these numbers come from?

DANA COLE: Oh, right. Where we came up with that. That was one of those decisions. We went through a lot of iterations of looking at the data and trying to let the data inform that decision versus letting our own judgment inform that decision, and I think like you've heard, it was a combination of the two; looking at the underlying data, variability, looking at that graphic or that table where you saw the blue boxes and where we had outbreaks and where we didn't.

I think -- and then just our judgment where, you know, it was -- I mean, this has been -- I mean, I hope you get the idea. It's been a series -- iterative series of decision making -- and because there was somewhat, you know -- our preference might have been to like just ignore old data because we recognize things have changed in 15 years, and so we really -- our ultimate decision on the 8% and the 50%, I think was -- it was, at the end of the day, qualitative, but I'd like to say it was semi-qualitative because we looked at the data and looked at the outcomes of each other decision we might have made, and ultimately felt like we really didn't want to overemphasize that early data, but we didn't want to throw it away.

And if you looked at the top graph and you saw how as you applied that decay function, that .7, I mean you're getting to almost zero weight as -- you know, for 1998 and 1999 -- and so that was part of our decision. It was semi-quantitative, I guess.

There is definitely the qualitative aspect that we really wanted to -- to not ignore the data in that first time period, but really under -- you know, underweight it, or weight it very little, and then put most of the weight in a five year period.

But I can't tell you that there was just an empiric criteria, it was a combination of looking at the data, looking at the effective decisions, and then making a decision that we really think that we can't have it -- the other functions did not suit our purposes, they just gave too much weight to one time period or another than we were comfortable with.

ARIE HAVELAAR: Arie Havelaar, the University of Florida. My question is also about the struggle that you had with including enough data for you estimates because you want your estimates, on one hand, to be current.

On the other hand, the number of outbreaks that you have for the last year or few years are not enough to have a really powerful analysis, and what you did now, if I understand your explanation correctly, is that you decided to have a moving window of five years and then have this exponential decay.

It feels like a very unnatural break in looking at your data because you take five years of data fully, and then only you start to discounting, and I could imagine other choices could have been made, like discounting from day one onwards, and other choices.

And I think none of these choices can be stated to be correct or incorrect, but I think what is very important is that the impact of those different choices and scenarios are presented so that we can sort of get a better idea of the uncertainty and the results made by those model choices.
And I understand from an early comment of Mike Hoekstra, that you did all those scenario analyses and I think it's key that you tried to have as many possible choices as you can, and tried to present the uncertainty so that we get a better idea of the robustness of the results against these choices, which I think it will be very difficult to say, "This is the right choice. That's the wrong choice."
It's all the choices that you can, so I'm hoping to see more of your results in that respect.

MIKE HOEKSTRA Thank you, Arie. Yes, we have those analyses in our back pocket. Indeed, there are attributions -- we have buckets of attributions overflowing.

And I think one piece that perhaps hasn't come through is in essence that at the end of the day we're pretty happy because the attribution is pretty robust across the scenarios that we looked at, and that's not so visible in the report where we formally attach statistical uncertainty to the estimates.
But, in fact, we have in parallel a set of scenario analysis assessments that also -- that show a considerable degree of robustness. In other words, we could have gone with a three year shelf and .8 decay. We could have gone with a fancy sigmoidal decay function and tried to attach greater scientific value to it, but we did not.

We arrived at what we thought was a bit of a middle ground, the bed whose softness factor was just right.

CAROLINE SMITH DEWAAL: I love to hear you all admitting the Goldilocks factor. I think that really is helpful. I'm Caroline Smith Dewaal, CSPI. I just -- I want to test a little bit this concept that the most recent data is actually the best data. What we're seeing in terms of reporting up from the states is that in fact the most recent data will have many fewer solved outbreaks.

So, in other words, to do this analysis, you need outbreaks with both a food -- a pathogen and a food attribution as part of the outbreak investigation.

What we're seeing, and again, I'm not on the program but I get to at least describe without slides what we're seeing in the outbreak reporting coming up from the states is that you are going to have many fewer solved outbreaks that have those two criteria met in order to be part of your study.

So, in fact, the pre-2008 data may be more robust, may be better, and may be close enough to -- I mean, the assumption you seem to be making is that things have really changed between 1998 and 2012, and while HACCP implementation in the meat industry for these pathogens may have changed it for the very early data, I'm not sure that we have data that would support that that mid set of data is less valuable than the most recent data.

So I just want to kind of make you push a little bit on that assumption.

DANA COLE: Yeah. Thank you. I think you summarized it best in how I was going to answer the question.

It's not that we think the most recent data is the best quality necessarily, but again, our analysis is limited to the four pathogens, and if you look at the variation in outbreak reporting, our four pathogens actually haven't suffered the same degree of change that some of the other pathogens have, like Norovirus and some of the others where there's been that changing in the reporting.

So, again, we -- you know, we actually discussed -- you know, we did look for trends in the data. We did look for trends as far as, like, are there actual trends in the data we can model independently? And ultimately we ended up with the decay function because the data are -- one, we feel like the four pathogens, at least in our analysis, have been fairly stably reported. We haven't seen the drop off quite as pronounced as you're describing in the database overall, and we were really getting at that we wanted the most recent time period.

And we had a lot of discussions about what constitutes the most recent time period, as you've heard -- and so, five years. And like I said, there's a lot of volatility in the data recognizing that a single outbreak in 2010, you know, of SE attributable shell eggs, can really skew any estimate that has 2010 in it. So we had to strike that balance. We really wanted to capture that recent time period so that we could feel like these are estimates reflecting foodborne illness, foodborne contamination today, the best we know it, but not ignore the past, because, again, we didn't see solid trends that you describe.

We looked for them. There may have been -- you know, again -- but the data sparseness -- we chose to go with the decay function and not try to estimate change over time. That's in Patty's talk.

PATRICIA GRIFFIN: No, I just wanted to add -- I'm Patricia Griffin and I'm on the Steering Committee, and I'm from CDC.

I just wanted to add to what Dana was saying in response to Caroline -- is that we agree that there has not been a lot of change in the most recent five years compared with earlier years, except there's been a big change in the sources of *Listeria* illnesses since 2002.

And if one is optimistic that we're going to make changes and that some of our food categories are going to become safer, then it would be nice to be able to capture that.

And if we have a system in which we equally weight all of the past ten years, we're not going to be able to capture those real differences in source attribution that have occurred recently.

So, I think what this group is trying to do is not just make estimates for right now, but devise a method that will work going forward, when we hope to see real sea changes in contamination of certain products with resulting decreases in illness due to those products.

GREG DINAPOLI: Thank you. Any final remarks from the panelists?

MICHAEL BATZ: I was just going to -- Caroline, I think it was a very good point. I think the question of how much data we've got, and obviously we have concerns about data quality if we have less information coming through.

I think one of the things about down weighting older data is that if there is a trend in a particular pathogen food commodity, the down weighting helps account for it.

But if there is no trend, the down weighting doesn't make it worse, right? Because there's no trend so you're not biasing towards anything.

So, it allows us to say -- to not necessarily posit there is a trend and therefore we are going to account for that, but to say that if there is a trend, down weighting should address some of that, and I think the down weighting of older data in sort of the value of information and stuff -- although it hasn't been done in outbreak analysis or attribution estimates before now, it certainly is not a novel idea, and it is sort of -- you know, we did build on -- and we might not have made that case strongly enough today either. There's a literature on down weighting older data for value of information and we tried to follow that as best we could.

GREG DINAPOLI: Thanks, Mike. Is that the last word for this panel?
(No audible response.)

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GREG DINAPOLI: Thank you. We'll move on to our next panel, "Estimating Foodborne Source Attribution for Illnesses Caused By *Salmonella*, *E. coli* 0157, *Listeria monocytongenes*, and *Campylobacter*, Part 2."

Dana and Dr. Bazaco will present. So I haven't introduced Michael. Dr. Bazaco is an Epidemiologist at FDA's CFSAN Michael spent time as a researcher and teaching fellow at the University of Pittsburgh Graduate School of Public Health before coming to FDA.

He received a Bachelor of Science in 2001, and a Master of Science in 2004, from Virginia Tech, and his Doctorate in Epidemiology in 2012 from the University of Pittsburgh.

Dana?

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DANA COLE: All right. I need instructions here. I'm not mechanically inclined. All right. So, now we're going to talk about the actual modeling methods and then the results. Next slide. Maybe I'm too impatient?

So, again, we explored -- just like our exploratory analyses, we explored a lot of different ways to actually model the data. But we also have some goals for our models that we brought to our approach to deciding what -- ultimately what model we wanted to use, and one of them is that we wanted to have a single modeling approach for all four of our pathogens, and we've seen a little bit of how variable the data can be across pathogens, across food categories, and that sort of thing.

But we wanted to have one model approach to generate attribution estimates for all four of our priority pathogens, and we also wanted that model to be as simple to achieve our goal.

We didn't want to have a lot of complexity to it. Again, I'm speaking to Dr. Griffin's point that we want a model that we can run again in the future, and estimate -- generate new estimates with newer data. We really wanted something that was repeatable, and you know, achieve the purpose for accounting for the factors we knew we had to adjust for in outbreak size, but yet, not overwhelm the data with complexity that sort of went beyond the data or our ability to really easily update these estimates over time and apply them and use them.

So, what we decided after several looks at the data -- several models -- again, was to choose the analysis of variance, the ANOVA model, for each pathogen. We felt that it met our needs with regard to adjusting for the variables we knew to be associated with outbreak illnesses, but it was fairly straightforward to run and could be applied to all four pathogens in the way that we wanted them to be -- a single model to be used to apply them.

So, what the model did is…

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…you can see the formula here. We had -- for each pathogen, we took the log of the estimated ill and then included a variable for whether the outbreak was multi-state or single-state, and a variable for the setting of food preparation, and then the food category.
So each estimate -- and then generated estimated illnesses using this model -- and then replaced a generated data set where the output of the model was then plugged into the outbreak data set with the predicted estimated ill.

So, I have an example here at the bottom of the slide how that worked. So, based on our model framework, all single-state -- so the first variable, the multi-state -- all single-state *Campylobacter* outbreaks in which a food was prepared in a restaurant, and the implicated food was chicken, then would be assigned the same model estimated number of illnesses.

So, that's how the model worked in that we took the model worked in that we took the model estimated number of illnesses and then for the variables in our model, we assigned that number to each outbreak.

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So, then, after we generated the model estimated number of illnesses, we applied our discount. And so, again, how that worked was, depending on the year that the outbreak occurred, the number -- estimated number of illnesses were either discounted or not.

So, again, if the outbreak occurred in 2011, then all the model estimated illnesses were used in the calculation of the attribution percentage.

In contrast, if the outbreak occurred in 2001, then probably less than 10% of the model estimated number of illnesses were actually included in the attribution percentage calculation.

So then we summed -- for each pathogen and each food category, we summed all the estimated number of illnesses across this data set in the numerator, and then divided by the sum of all the illnesses for the given pathogen, in the denominator, multiplied by 100, to get our pathogen-food pair attribution estimate.

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So, for estimating the credibility intervals or statistical uncertainty associated with our point estimates that we calculated, we did 10,000 Bayesian bootstrap replications of the data set.

So, in other words, we had this data set with the model estimated number of illnesses that have been discounted according to the year that they occurred, and we applied a distribution -- a Dirichlet (inaudible) distribution, that was informed by the distribution of the food categories in the data set, and then sampled the data set 10,000 times and generated basically 10,000 new data sets that were informed from the original data set.

And for each data set then we treated it as its own data set and calculated the attribution percentages that we would get using each data set.

So, we have 10,000 now attribution estimates, and then put those into distribution, and then used the interval defined by the five percentile and the 95 percentile as our credibility interval for the point estimate that we generated from the original data set.

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So, our results overview. I'm going to give you a summary of the database itself, or the data that we used in the model, and then focus a little bit on the data from the most recent five years, because of course that was the data that was over 50% informed, or 50% of the final estimates that we had, and then show you the estimated attribution percentages in our 90% credibility intervals.

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So, first our summary of the data. So, over the 15 years of our study period, we had 2,739 reported outbreaks caused by one of our four pathogens that we were studying.

Eighty-four of these were caused by multiple pathogens, so we excluded those because we were looking at single pathogen outbreaks.

And then there was another 1,011 that there was no food vehicle identified, and we've spoken to that already this morning, that not every outbreak investigation successfully implicates a food, so we had to exclude 1,000 because there is no single food identified.

We also excluded three outbreaks that occurred in outlying U.S. territories and then 689 outbreaks were attributed to foods that were in that complex food category that Joanna described this morning.

So in other words, we couldn't say for certain what food category the food belonged to because it had multiple ingredients that may have been contaminated belonging to multiple food categories, so 689 were excluded for that, which left us 952 outbreaks that was caused by one of our pathogens and had a simple food implicated.

Five hundred and ninety-seven of those were caused by *Salmonella*, so that was the most -- that pathogen was most frequently in our data set. One hundred seventy caused by E.Coli 0157, 161 caused by *Campylobacter*, and then only 24 were caused by *Listeria monocytogenes* or LM.

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So I don't expect you took look at all the data in this table, but just wanted to show you sort of the effect that our log transformation and our discount function had on the actual estimated -- average estimated size of outbreaks.

So this table is in the full report, in the Appendix, so I encourage you to go there to look at the individual data points, but -- oops, just to blow this up.

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Hopefully you can see this a little better, just to show you, for example, for *Salmonella*, if you look at the observed average outbreak size it was 31 in the data set, but after the log transformation and the discount function, our average outbreak size for *Salmonella* in beef was only 22.

So you can see that we definitely limited the impact of some of the larger outbreaks by doing this. We smoothed the data quite a bit -- the outbreak size data quite a bit -- and again, the discount function actually discounted the outbreak illnesses depending on the year that the outbreak occurred.
So this is just an example of how the -- on the results of both the log transformation and the discount function.

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So, again, because this five year shelf, as we call it, was given 67% of the weight of the data, I thought we should take a look at the outbreaks and the illnesses that occurred during this five year shelf.
So for -- again, we had 15 years of data, so you consider there are three five year time periods for the -- associated with the data -- so if the outbreaks were distributed evenly across the 15 years of study data that we had, then you would expect approximately 30% or 33% of the outbreaks to occur in the five years, if there in fact was just steady reporting of outbreaks.

So it's somewhat informative to look at the distribution of the outbreaks that occurred in this most recent time period and get an idea of what was informing -- or contributing the most information to the attribution estimate.

So, again, *Salmonella* -- 30% of the outbreaks occurred in this five year time period, but 45% of the estimated illnesses -- for *E. coli*, again 30% of the outbreaks, but 24% of the illnesses, gives you an indication of sort of the size of outbreaks as we move in the most recent time period, relative to those in earlier time periods.

And *Campylobacter*, again, 33% of the outbreaks occurred in our most recent time period, with 17% of the illnesses.

And then when you get down to *Listeria monocytogenes*, or LM, 50% of the outbreaks occurred in our most recent five year time period, and 60% of the illnesses occurred in our most recent five year time period. So, these outbreaks clearly -- more of them occurred in the most recent time period relative to the previous ten years.

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So, here's -- this is again in the report, and so this is not the best graphic for looking at individual estimates, but what I want to emphasize here is when you look at the attribution percentages across all four pathogens in a graphic such as this, some patterns start to become clear when you look at it overall. The first pattern that you see is that *Salmonella* and *Campylobacter*, compared to the other two, were distributed across more food categories relative to the other two. There's many more estimates for food categories for both *Salmonella* and *Campylobacter*.

Another feature is that you have some estimates that are distinctly different seemingly from the rest of their estimates, so we have one that stands out here, we have a couple that stand out here, and couple that stand out here. So, just sort of taking the big view here and what do we see?
And then we also see another feature -- is that we have a lot of variability in our credibility interval. Some have very wide credibility intervals, some are very small, so I'm going to go a little bit deeper into the results now and talk about these features in more detail.

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So one way of comparing the results that you have across the four pathogens is to look at the top food categories that were responsible for 75% or more of the illnesses in the data set.

So if we look at that, you see, again, some different -- you can again see some differences across the pathogens. Again, one -- *Salmonella* was distributed across seven different food categories, so seven different food categories explained 77% of *Salmonella* illnesses in the data set, versus *E. coli* 0157, *Campylobacter*, and LM really only have two food categories that account for at least 75% of the illnesses.
So, again, another feature then is that these two food categories for *E. coli* 0157 were beef and vegetable row crops, for *Campylobacter*, chicken, and then this dairy estimate is very high -- 66% of *Campylobacter* illnesses are attributed to dairy, and we'll talk more about that in a bit.

And then *Listeria monocytogenes*, or LM, again, two categories dairy and fruits, but again, although the point estimates accounting for over 75% of the illnesses are -- there's only two categories explaining them.

If you look at the credibility intervals, again, you see a lot of variation of -- the credibility intervals for LM are very wide relative to some of the other credibility intervals.

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So, going back to this again, let's talk a little bit about the credibility intervals. So, wide credibility intervals -- because this is a statistical estimate of uncertainty, a wide credibility interval indicates that we have greater uncertainty about the actual point estimate that's contained in that interval.

So, again, if you look at the top of this -- remember how many outbreaks we had to inform each estimate -- the *Listeria monocytogenes*, or LM, only had 24 outbreaks in the data set to inform our estimate, and thus we get these much wider credibility intervals around our point estimates that are explaining our top two categories.

And if you look at them, they actually overlap quite a bit with some of our other estimates that have much lower point estimates. And again, this is a very small data set and so we have -- that's one aspect of that credibility interval, is the number of outbreaks or the sparse data. The other aspect is the variability observed in outbreak size after discounting.

So then -- and that gets to the point estimate for *Listeria* in fruit. Again, I said one component of the credibility interval is the number of outbreaks. The other component is the variability in outbreak size, and it happens that the *Listeria* in fruit outbreak -- there was a cantaloupe *Listeria* outbreak, or LM outbreak, attributed to cantaloupe that occurred in the most recent five year time period that was very large. It was associated with 147 illnesses, where the average outbreak size for *Listeria* was much smaller than that, around I think 18 to 20 illnesses.

So, again, you see that that -- the combination of a very large outbreak in a recent time period, combined with a small number of data sets, you have a relatively high point estimate, but with a very wide credibility interval, indicating a lot of uncertainty around that point estimate for *Listeria* in fruit. Likewise, we have this *Campylobacter* in dairy estimate that seems very large -- 66% of our *Campylobacter* illnesses were attributed to dairy.

Well, when we dig down to that data underneath that estimate. A lot of our *Campylobacter* outbreaks are associated with consumption of raw or unpasteurized dairy products.

And so while our outbreak data tells us this is a very large estimate, and the uncertainty interval doesn't seem really wide as far as the credibility intervals -- statistically it seems somewhat reasonable -- we know qualitatively that we have a lot of uncertainty associated with that interval because we know that the raw milk consumption is not necessarily an exposure widely distributed in the population.

Few people actually drink unpasteurized or raw milk so we know that this is a source of uncertainty associated with the database, and the reporting of -- detection of outbreaks and that sort of thing -- and so we have this attribution estimate that's relatively large for this one food category relative to the others in *Campylobacter*.

Do we really have a question and answer period now? I think we go on to you now. So, you already had an opportunity to ask questions, so we're going to just keep it rolling here, so save your questions until after Dr. Bazaco. He's going to walk through -- I've done a little bit of interpretation of the results, but he's going to go much more deeply into the interpretation of the results and our strengths and limitations of the analysis overall. Thank you.

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MICHAEL BAZACO: Thank you, Dr. Cole. So, as Dr. Cole mentioned today, I'm going to wrap up the session by talking a little bit about some of the assumptions that we made developing the attribution model. In addition, I'm going to talk about some of the strengths and limitations of the model, and how they should be considered when looking at the results and conclusions.

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I just want to give a quick overview of what I plan to discuss. As I just mentioned, first I'll discuss the assumptions that the IFSAC team made with this model, and then I will discuss some of the limitations our model has, such as sparse data, exclusion -- exclusion of some outbreaks, and the representativeness of outbreak data as a whole. Next I'll go into the strengths of the new model and method and outbreak estimates as a whole.

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We made two major assumptions when we decided to pursue our model. The first of these assumptions was an assumption of generalizability, meaning that the outbreak data that we are working with here is generalizable to foodborne illness in the general population. There are a few things that we have to look at with this assumption. First, we assume that outbreak illnesses are the same as sporadic or non-outbreak illnesses. Secondly, we assume that foods implicated in outbreaks, and therefore in the -- the foods implicated in the outbreaks, and therefore the data, are similar to the foods that cause sporadic or non-outbreak illnesses. Lastly, we're assuming that institutionalized populations, and foods implicated in outbreaks located in institutions, are representative of those factors in the general population as well. Now, as you learned earlier in the talks, IFSAC has developed a new categorization scheme for these foods. Dr. Cole talked earlier about which categories that we used for the model, and although these categories are specific, due to the amount of data we have, some categories include a variety of products. For example, in this analysis fungi and nuts are in the same category. In addition, there is variety across some of the pathogens, or some of the commodities themselves -- fruit has cantaloupe, and also has things like oranges. So this leads to our second major assumption, which is that we assume that risk within these categories is evenly distributed across the category.

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Outbreak data is sparse, as we've talked earlier about this. This is especially true with pathogens like *Listeria monocytogenes*, LM, where outbreaks and disease occurrences as a whole, are fortunately very rare. However, when you have both sparse data and an exceptionally large outbreak like we saw with the 2011 LM outbreak involving cantaloupe, it will be reflected in the results as you can see with the elevated attribution fraction for LM in fruits in our analysis, and also in the credibility intervals.

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As mentioned earlier, in developing this model, we only analyze a subset of the total outbreak data that has been collected. We focused on data from outbreaks implicating a simple food, meaning that the food product would be grouped into only one category, like apples, milk, or turkey. We did not include outbreaks involving complex foods like lasagna or chicken salad. In addition, for many outbreaks no food at all was even identified, so we cannot include these in our analysis. Some outbreaks involve multiple pathogens, and since the goal of this project was pathogen specific, they were also excluded for obvious reasons. We also did not include three outbreaks that occurred in outlying U.S. Territories.

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Another concern that we had when using this data was the representativeness of institutionalized populations. Some of the included outbreaks, 10%, took place in institutions such as nursing homes, hospitals, and prisons. Because of this, we must consider that these populations are demographically different from the general population. Nursing home populations, for example, are older. In addition, institutionalized populations usually have fewer food options and a lower diversity of what is available for the people involved -- the people that are there. In many case they are also more closely monitored, so cases of illnesses may be more easily identified and this can lead to a surveillance bias.

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The estimate for *Campylobacter* in dairy reveals another potential limitation using outbreak data. There have been a number of published studies looking at sources of sporadic *Campylobacter*iosis, and they show attribution of different food categories in studies of outbreak associative case. In the studies of sporadic illnesses, or non-outbreak illnesses, the attribution rates to dairy were very low, while in studies of outbreak related illnesses, dairy attribution was actually very high. Our model attributed 66% of *Campylobacter* illness to dairy products, and this is one reason that it's important to look at additional sources and studies when utilizing these findings. It is also important to -- it is also an important reason IFSAC has chosen to dig deeper into the *Campylobacter* attribution issue in a future project that will be discussed later on this afternoon.

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One slide back -- another issue that *Campylobacter* dairy estimates brings to the forefront is the impact of unpasteurized milk and products made with unpasteurized milk, such as soft cheeses, like queso fresco. These products accounted for 60% of the 161 *Campylobacter* outbreaks that we included in the analysis. However, unpasteurized milk and unpasteurized milk products are not regularly consumed in the general population, and therefore it becomes problematic extrapolating this to the general population. Also, since regulation of these products is not uniform from state to state, the extrapolation becomes even more difficult. It's important to consider the impact of unpasteurized dairy products when interpreting these results.

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So this analysis represents a major step forward in attribution modeling for foodborne illness. We incorporated input from subject matter experts from across all three Agencies. These included Epidemiologists, Statisticians, Commodity Experts, Microbiologists, Risk Scientists, Policy Experts, and more. In addition, the estimates utilized Bayesian bootstrapping techniques to quantify the uncertainty around point estimates. This gives us a measure of precision that we can use to look across pathogens and compare the confidence that we have in our different estimates. Also, in this analysis we were able to incorporate all of the years of data that we had available to us from 1998 to 2012. This is important because it allows us to get a big picture look, and we do not lose the impact of significant outbreaks in the past, such as the sprout *Salmonella* outbreaks, which is important as we move forward with actions such as the produce safety rule. However, we do weight more recent outbreaks -- we do weight the more recent outbreaks higher than we weight the historical ones.

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We chose to use a model to estimate the attribution fractions in this analysis. Another reason we chose this approach was the limitation of other types of analysis. There are biases associated with attribution estimates that only look at outbreak illnesses. The impact of large outbreaks can greatly skew the results and impact the overall conclusions, as was mentioned earlier. Conversely, when you only look at the total number of outbreaks, large outbreaks count as much as very small ones that may include only two

to three cases. In this analysis, as we talked about earlier, we tried to reach this Goldilocks paradox. We built a model that took both of these factors into account. As we mentioned earlier, when discussing the -- as I mentioned earlier, when discussing the LM fruit estimate, this model cannot alleviate all of the impact of very large outbreaks, but the impact is limited quite a bit when there is adequate amount of data, as we have with some of the other pathogens.

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Another advantage of using the model approach here is that it allowed us to account for other co-variants that were associated with outbreak size. As Dr. Cole showed earlier, both the location of food preparation and single-state versus multi-state outbreak designation were two of these variables. Multi-state outbreaks tended to be larger than those in only one state. In addition, outbreaks that were prepared in the home were significantly smaller than those prepared in other settings, and the model allowed us to account for these factors when generating our estimate. The use an ANOVA log transformed modeling approach also allowed us to smooth the data and limit its variability. Additionally, the use of all 14 years of data also helped to smooth the variability across time, as we showed earlier. We utilized the five year shelf and decay function in order to better achieve this goal and make a higher emphasis to the more recent outbreaks.

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With all of this being said, I would like to now present our conclusions from the analysis. First I'll talk through the conclusions for each pathogen, and then I'll discuss the context of the conclusions and try to help with their interpretation. Most of you probably have the report in front of you, but if not, the results are included in the final report in your packet so you can follow along. *Salmonella* illnesses were attributed to multiple food categories, and the attribution estimates have the least amount of statistical uncertainty compared with the other pathogens in the model. *Campylobacter* infections spanned a broader array of categories, but the point estimate for the dairy category was notable at 66%, and had wide credibility intervals, 57% to 74%. It is important that the high percentage of unpasteurized milk and unpasteurized milk products, such as queso fresco and other soft cheeses, is considered when evaluating this estimate.

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Moving on, we estimate that 82% of *E. coli* O157 illnesses were attributed to beef and vegetable row crops. This suggests that interventions for *E. coli* O157, focusing on these two food categories may be most effective in reducing illnesses. For LM, *Listeria monocytogenes*, 81% of illnesses were attributed to dairy and fruit, however, with the limited number of LM outbreaks and the wide credibility intervals, we dictate caution in interpreting the proportion of *Listeria* illnesses attributed to these food categories.

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So, to summarize, IFSAC has developed an improved method for estimating attribution percentages from outbreak data. We did this working together and incorporating subject matter experts from various fields across all three Agencies. The estimates that we present here should be interpreted in context. It's important to consider the credibility intervals when evaluating the precision of the estimates, as wider credibility intervals indicate more uncertainty. We do urge caution when interpreting and utilizing these results. The limitations of the study have been discussed and it's important to consider these. The LM in fruit and *Campylobacter* in dairy estimates are a couple of examples to consider. Lastly, these results should be used with other scientific data when decision making with regards to food safety programs and activities. After lunch you are going to hear a bit more about how FDA and FSIS plan to use these new estimates in other projects and in their food safety

activities. In addition, as you've heard throughout the morning, IFSAC is not finished. We are currently working on new projects, continuing current projects, and developing new projects, and you'll hear more about those this afternoon as well. Thank you, and now we'll move to the questions.

GREG DINAPOLI: Thank you, Michael. I would invite the working group members for the question and answer.
Go ahead, Chris.

CHRISTOPHER WALDROP: Hi. Chris Waldrop, Consumer Federation of America. As part of this public meeting, as part of this sort of rolling out and explaining this, are you going to be making the models, the method, and the data publicly available so that other stakeholders can start playing around with this and build upon what you've done, and be able to sort of really look into the models and the methods so they can then, you know, continue to have this dialogue and this conversation?

DANA COLE: I don't know the full answer to that. That's why I'm looking around amongst my colleagues here.

MICHAEL BATZ: I think that's a Steering Committee question.

DANA COLE: Yeah. I do. As far as the method and the results and that sort of thing, we are -- as was mentioned earlier, we really do want to have our methods and our model vetted well by peer review, so we are working on, you know, a manuscript that will provide a lot more information. We plan to -- like we've talked about a lot of decisions that have been made -- and provide that background data that informed those in the form of some Appendixes and that sort of thing.

As far as the other question about, you know, actually the database and that sort of thing, the outbreak data itself is available online through the foodborne outbreak online database, FOOD, but I'm not sure -- I don't know that we've gone as far as making actual plans for how we're going to make the full methods and results and outbreak data available, per se, for this project. We're still in the process of trying to get it fully vetted and that sort of thing before we commit, if you will, to a single set of data -- a single database and set of methods -- as far as that's concerned, the final decisions.

CHRISTOPHER WALDROP: Sure. Well, just in terms of trying to get information from the public, and having this public meeting, I think it -- the more you can put out there the better so that people can respond to it, be able to actually dig into it, and then get you some feedback that you need to them go forward on other projects.

GREG DINAPOLI: Thanks, Chris.

CRAIG HEDBERG: Yeah. Craig Hedberg, University of Minnesota, School of Public Health. Just following up on that, I mean I think that, you know, peer review is nice, but, you know, you guys are all public agencies and you're dealing with public data that I think belongs in the public, and so I would encourage the Steering Committee not to delay long in deciding to release as much of this as can be released, as a general matter of principle. And I think that, you know, as you work through a lot of these issues, you know, the peer review process can be a very slow one, and that, you know, in the interest of advancing the science -- I mean, you're a very robust and diverse group, but there is many other intelligent, thoughtful people, outside of your group who could provide some useful input to your deliberations as well. So I would encourage as early and as broad a release as you can.

SHERRI MCGARRY: Sherri McGarry, FDA, and one of the Steering Committee Members.
If I can just jump on that, if you don't mind, so the technical group doesn't feel they have to reach too far. And Pattie Griffin is sitting in front of me, so I may tag her as well. But I think, you know, as IFSAC has been evolving from day one, and our strategic plan -- as Chris Alvares had mentioned, transparency has been key to us. Communicating with the public, getting input, and we fully intend to continue along that path. As you've kind of heard, there have been a lot of deliberations in this final project of releasing the attribution estimates and the methodology, and there's a lot of kind of background data and information, and so it's more a matter of trying to figure out what is that collection that we want to share. And at the very basic level, I think we're looking at the report in particular having a technical publication available. The timing of that, exactly what that looks like, still needs some deliberation, but I think we fully intend to share more information as our resources kind of can allow us as we move forward, and any Steering Committee members, feel free to jump in if I misspoke.

GREG DINAPOLI: Chris, do --

CHRISTOPHER ALVARES: So, I think -- I mean, I'll just make one additional comment. I mean, Sherri is right that we do as maybe a Steering Committee, need to kind of get together and talk about the steps as far as the manuscript, the data release, and such. But I think fundamentally the data -- we do want to make it available. I think FOODNET has a source online for accessing a lot of this data, but I realize that doesn't always necessarily mean you have the exact same data set that we've used in our model. Sometimes outbreak data information gets updated over time and so I think as part of this process we really would have to come up with some really -- I think from my perspective, valid reasons why that wouldn't be -- why we wouldn't release the actual data set that we used for this analysis so that others could build upon that, reproduce that work, and help us to, you know, evolve it even further.

GREG DINAPOLI: Thanks, Chris. Caroline?

CAROLINE SMITH DEWAAL: Hi. Caroline Smith Dewaal.

GREG DINAPOLI: Caroline, sorry.

CAROLINE SMITH DEWAAL: This is also a lot of information to absorb, so this -- you may have explained this, but I'm observing in the underlined data, which is on Appendix B, Table 1, that turkey, in the *Listeria* data, has as many illnesses as attributed to dairy, and four outbreaks. You've identified the key foods as being dairy and fruits, so I'm wondering what were the factors that flattened turkey so that it wasn't one of the recognized foods that you've identified in this report?

DANA COLE: Can I go back to one of my slides?

GREG DINAPOLI: Laverne, do you think you could go back to --

DANA COLE: The one that showed the five year shelf? The data distribution with a five year shelf?

DANA COLE: This is a perfect example, I think, of the effect of our shelf and discount function, and is different from the earlier Painter estimates that did not include the discount function, and weighted all outbreaks the same. So, again, looking down, this is what was notable about the *Listeria monocytogenes* outbreaks, is that 50% of them were in this five year shelf, so when it came to those attributed to

turkey, they tended not to be in the five year shelf, so their illnesses were discounted and so the estimate, then, from those -- for that food category was discounted. So, it has to do with the time period where turkey was more frequently associated -- or the turkey outbreaks occurred -- the LM turkey outbreaks occurred relative to when the other outbreaks -- food category outbreaks associated with LM occurred, and so that's a key case in point where the combination of the five year shelf, and then discounting older data, ended up minimizing those food categories that may have been more frequently occurring prior to the most recent five years. And also, the size of the outbreaks are informative to that, too. Again, I highlighted the fact that that cantaloupe outbreak happened -- occurred during the five year shelf, so it was heavily weighted relative to some of the others. But, again, overall, 50% of the *Listeria* outbreaks were in that five year shelf, and 60% of the illnesses, again, having to do with those food categories that were implicated relatively over time.

CAROLINE SMITH DEWAAL: Just a caution in this interpretation, though --

DANA COLE: Uh-huh.

CAROLINE SMITH DEWAAL: If we were dealing with Canadian consumers, the outbreak data would look different, and they've had more recent outbreaks linked to sliced turkey products, for example. So, again, we need to be really, really cautious that this is U.S. data applied to the U.S. population, and if the turkey industry is doing something right, we need to make sure they don't stop doing that as a result of, you know, turkey not being identified here. So, I just would note, turkey does seem to be something that people should be aware of.

DANA COLE: No, that's a good point, and another argument why we didn't want to just truncate the data either and ignore outbreaks, historic outbreaks, because again, you don't want to send a signal that it's not a food risk, that there can still be breakdowns in the system.

NEAL GOLDEN: I would also just like to add -- so, my name is Neal and I'm with FSIS, and I had the fortune to lead the sub-work group that did the discounting and shelf effort, and it's come up a couple of times now so I thought I would add to the conversation that as was explained, we ultimately went with a more semi-quantitative approach, but we actually did look at an alternative approach, a more quantitative approach, where we created a statistical test to essentially say on the commodity pathogen basis, do we see any evidence to truncate the data as we see them? So, for example, if we saw a trend that actually -- in the case of turkey, maybe turkey was decreasing over time -- that if we used the old data, then we would be sort of biasing the new data to historical evidence, and not what we were seeing currently. But, if we didn't see any trend then why not use all the information, because it hasn't changed over time, so we would use it all and it would be most -- it would be more robust. But in the end we found that using this quantitative statistical approach that there was a paucity of information to be able to detect the trend. So we compared and contrasted those and ultimately went with a more semi-quantitative approach.

DANA COLE: And I just had the slide put to this one so you can see, turkey has not disappeared from our attribution estimates. We do have an attribution estimate for turkey, it's just down there, and again, with the confidence -- the credibility intervals -- it's down there and has a fairly wide credibility interval that overlaps quite a few of our other estimates.

BARBARA KOWALCYK: Okay. Barb Kowalcyk, RTI International. I had two quick -- well, three comments.

First, I just wanted to echo the earlier comments about data sharing, and it would be good to get the actual data sets versus reports, or so forth, so that we can analyze it. But in any case, the other comment I had -- and Dana, you just mentioned this, that the LM results here are driven largely by the cantaloupe outbreak. I'm assuming that you did do a sensitivity analysis where you threw those kinds of outbreaks out. Do you plan on publishing those results? Because in my opinion sometimes it's very beneficial to look at the results from across your sensitivity analyses, and that would be helpful, I think. And my last question is, you know, some of the assumptions that were made in this are pretty substantial and could be debated. For example, that food vehicles for sporadic illnesses are the same as food vehicles for outbreak illnesses. What are your next steps to address, kind of, those types of assumptions, and be able to do something that might not be so dependent, if you know what I mean?

DANA COLE: So, one of our analyses that was mentioned that we didn't have results to show because we're still doing the analyses was our comparison of the foods as consumed -- reportedly consumed by NHANES participants, which we're assuming is reflective of the population and what -- in other words, what the population is exposing themselves to versus the distribution of foods in our data set and our outbreak data set to sort of give us some idea of like, here's what the overall population -- the distribution foods as the overall population is exposing themselves, and then what -- how does that compare to what we're actually seeing in our outbreak data set. Does it -- you know, what's the subset and that sort of thing? So, we are doing that as sort of a part of -- in another project, as part of the uncertainty analysis associated with that, but it turned out to be much more complicated, statistically speaking, than we initially thought. It sounds easy in concept, but in actually linking the foods and matching the foods, and making sure that we apply methods that are, you know, really statistically valid, and the assumptions, as you say, when you start to do these things -- mixing data from different data sources. So, that is one thing though. Nonetheless, we are undergoing those analyses. I think we're starting to see that there are -- I mean, like the raw milk thing that we already know, but we're starting to see in our analyses that, you know, the distribution and consumption in the general population, if you were just to do an exposure model and see, okay, if all foods were equally contaminated -- and just based on the probability of exposure, what would be our categories that would rise to the surface as far as exposure? We're starting to see some shifts, you know, in the outbreak -- where the outbreak data clearly reflects foods that are either more frequently implicated in outbreak -- we can't make statements about how that compares necessarily directly to sporadic disease, but it starts to give us some insights about the difference between what the population exposures are versus what we see as contributing to outbreaks, and then the illness -- the sporadic -- is somewhere in between that, which, again, we're collecting -- we're starting to examine. You know, looking at the case control study data, are we examining that using -- applying new techniques to examine that data and starting to characterize those exposure profiles a little bit better in the sporadic cases, you know, it will also inform us as to what kinds of signals we're getting that -- and then see how those compare to the outbreak. And that's why, you know, the blending technique was attractive, because you start to leverage the signals you're getting from both sets of data.

BARBARA KOWALCYK: That's very helpful. Thank you for the further explanation. And just to go back again to the data sharing, it would be helpful because I think that there a lot of potential partners and stakeholders that have different ideas and access to different databases that could maybe be used to supplement the work that you're already doing, and having access at least to the databases that were used for this analysis would be helpful.

GREG DINAPOLI: Thank you.

CRAIG HEDBERG: I just have one quick question. So, we just had a *Listeria* outbreak associated with candy apples. Would that be considered a fruit or would that be thrown out as a complex food?

CARY PARKER: Your name?

CRAIG HEDBERG: Craig Hedberg, University of Minnesota.

DANA COLE: In that case we were fortunate to isolate the contaminated ingredient, so that will be classified as a simple food outbreak.

HAL KING: Along those lines -- Hal King, Chik-Fil-A. I also work in public health innovations, a company I own. I think it's going to be important for industry, and I think for the public when you release this information, as it goes out before publication in peer review journals, that you -- trying to explain to the public or industry what the model is and what the model means, and all the assumptions of the model, is going to go way over -- not that they don't understand it and have people that can understand -- but way over their heads on what they should do about it. And I think the biggest issue -- I mean, I would recommend when it comes out, even in the media, even from this event, you state that 36% of the total outbreaks were analyzed, not 100% of those outbreaks throughout those years. And then what you're finding is very important. I applaud what you're doing to do this model. It's very, very important, but when you start to see exclusion of other things -- just dairy, for example, and vegetable -- and fruits for *Listeria* -- like the candy apple was obviously a fruit -- but I think for deli meats -- and the people in the grocery industry are starting to see deli meats not being so important -- it drives a lot of the industry folks to actually develop products and tools to reduce that as intervention steps in the industry to not see that as a value to that industry. Does that make sense? So, you can come away with a message, "Well, it's not such a big deal anymore," then they start working on these intervention steps, and again, ultimately we want to take attribution data to the "how?" We want to know attribution of how did it happen in these settings, because otherwise we won't get to the intervention. You can't just do an intervention of "Don't eat this food," except when there's a recall and we know it's been contaminated. So, when I said -- I want to make some public comments this afternoon to that effect. Thank you.

GREG DINAPOLI: Would you mind identifying yourself and who you are affiliated with?

HAL KING: I did.

GREG DINAPOLI: I'm sorry, I didn't --

HAL KING: I did. Chik-Fil-A. I'm the Public Health Director there, and also on a company called Public Health Innovations.

GREG DINAPOLI: Okay. Thank you very much.

CARY PARKER: There is actually two questions from the webcast audience.

GREG DINAPOLI: All right. Thanks, Cary.

CARY PARKER: Sure. It comes -- two questions from Steve Roach at Food Animal Concerns Trust.

Number one, did you look at the *Campylobacter* data with the raw milk / cheese outbreaks excluded, and if so, what were the results? The second question, have you tried to use the model to look at things such as *Salmonella* serotypes, or multi-drug resistant *Salmonella*?

DANA COLE: I know that Mike Hoekstra and Mike Batz have explored the unpasteurized milk question in great detail, so I'll let them answer.

MIKE HOEKSTRA: We did attempt to decompose the dairy category into dairy that was associated with raw milk products, and dairy that was not associated with raw milk products. At the end of the day we feel like our ability to do that in a coherent and defensible fashion was limited. When we did it, the dairy percentage for *Campylobacter*iosis does decrease, but does not go away. However, that's a limit -- again, that's a limited statement because we felt like we have some considerable difficulty in extracting those outbreaks of *Campylobacter*iosis that were associated with raw dairy product in the sense that the raw data is not explicit and makes it rather difficult. We did a variety of scenario analyses where in essence we said if we call all of these raw milk and throw them out, then what happens? And we can make the dairy commodity percentage for *Campylobacter*iosis pretty much go away with an aggressive and unrealistic allocation -- exclusion -- rule. We, in fact, it is embedded in this model that *Salmonella* Enteritidis is treated as a distinct pathogen from the rest of Salmonellosis and we did further analyses at the level of *Salmonella* by serotype, and we considered whether or not we could do, or should do, analyses of the other pathogens by some further partitioning of the ideology. So, yes, *Salmonella* by serotype is at least partially embedded in our analysis. We would perhaps like to go further, because there are some *Salmonella* serotypes where in essence there's speculation that the causal pathways are distinctive, and we'd like to pick that up. But, again, sparse data makes the defensibility of such a maneuver, at this point in time, tenuous. I would like to say that in terms of -- there was a question about scenario analyses -- dairy in *Campylobacter*iosis, and fruit in Listeriosis, stand out there. It's a back of the envelope, but it is true that there are poor man's further analyses which basically say, "We have a reason to exclude dairy, or to try and think about dairy in *Campylobacter*iosis as a separate matter," then all the percentages on the other commodities are still accessible and can still be thought about. For example, if *Listeria* is 50% fruit, 25% turkey, and 25% dairy, if you throw out the fruit, then it's 50% dairy and 50% turkey. In other words, those kinds of simple exclusions are available for interpretation of the data, and indeed are part of the general statement about other notions, other bodies of scientific information, other knowledge, should be used in terms of how to interpret and how to respond to this particular body of information.

GREG DINAPOLI: All right. Thank you, Michael. That’s' it.

DANA COLE: Did you have something to add?

MICHAEL BATZ: Yeah, I would just add that I think Mike mostly covered this -- but I think with the outbreaks one of the -- a couple of examples of issues with the data are there are outbreaks where it's not clear whether the milk was pasteurized or not, so what do we do with those? There are also some other -- some of the institutional outbreaks -- large institutional outbreaks involved -- prisons, or improper pasteurization of milk at a prison, or something like that, so it ends up going down this pathway feeling like you're really cherry picking this data to sort of pull this out and throw this out and throw that out until you get the numbers you like. So I think that's why we ended up saying these are the estimates with them in there. We did, obviously, look at those different scenarios, and I think that the other thing is that if you excluded dairy all together, the other categories would rise proportionately to it.

Everything adds to 100%, so everything else would just rise correspondingly so the relative ranking of the other foods may not change if you excluded dairy.

DANA COLE: And I just wanted to add in the -- speak to the idea of doing additional sort of sub type analyses, like, for example, resistant pathogens or specific serotypes. I think it's important to point out that overall our attribution collaboration is tackling issues of attribution, both -- I mean, I think you got that sense from our earlier overview talk that we are looking at attribution from the sense of overall attribution, as I would characterize this effort where we're trying to get a set of attribution percentages for all four pathogens that we have prioritized in IFSAC, and use a common set of analytic methods. But then when it comes to questions of specific pathogens or specific types of pathogens, then we feel like those require, you know, a set of methods somewhat more tailored to the pathogen or the question. And so, we do have other analyses where we focus very specifically on a given pathogen in our methods that are very specific to the data that we have for that pathogen. So, you know, again, when we -- you know, getting back to my statement about our choice of the ANOVA model, we could have done a separate model for each pathogen, tailoring each estimate for each pathogen based on all of the information we have to bear, but our effort for this particular project was to have a common method so that we could evaluate across the four pathogens that we've prioritized, sort of the attribution and the attribution percentages. But we recognize there is a lot of questions -- a lot underneath that -- and so, for example, the *Salmonella* Enteritidis project, where we have a very specific pathogen and *Salmonella* Enteritidis that we have questions about and want to estimate, we've approached that very differently with, you know, analyses very specific to that pathogen. So we recognize that, you know, when -- there is more to be done as far as individual pathogens and tackling that, and you'll hear more about that this afternoon.

GREG DINAPOLI: Thank you. Please?

SCOTT HORSFALL: I'm Scott Horsfall with the California Leafy Greens Marketing Agreement, and I have a quick comment and then also a question. From the standpoint of industry, I think what we learn the most from are those kind of sporadic big outbreaks, so I think I understand from a statistical perspective the reasoning for smoothing those out over time in the way that you've done. From and industry perspective, from the standpoint of building programs and methods for dealing with the -- some of the problems at the source, you know, we really do learn a lot from those individual outbreaks that are larger in nature. We don't -- I guess I would just caution you not to smooth them out to the point where we lose the lessons that we have to learn from them. So that's just a comment.

My question is whether the model also takes into account, or do you look at the contamination along the distribution path, whether it's in farm, processing, in the home -- you mentioned that a couple of times -- at restaurants -- and whether there's a way to tease that out of the data as well. Thank you.

MICHAEL BAZACO: To answer your question, this project itself did not address that, however, in future research we're looking at that farm to table continuum and looking at contamination along that line, because it is important to the three Agencies. So that is something that we're looking forward to and you'll hear more about that this afternoon in our future projects discussion.

GREG DINAPOLI: Dr. Braden?

CHRISTOPHER BRADEN: Chris Braden, CDC. There is one thing about the interpretation of this data and what Chris Waldrop had said earlier about what do you do with the information in different sectors? And I would like to address one of those issues now. I think it may come up again when we talk about how the Agencies use this information, but it really is aimed at what regulatory Agencies need in order to allocate some of their resources and prioritize their activities, and that's reflected in the categorization scheme and so forth. What I think we need to be careful of is how the consumer views this data, and just as for the categorization schemes, you know, they're not going to be going into the grocery store to buy legumes, they call it another name. And it's a whole different type of information that the consumer is really -- would be finding useful. And I think we have to know that this data really is not meant to be something that the consumer can use to say what is my risk or what is the risk of this particular food? And I think that's an important message, also, as far as how this data could be used. It is not analyzed on the basis of an individual serving or an individual consumer. What we really need to say to consumers still is that -- you know, the message being that a balanced and varied diet is the best diet, you know, for most people, some people being more prone to infections may need to take some additional types of caution, but in general, it's the usual types of food safety activities for the consumer that we know and use. You know, the cook, clean, separate, and chill, is that type of consumer message. So I wanted to make a distinction here about what we're talking about and how this data should be viewed, you know, and its intended use for Agency level, or industry level decision making, but not on the consumer level decision making.

GREG DINAPOLI: All right. Thank you. Any closing remarks? One more question? We'll take one more question.

ATIN DATTA: Hi. My name is Atin Datta. I'm from FDA. I was wondering about if you can comment on multi-pathogen outbreaks? Are those -- constitutes one of those four? And if it is, I'm wondering if you include those in your calculation, does that change your attribution categories and things like that? So, the first question is, those multi-pathogens, do you know what the pathogens are?

MIKE HOEKSTRA: The database contains outbreaks historically that were reported with multiple etiologies -- with multiple etiologies that were restricted to the four pathogens that we considered. The number of outbreaks that were excluded, the 84 outbreaks, not substantive -- did not have a substantive impact on our analyses.

ATIN DATTA: Okay. Thank you.

Recording timestamp=03:19:44

GREG DINAPOLI: All right. Thank you. That concludes the morning session, and be back in an hour. So I've got 1:15ish -- 1:15ish.

(Lunch recess.)
(Off the record.)
(Back on the record.)

Recording timestamp=03:20:04
GREG DINAPOLI: I'm going to ask Chris Alvares and Sherri McGarry to come on up. Before they do, I'll give a brief intro and give everybody a second to settle in.

Chris Alvares is the Director of the Data Analysis and Integration staff in ODIFP at USDA FSIS. Chris leads a staff of analysts who provide data analysis and reporting in support of FSIS and our mission.

Sherri McGarry is Senior Advisor in FDA's Office of Foods and Veterinary Medicine, in the Office of the Commissioner. She's dedicated to policy development and the implementation of the FDA Food Safety Modernization Act, including serving as the Agency's lead for product tracing, and is involved in risk information prioritization and strategic planning across FDA's Foods and Veterinary Medicine program. At this moment I'll ask Chris to come on up.

Recording timestamp=03:21:40

**Use and Application of Attribution Estimates by U.S. Federal Regulatory Agencies – FSIS Perspective**

CHRISTOPHER ALVERES: One more technical check before we get started.

Slide 1 (Webcast Recording Slide 120 of 172)
Thanks. I'm going to lead off this afternoon's discussions with the first of three perspectives from the different Agencies, and then we'll have a panel discussion after that.

I do want to just talk a little bit about FSIS's perspective, how we utilize attribution within our Agency's activities in the number of different ways, and talk about how we see the work that was discussed this morning fitting in to those activities, those future plans, and share a little bit about how we see this connecting very directly to what we do on a day to day basis at FSIS.

Slide 2 (Webcast Recording Slide 121 of 172)
So, attribution is important to us in a number of different ways. We use it in maybe two main areas. One is performance measurement, how we evaluate ourselves as an Agency in terms of achieving certain long term goals, and achieving certain priorities that we define for ourselves.

We also use it in the context of what I'll generally call policy development, or -- but that really covers a number of different areas.

It includes, you know, some risk assessment areas, economic analyses -- these all inform policy initiatives -- performance standards. I'll talk a little bit about how FSIS uses those, and also new initiatives. I'll give you one example that I think is pretty closely tied to some of the work you saw this morning.

And finally, I do want to talk a little bit about IFSAC itself. We see IFSAC as a really important collaboration, as I mentioned this morning. And I'll talk a little bit about how we incorporate and really affirm that importance in some of our Agency activities.

Slide 3 (Webcast Recording Slide 122 of 172)
So, performance measurements. Generally speaking, as an Agency, we use performance measurement to assess our progress towards certain goals.

One of the key ways that we've been focusing our efforts has been on improving public health and reducing foodborne illness due to the foods that FSIS regulates; meat, poultry, and processed egg products.

For a while -- since -- really I think since about 2009, FSIS has been using a measure that we generally call the -- sort of an FSIS All Illness Measure. It has a lot of parallels to some of the work that we saw earlier today, and I'll talk a little bit about those, but it is a key measure for us in terms of trying to drive down that All Illness Measure, trying to address illnesses due to products that we regulate, and this measure is one way that we, at a very high level -- almost corporate level, for lack of a better term -- really measure our performance and track how we're doing.

As a subset to that, we have an Agency priority -- USDA Agency Priority Goal focused around *Salmonella*, in particular, and reducing illnesses due to that, and we've incorporated these activities into an FSIS strategic plan.

We have a five year plan. One of the goals -- Goal four in particular -- is focused on promoting interagency collaborations, and IFSAC has really been -- we've defined that as the way that we want to measure our performance in terms of interagency collaboration, contributing to projects that help us work better with our partner Agencies.

Slide 4 (Webcast Recording Slide 123 of 172)
I think I have to point in a different direction each time.

Um, the "All Illness Measure," -- so just to talk a little bit about this, it is a measure that we use to track sort of FSIS specific priorities, so it's focused on pathogens similar to what you saw earlier today, but we're looking at *Salmonella*, *E. coli* O157:H7, and *Listeria* in particular, but those are the ones that really when we define this measure, those have been the priorities for the Agency.

We are looking to expand those, to add additional ones particularly. For us, the top of the list would be to add *Campylobacter* and the non-O157 STECS, but I think that has to fit into the larger context of the work that IFSAC is doing to better align our initiatives with theirs.

And so we really are working to do that in concert with the work that we've talked about earlier today, and the future direction -- future projects going on at IFSAC.

It's a summary measure, so what we do is we try to estimate the illnesses due to each of these products in meat, poultry, and processed egg products, and really sum them all up, but at the time, we're still -- we still have the ability to tease that apart and to dig deeper.

So, there was a question earlier today about whether we're losing information by using the commodity scheme that we have, and I think in some ways we really view that commodity scheme as a point where across the three Agencies we kind of can drill down to a level that -- for the three Agencies, we really can describe things in common language.

But, within FSIS, we want to be able to dig deeper. We can take, you know, aspects of that commodity scheme, like chicken, and start to tease out through our sampling programs, where are seeing *Salmonella* more likely to be occurring? Is it in the whole chickens? Is it in the parts? Is it in the ground chicken products?

The outbreak data, I think because of some the sparsity, makes that a difficult level of granularity to reach, but we think that through some of our sampling activities we can help shed greater light on

particular blocks (boxes) in that commodity scheme and help us understand better the characteristics around some of those maybe bigger common themes.

We do have some differences in how we're doing things. For example, our initial version of the "All Illness Measure" uses a three year window. We saw some really good data this morning that indicates a three year window might be maybe overly sensitive or overly variable, and so that's something that we really want to standardize and work with the IFSAC group to use a common timeframe, a common range, and I think a lot of the work discussed this morning will ultimately work to replace or really improve our "All Illness Measure."

And the final thing I want to mention is that this "All Illness Measure" is not simply just a measure of what we're seeing in the data, but we're trying to use it to link to long-term outcomes.

For us, the big long-term outcome is Healthy People 2020. We want to make sure that our efforts to reduce illnesses and achieve those Health People 2020 goals are effective.

We do that by trying to link the "All Illness Measure" to those outcomes, and so we're setting goals for ourselves to try to drive down illnesses from the attributable fraction that our FSIS products represent -- and help ensure that we're doing our part to meet those long-term objectives.

Slide 5 (Webcast Recording Slide 124 of 172)
The *Salmonella* Action Plan is another public document that really describes some of our Agency priorities. *Salmonella* has been a big priority of the Agency. We've really seen that as an area where we need to drive some significant improvement.

Just recently, maybe last -- I guess maybe it's a year now, or maybe a little bit longer -- we put out a *Salmonella* Action Plan. A number of those initiatives are very kind of specific and policy focused, but there are some big themes in there and several of those themes, including performance standards, depend on some of the work that IFSAC is doing, some of the work that is available in terms of attribution, determining, you know, how do we reduce illnesses from certain commodities?

If we can reduce those illnesses in those commodities, what's the impact on foodborne illness? What are the impacts on illnesses in general?

So, performance standards are part of what we talk about in that action plan. Improving sampling designs -- some of our rulemaking has been committed to in that action plan -- and so at a very high level policy perspective, we've defined goals and objectives that really require some of the work that is being done through IFSAC and the attribution work.

Slide 6 (Webcast Recording Slide 125 of 172)
Performance standards -- I talked a little bit about that. I'm not sure that everyone necessarily understands performance standards, so just to describe them very briefly, performance standards are a mechanism, a tool, that FSIS uses to drive -- to really drive industry improvement.

So, at a very high level what we do is we try to describe, you know, the current--maybe it's a prevalence estimate, maybe it's some measure of what we're seeing in terms of pathogen load in products -- *Salmonella* in turkey and chicken -- whole turkeys, whole chickens, for example.

And we look at what's going on in the industry and then we try to set standards, performance standards, that we're looking for industry to meet.

And that's been, I think in a lot of ways, very successful. We still have a lot of work to do. We've been recently updating a number of our performance standards.

Just a month ago, the Agency proposed some new standards around chicken parts and tighter standards around whole chickens and turkeys and we think that that's going to be effective in reducing illnesses, but it really depended a lot on our ability to attribute foodborne illness to specific products.
Another area that I want to mention is a new initiative in some ways. Pork sampling -- for a while, FSIS had been sampling pork products, but really focused on the carcasses that were being presented at slaughter.
We were seeing very low rates and to the point where we just weren't sure that it was a good use of resources, and we made a determination to stop sampling of those.

But it's clear from the attribution data and from the outbreak data that there are still illnesses occurring due to pork products, and really what we did was we kind of reassessed internally and we decided we needed to revisit this -- the issue of *Salmonella* in pork products.

So, just in the past quarter or so we've implemented an exploratory sampling program to try and look at the different pork products that are being produced. Where are we seeing *Salmonella* in that?

Depending on those findings, we're going to use that to really drive any future directions. Do we need to initiate a more routine sampling program? Do we need to think about performance standards in those areas as well?

But it was really a lot of the work of the IFSAC group of analyzing the outbreak data that's helped us really recognize that we need to revisit this area and refocus some attention in pork products in particular.

Slide 7 (Webcast Recording Slide 126 of 172)
So, how do we plan to use the new IFSAC estimates? As I mentioned, we have a number of ways that we're using maybe prior or really early versions of the work that was presented today.

We think that what's being presented today is a significant advancement in terms of how we measure attribution, how we measure illnesses, and so to that extent we really believe strongly that the work of IFSAC should ultimately replace and update -- and be used to update the way that we're measuring performance in our Agency, the way that we're focusing some of our policy directives, policy initiatives. So, we plan to look at our "All Illness Measure," and assess -- incorporating the methodologies talked about today. There are still some questions. We have a number of internal activities as well that we need to consider. For example, maybe next year, we're about to update our five year strategic plan. That might be the perfect time to incorporate an update to the measure.

Performance standards -- historically we've been focusing on sort of a fixed reduction that we wanted to achieve in the industry. Now we're starting to think about it more in terms of, what do we want particular aspects of the industry to achieve to help us meet that "Healthy People 2020 Goal?" And again, we need to incorporate attribution and foodborne illness into that overall thought process as well.

So, performance standards are now looking more holistically at our long term objectives, ensuring that all the different contributors to those illness sources are also working towards improvement as well.

Slide 8 (Webcast Recording Slide 127 of 172)
So, just in summary, we really see the IFSAC collaboration as important. We really see the work, particularly what was discussed today, but all the work that's been going on over the last three years or so to be ultimately informing in improving what we're doing within FSIS.

We see that these new methodologies are going to help us better measure what we're doing. We think that by harmonizing our approaches with the other Agencies, we'll be able to work in better coordination with FDA, with CDC, to be able to provide a more unified approach towards some of our long term goals as a nation.

We're also committed to this collaboration. We're committed to communication and transparency. We want to make sure that our methodologies are not just understood by us, but are well understood by the other Agencies we're working with, and as an extension of that, are ones that we can explain to the public, not just in terms of our own initiatives, but in terms of the context of foodborne illness as a whole.

Slide 9 (Webcast Recording Slide 128/129 of 172)
I think I covered a lot of this already so I'll just kind of wrap up and just say that it really is feeding into our decision making, our long term planning, it's helping us focus and improve our communications and our transparency, and our coordination across the Agencies.

I think ultimately that's going to leave FSIS in a better place. It's going to help our industry as well to have a better understanding of the inputs and the drivers to how we make some key science-based and data-driven decisions in our Agency.

Thank you, and I think I'll pass it to Sherri then.

Recording Timestamp=03:36:58

**Use and Application of Attribution Estimates by U.S. Federal Regulatory Agencies – FDA Perspective**

Slide 1 (Webcast Recording Slide 131 of 172)
SHERRI MCGARRY: Thanks Chris. And much like the common ground that we find among the three Agencies and IFSAC, I'd say that the way that FDA and FSIS are applying the IFSAC information, the body of knowledge, the attribution estimates to our work is very similar as well. So there's a lot of -- again, a lot of harmony and collaboration among the three Agencies and also between the two regulatory Agencies. What I'd like to do today is something similar to what Chris was doing -- is give the perspective. It is similar, what we call -- the granularity and the initiatives are a little bit different, but the concepts are very much the same for FDA, as Chris had also described FSIS -- so let's see what happens here.

Slide 2 (Webcast Recording Slide 132 of 172)
Okay. So, what I'd like to do is just give you what our vision is in the Food and Vet Medicine program at FDA of a risk informed food safety system, how IFSAC's work, including attribution estimates, fit right in

to that kind of vision that we have for this risk informed food safety system, and a preventative food safety system. I think you've heard others talk about the Food Safety Modernization Act. I'll talk about that a little bit as well. The role of IFSAC, and again, the FDA perspective of the role -- again, very similar to the other Agencies -- and then I'll get a little more granular in the importance of the attribution estimates in particular to FDA's work, and kind of intervention strategies and our next steps, and the future directions, and talk a little bit about the projects that are on the horizon that are of particular interest to FDA and why. I won't go into grave detail because I think Dr. Griffin will be talking about those projects.

Slide 3 (Webcast Recording Slide 133 of 172)
A very important report was issued in 2010 by the Institute of Medicine on enhancing food safety, it really outlined some steps for a more risk informed food safety system in incorporating more science, and again, risk informed approaches in a systematic way to improve food safety and reduce foodborne illness. FDA, and particularly in the food and vet medicine program, embraced the recommendations in that report and have integrated that into our strategic food and vet medicine strategic plan, which covers until 2006. And again, both a risk informed approach as well as science based decision making.

Slide 4 (Webcast Recording Slide 134 of 172)
I'll pull a little bit out of that IOM report from 2010 and highlight how that applies to IFSAC in the attribution estimates. In particular, you'll see in red the decision making and IFSAC information attribution estimates will certainly inform our decision making. I'll, again, go into a few more -- a little more granularity of how that actually takes place. And then, again, the IFSAC effort really is a public health focused effort looking at public health foodborne disease outbreak data, and focused on that public health. And there are other things that as a regulatory Agency we need to add on to that public health data that we've received from IFSAC and their efforts as well as other data that we have. When we're thinking about utilizing our limited resources, we really have to be smart about analyzing the information and really focusing our intervention strategies, so we have the ultimate goal of and collaborative goal of reducing foodborne illness.

Slide 5 (Webcast Recording Slide 135 of 172)
So this is an outline of how we've taken the IOM report of enhancing food safety and having a risk informed food safety system, and applying it to the food and vet medicine program at FDA. And you'll notice -- I'm going to start here on the left hand side -- hopefully it's -- yeah, the left hand -- developing the strategic goals, and in a few slides I'll also describe exactly how the IFSAC work and the attribution estimates in particular, will apply to each of these steps. But essentially, setting those high level strategic goals, and then the high level priorities, which are -- if you think of a budget document, that might be what you think about with the high level priorities -- they're not going to be quite as granular as the pathogen and the Agents, but in some instances we are quite specific, such as the reduction in SE illnesses with the implementation of the egg rule. And, of course, any of those priorities will need to have resources committed to them, so, again, the IFSAC work will help guide and inform where we're putting our resources. And then we get to a more tactical approach when we're setting those specific risk informed priorities and the activities, and interventions that go with them. And, of course, as Chris had mentioned, there's always that -- well, how are we doing? What kind of progress are we making? And I think the IFSAC work will help us a great deal in trying to determine how much progress we are making in our intervention strategies.

Slide 6 (Webcast Recording Slide 136 of 172)

Thinking of the role of IFSAC with regard to FDA in particular, it's more than just the attribution estimates that you heard about in the report today. That was -- that is a major accomplishment -- but it is the body of information that IFSAC is generating that really can be applied to the FDA work, to others outside of the government Agencies, to help inform their food safety strategies. So it's not just the attribution estimates, but as others have mentioned, it's this complimentary suite of projects that build the body of scientific knowledge for attribution estimates, and then, of course, the estimates themselves, and also finding ways to look at trends over time to see if our food safety interventions are being successful, and if they're not, where are the gaps? And so we can fill those gaps and make more progress. So, it's a key input for this vision of a food safety -- a risk informed food safety system.
A couple of things that have been mentioned already -- because I wasn't sure quite how much they'd be mentioned -- is the food categories, of course, are really much more relevant now with expansion of the categories than they were previously, and so we're -- it's an evolution. We're making progress each time. I see that as an important message from IFSAC in that this is an evolving process. For example, we focused on the simple foods and the attribution estimates that were generated. Well, we all know that's a step, okay? We're going to have to tackle the complex, but we're building that body of information. The other thing I mentioned with regard to FSMA, the Food Safety Modernization Act, is we believe the attribution estimates will hopefully -- and the methodologies that are developed -- hopefully help us and guide us in determining progress with FSMA implementation. And, of course, that continuation and commitment to collaboration and harmonization across the Agencies is, I think, vital not just to our Agencies, but to the consumers as well, that we're working together, collaborating, and sharing our body of knowledge, and I think that goes along with the transparency that you've seen so far in the webinars that we've held. So this slide is a little bit busy, to say the least, but hopefully will provide a little more granularity in how we're going to apply the information, the body of knowledge, the outputs from IFSAC, and specifically the estimates. The HHS priority goal for the reduction of SE was mentioned already so -- let's see if I can make this work.

Slide 7 (Webcast Recording Slide 137 of 172)

So that's one area that's already in our strategic goals and an HHS priority. And, of course, there's an IFSAC project that is contributing information to that effort, so we've already -- we already have an activity that completely aligns with IFSAC work, and in fact is contributing to HHS's goals. And then, again, for the four pathogens, we'll be looking, moving forward -- and for these four pathogens, should some of these be some of the pathogens in commodity foods at the high level similar to SE in eggs -- so should *E. coli* O157 and one of the commodities that have been identified in the attribution estimates, combined with other scientific data that we have, should that also be in one of our priority goals? Again, this shows you where the fit might be for the IFSAC work, and then here's where we get to, what are the actual interventions? So, here, we'll get in -- so if I use the example again of *E. coli* and maybe leafy vegetables, what are some of the specific activities that we might entertain and maybe fill some gaps to try and reduce illness associated with those -- that pathogen and that product. So that's where we basically -- we come here again. It's really all about targeting and focusing our intervention strategies where we'll get the greatest public health impacts. The other really interesting feature that I've found in the IFSAC work, and I've only been with IFSAC for almost two years now, is it helps drive our recognition of some data gaps that we have that we need to fill. And so it's not just, "Oh, we really need this more data," but then I can go back as a Steering Committee member to -- within FDA -- and the policy makers -- and say, you know, "I think we really need this source of data." In some instances its sampling data that we don't have that we need, and prevalence or baseline information, and in other cases it's going back to CDC and saying, "Hey, you know, within IFSAC, I think this type of data is not being collected now. Might we collect it because it would really help FDA in looking at progress for intervention strategies." And, of course, we want whatever these projects are, initiatives or data collection, to be a

priority among the three Agencies, so it's also looking at what are the other Agencies needs as well? And I've mentioned FSMA already as far as trend analysis. With the estimates themselves, again, hopefully as we progress in our methods we can identify ways to see if the attribution estimates can help in our performance assessment for implementation of FSMA over time -- over a significant amount of time, probably, since we haven't finalized the rules just yet. But that's right around the corner.
So, what I'd like to do, maybe -- okay -- I just -- please -- thank you.

Slide 8 (Webcast Recording Slide 138 of 172)
There are probably a few caveats in applying some of the attribution estimates in FDA's risk informed kind of vision and in our decision making of where we put our resources, and one obvious caveat as has been mentioned by one of the commenters, is four pathogens. Granted, they are -- they account for a significant amount of foodborne illness, but we do have other pathogens we need to look at and determine, when we prioritize our efforts, where do they fit in that picture? So, things like Vibrio, things like Norovirus -- you know, other pathogens, and not just pathogens, but also chemicals. So we have kind of an array of hazards that need to be looked at when we're looking at prioritizing. However, these attribution estimates are really critical in our work in looking at where we should put our resources.
The other point that was mentioned, and hopefully Dr. Griffin will be also talking about it, is that the current estimates and previous estimates are what I call point of contamination neutral. They don't differentiate where the contamination or the spread of contamination may have occurred for that specific commodity. And from a regulatory perspective, that's really important to us. It's also probably important to industry as well. If we want to -- again, it goes back to honing in the -- our intervention strategies in reducing foodborne illness. If we want to do that, we can probably do that even better if we have a better sense of where the contamination and the attribution falls in the continuum from -- you know, basically in the food supply. So, we are hoping that down the road we'll be looking at this a little bit closer, but again, there are a lot of caveats there. But the current estimates don't differentiate and there's a lot of good reasons why they don't, but that is one kind of limitation in our applications.
The other point that I've mentioned before is the importance of combining the attribution estimates with other data, other sampling data that we have -- external sampling data, as well as our inspectional information. So, if we're looking -- I'll give an example -- under FSMA Section 204, for product tracing, we need to determine high risk foods. Clearly, the attribution estimates generated by IFSAC will be an important data input, but also, we need to look at some of the additional information such as inspectional information and sampling information, so it's an important input, but we do have to look at other components when we're setting our priorities and looking at resource allocation.

Slide 9 (Webcast Recording Slide 139 of 172)
So, this kind of gives you a little more granularity in how we are going about incorporating the attribution estimates as we move forward, and combining it with other information. So if we work from left to right on the slide, and again, this is just an illustration. I probably don't have every part and parcel of this process, but it gives you an overview of how the IFSAC work fits in. So we've got our strategic plan that kind of lays out where we're going to be going, and of course, this is a continuum so it's going to all feed back into the strategic planning. But this is where we talk about the attribution information being really critical from the public health standpoint for determining what are our risk informed priorities? And then what are our activities? And there is a -- basically many options as far as the activities that we would entertain and devote recourses to, whether it's research, whether it's policy development -- and it doesn't necessarily have to be research that FDA's embarking on. It may be funding external research to fill a gap that we have that was potentially identified through the IFSAC attribution estimates and combined with other data. And so these are the range -- example of the range of activities that we would look to explore for our resources based on the input that we have here.

And then, of course, looking at the performance -- and again, kind of going back in full circle -- again, just trying to provide a little granularity on how we'll apply the attribution estimates combined with other data.

Slide 10 (Webcast Recording Slide 140 of 172)
And one more step further, if we take *E. coli* O157 and leafy greens, just as an example again - - this was one area that was identified in the attribution estimates where we had a high level of confidence and also for *E. coli* O157, a fairly narrow group of commodities, which really tells us, if we have some focused interventions we could really make a significant impact in reducing foodborne illness. So, I think this is a great example of how we can really target our resources and hone in on the specific needs to fill that gap and reduce foodborne illness. So, if we look at the activities, find the gaps, and then some examples -- we've already identified some of these -- and that is to look at soil amendments, and look at the risk assessment and the attribution estimates -- kind of feed into that risk assessment as we look at the effectiveness for soil amendments and the risk involved in that. Also, we'll be developing a good agricultural practices industry guide. That's another example of policy development that we plan on moving forward with, and also the importance of technical assistance to industry and providing that kind of outreach to consumers as well, and potential risks and safety approaches for *E. coli* O157 and leafy greens. And also to promote, frankly, the positive things that have been going on in that industry, and the leadership that's been taken in improving the safety of leafy greens and *E. coli* O157.

Slide 11 (Webcast Recording Slide 141 of 172)
So, I've talked about mostly priority setting, but clearly there are other areas within FDA that will be using the attribution estimates, and again, supporting the development of regulations, informing as I mentioned, the risk assessments, and identifying the food contamination data gaps. One example is the SE in eggs. There is kind of a very limited amount of information on shell egg contamination, and that's an area where we potentially have a data gap and could explore further. We also need to look at the feasibility when we're deciding on where to put our resources, again, for the greatest public health benefit. What is the feasibility? Where is our regulatory authority? Those, again, are just examples of things we'll be considering.

Slide 12 (Webcast Recording Slide 142 of 172)
So, future directions. Again, I don't want to spoil the next speaker, but some key projects -- Campy in dairy -- it's been talked about already that there are some challenges with that data, limited outbreak data, wide ranges of uncertainty in the point estimates themselves, and so, really, what we'd like to see is that to be delved in a little bit deeper from the epidemiological side, and seeing, are there other ways, are there alternate ways we can look at attribution for *Campylobacter* and dairy products? So that's one area that we're hoping to look into a little bit further. Of course, we want to continue our collaboration with our stakeholders. I think as we look at our -- developing our strategic plan -- we may want to find ways to really engage the external stakeholders more than what we have outside of a public meeting, and I think we're very open to input on how we might do that best. And then, of course, continuing with that collaboration as a tri-Agency approach, and for FDA, building upon the systematic approach for our risk informed and preventative food safety system. Thank you.

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GREG DINAPOLI: Thank you, Sherri. Next up is Patricia Griffin. Dr. Griffin received an M.D. degree from the University of Pennsylvania School of Medicine, trained in Internal Medicine at the Hospital of the

University of Pennsylvania, and Gastroenterology at Brigham and Women's Hospital in Boston, and Mucosal Immunology at the University of Pennsylvania, and in Epidemiology at CDC.
She's currently the Chief of Enteric Diseases Epidemiology Branch at the CDC. Welcome.

Recording Timestamp=03:56:32

**IFSAC Strategic Vision and Directions for Future**

PATRICIA GRIFFIN: So it doesn't -- so you're saying the clicker doesn't work? So I just have to ask you to advance? All right. Great.

Slide 2 (Webcast Recording Slide 145 of 172)

So, okay. So, good afternoon. So I get to recap the day briefly with respect to the IFSAC vision.
We created IFSAC to address complex analytic issues that require across Agency cooperation and agreement with the initial objective to measure foodborne illness source attribution, and we identified four pathogens for the initial work.
We communicated at public meetings, the first one in January of 2012, then in this one, and also at other venues, and our major accomplishment that you just heard today is new methods and estimates for source attribution.

Slide 3 (Webcast Recording Slide 146 of 172

So, this is the last federal talk of the day. I'll give you an overview of the strategic plan, go through our short term plan that you heard a bit about this morning from Chris Alvares' talk, our longer term plan, and then summary.

Slide 4 (Webcast Recording Slide 147 of 172)

So, when we embarked on this our vision for five years was ever more accurate attribution estimates of the food sources of acute gut illnesses caused by the four priority pathogens using data from a variety of sources, some of which I've indicated on this slide, and using the most appropriate methods for each pathogen. That may blend data from various sources that have uncertainty bounds, and are updated as needed.

Slide 5 (Webcast Recording Slide 148 of 172)

So, along the way, we expected exploration and used some various data sources and methods resulting in differences in attribution percentages for specific food pathogen pairs sometimes based only on differences in data sources in methods, not on true changes in the sources of illness. That's what we expect as we go along this process.

But we do expect gradual improvement in the quantity and the quality of our data, and we're also recognizing that we'll have requests from public health officials and food safety regulators to provide more analyses, faster.

Slide 6 (Webcast Recording Slide 149 of 172)

So, I'll now talk about the short term plan, and for our short term plan, as you heard outlined this morning, we had four goals, and I'm going to remind you of each goal, and then just give one slide to remind you of how we accomplished that goal.

So, the first -- next slide…

Slide 8 (Webcast Recording Slide 150 of 172)
…was to improve the method to assign foods implicated in outbreaks to food categories.

Slide 9 (Webcast Recording Slide 151 of 172)
And then this is our new food categorization scheme that you heard about this morning.

Slide 10 (Webcast Recording Slide 152 of 172)
Our second goal -- can you forward? Forward, yeah was to examine uncertainties associated with outbreak based source attribution…

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…and in examining what we -- what we chose to examine was how sporadic cases differ from cases in outbreaks of the four priority pathogens.

So we had a project in which we compared sporadic cases in FOODNET surveillance, and FOODNET is a surveillance system that CDC has that covers 15% of the U.S. population, so we compared those sporadic cases to outbreak illnesses, and our result was we found that those cases were highly similar by age, sex, and illness severity, except for these children, like this cute baby in the picture -- less than three years old -- which were under represented by *Salmonella* outbreaks.

Next slide.

Slide 12 (Webcast Recording Slide 154 of 172)
Our third goal that you heard about in detail this morning was to use data from outbreaks to estimate foodborne illness source attribution for the four priority pathogens with credibility intervals,

Slide 13 (Webcast Recording Slide 155 of 172)
And this is the graph that we spent some time going through this morning.

Slide 14 (Webcast Recording Slide 156 of 172)
And then our last goal of our short term plans was to determine gaps and identify some solutions for them.

Slide 15 (Webcast Recording Slide 157 of 172)
So one gap is that we lack attribution analyses based on data other than outbreaks. As one solution, we began work on a model that uses other types of data, and this is a modified Hald model named after Tina Hald.

Another solution is that we used a new method to blend information about sources of both sporadic and outbreak related *Salmonella* serotype Enteritidis illnesses.

And a second gap we identified was that we lack full understanding of the reasons for changes in outbreak data over time, and we began a project to address that that I'll talk about later.

Okay.

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We also responded to requests from the Department of Health and Human Services, and this was related to an HHS high priority goal, to reduce serotype Enteritidis infections from eggs.
And so IFSAC estimated the proportion of foodborne SE illnesses due to shell eggs in the baseline period of 2007 - 2009.

So that goes through our short term plan and accomplishments.

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And now I'll go into just a brief overview of our longer term plan as outlined in our strategic plan.

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But first we have some observations from the first two years that inform how we carry out our longer term plan, and that's related to three types of data.

Outbreak data is the best U.S. data source now, but we need more than a year of data to make estimates for most pathogens, and we have other major limitations.

For example, *Campylobacter* source attribution estimates differ markedly from estimates that do not use outbreak data, and for *Listeria*, we have few outbreaks so the attribution estimates have wide credibility intervals. And there are other known and unknown biases with outbreak data.

For food testing data, we have very limited data other than from meat and poultry, and lack of this data limits the usefulness of models that include data on food consumption and food testing, and these types of models are used extensively in other countries to measure progress. So, at this point, we don't have that.

The third is sporadic case data, and on those sporadic cases exposure information is rarely available.

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So our longer term strategic plan written in January 2012 outlined four major goals. One is to improve the best current source attribution estimate, the second to measure changes in source attribution over time, third, to determine a way to synthesize results across projects and also to continue communicating effectively about differences in estimates that are due simply to changes in data sources and methods.

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So the longer term plan includes two over arching goals. The first one was to develop foodborne illness source attribution models using a variety of data sources as an alternative and a supplement to outbreak-based approaches, including a model that uses consumption data.
We plan to evaluate discrepancies between these various approaches and their strengths and limitations, and then to determine the best approach for each pathogen based on the data available.

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Then the second of these two overarching goals was to determine methods for generating blended foodborne illness source attribution estimates, blending data from both outbreaks and data from sporadic cases, and with those to generate best current estimates always with uncertainty bounds to revise them periodically and to recognize that different pathogens may require different methods.

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So, I will briefly cover projects for this -- the last three years in our strategic plan -- and we divided them into three types of projects, those that are continuing -- in other words, we've started them already -- those that are planned -- in other words, the Steering Committee has approved these projects and we are planning to do them -- and those that we are considering, and for all of these projects, we're glad to get your input.

So, projects that are continuing -- for the four priority pathogens, as you've heard, we plan to submit a manuscript to a peer review journal describing estimates of source attribution based on outbreak data. For *Salmonella*, we plan to estimate source attribution from a product model -- it's a modified Hald model -- that uses food testing data and food consumption data -- and to determine whether this model can assess changes in food sources of *Salmonella* infection over time.

We also plan to look at sporadic versus outbreak illnesses and compare foods associated with outbreaks to foods eaten by participants in the NHANES survey.

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So those are the ones that are continuing, and then I have two slides on projects that are already planned for the next three years.

The first is for the four priority pathogens, and that's to create a template for presenting updated foodborne illness source attribution estimates at regular intervals, and the goal would be annually.

For *Campylobacter*, we want to evaluate data sources and methods other than outbreak data for making source attribution estimates, and we're planning to re-analyze a FOODNET case-control study that we conducted in 1998 using a new method that we already devised, and with that we'll examine differences in the attribution percentages between these results and those based just on outbreak data.

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Other projects that are planned -- we plan to examine possible reasons for changes in outbreak data over time. For example, does recognition of a new food vehicle result in more outbreaks being recognized as due to that food that may have been occurring all along and just weren't recognized? And last, we want to examine how data on contamination at various points in the food chain can inform source attribution, and you just heard Sherri talk about the importance of this to FDA.
We want to evaluate data that may help us to estimate the percentage of illnesses that can be attributed to contamination points at points of consumption and at earlier points, such as point of processing, or way back at the farm level.

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So, the last type of project is those that are being considered, and of that, the first is to develop a method to incorporate data from outbreaks due to complex foods into the attribution estimates. And the other is for *Salmonella* Enteritidis to propose a method to estimate recent sources of these illnesses using exposure information from cases in FOODNET.

The FOODNET sites, which encompass 15% of the U.S. population scattered over ten sites throughout the country, have been gathering data on exposures of people with *Salmonella* Enteritidis infections for the past year.

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So, finally, the summary, okay?

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So, IFSAC was born of a need for a coordinated approach among the three Agencies to generate estimates of foodborne illness source attribution derived from the best science available, and to use that to inform food safety policy.

IFSAC has achieved its short term strategic plan goals. The results presented today, we think represent a major step forward in the development of robust, harmonized, estimates of the percentage of foodborne illnesses that can be attributed to various food categories, and combined with other data, they can inform Agency priorities.

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So, IFSAC is now embarking on a longer term strategic plan, and I already went through those four parts of the plan, and using feedback from this meeting and other input, IFSAC will formulate a strategic plan for the following five years, year six to ten of the collaboration.
And we'll continue to communicate with stakeholders in a variety of ways to share information and to obtain your feedback and advice.

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So, thank you for your attention and your questions throughout this meeting, and I think that this part of the meeting is now open for questions.

Recording Timestamp=04:10:50
Question and Answer Period

GREG DINAPOLI: So I invite the folks that are on the panel just to answer some questions, if we have any. Go ahead, Caroline. Thank you.

CAROLINE SMITH DEWAAL: Caroline Smith Dewaal, Center for Science in the Public Interest. I apologize for always being the first person to the mic. I have been beating everyone back, as you can see in the room.

I really want to congratulate all the Agencies for a tremendous amount of work. I mean, IFSAC, from its beginnings to now, has really progressed and you've done some really fantastic work.

I want to just offer a couple of observations. One is that you're very focused internally on the needs of the Agencies and I would like to challenge you to start to think about the utility of this data externally, and I am particularly concerned about the industries right now who will be challenged as FSMA comes on board with doing a hazard analysis.

So, for food products like fruits and vegetables and sprouts, and others -- I mean, how can industry use the data on outbreaks, on the size of outbreaks, on the foods -- on the pathogens associated with different food commodities -- how can we get that data to industry in a usable way so they can use it in constructing their hazard analysis?

SHERRI MCGARRY: Sherri McGarry with FDA. Great comment, Caroline, and I think we together believe that we do need to do more for sharing information and getting external input, so we completely agree with you on that front.

With regard to implementation of the Food Safety Modernization Act, I think the work of IFSAC really aligns well with the approach of the hazard analysis and how this data can really be used by industry as a data input. Industry, as you know, has a lot of their own data -- sampling data and other types of things -- that will help inform their decisions and strategies, and I think we look at this approach to enhancing food safety in a collaborative way with industry as well in utilizing -- they should be looking at their data, and are responsible for producing safe food.

So, I think we can certainly entertain ways to share our methodologies and our information and try to figure out the best way to communicate with our stakeholders on practices that they might look at to enhance food safety.

But, I really think that goes back to the strategies that we're looking at implementing also under FSMA, and the actions that we might take which we'll be communicating with the industry on. So there's a lot more to talk about in that area.

CHRISTOPHER BRADEN: So this is Chris Braden from CDC, and I agree with you, Caroline. I think there's opportunity to make sure that the data is shared appropriately so that multiple sectors can use the data as appropriate.

But there's also the opportunity I think to actually partner with some industry members that are willing to do so. At CDC we've done that in a couple of instances, I think most recently with Walmart, in taking some ideas about saying, here is where we're seeing, you know, illnesses and severe illnesses, emanating from a certain food commodity, and taking that information really with them in their development of their -- for instance, their poultry safety initiative. We worked quite closely with Walmart in doing that and developing some purchase specifications, and in that way.

So, there's also even I think on our part at least -- I know it may be harder for the regulatory Agencies to do some of this, but to actually do some public/private partnerships in food safety in that way, using some of this type of information to inform their policies.

GREG DINAPOLI: Betsy, go ahead.

BETSY BOOREN: Great. Betsy Booren, North American Meat Institute. I was struck by, Dr. Griffin, your comment about the challenges of having food testing data, and it struck me here, as somebody who represents the meat and poultry industry -- we probably have a very robust data set compared to other food commodities.

But the other aspect of this is, as we're discussing, is what's next? And I see attribution playing a very important role in the regulatory and public health Agencies, and the risk management, and I am very hopeful that these three groups, and perhaps with other inputs, start talking about doing more risk assessments from an interagency standpoint and offering similar opportunities for stakeholders to provide input.

We use risk assessments with the attribution that you're talking about today as an industry to help us set better food safety management programs. I think a lot of people use this data in a variety of ways and I think there's a lot of the -- "what next" -- that are very excited to work for it, and I encourage the three groups here to find ways that we can contribute to that, but also expand these analyses to other risk management types of programs.

SHERRI MCGARRY: That's a great point, and earlier in the day we talked about a collaboration with IRAC and I think that set the stage for this type of a collaboration in looking at the methods used by – and in the risk assessments -- as well as what we're currently using with IFSAC.

So I think there's already a stage set for that and if I think about one of the projects in particular that we have decided to move forward with, it would be, I think, very applicable. The one in particular where we're looking at points of contamination. Not that we're going to attribute to a specific point, but maybe we'll kind of bucket things.

But I think risk assessment could -- or the methods used in risk assessment may be a great -- a great opportunity to collaborate there on methods.

DAVID GOLDMAN: This is David Goldman from FSIS. I just add here to your point and to Sherri's comment that the Hald model, and our development, continued development of that model is one example of where we are trying to account for product contamination data across the entire food spectrum in order to apportion the attribution estimates for *Salmonella*. So I think that's an example of one where we're trying to think beyond, you know, Project 13, which you heard featured here today.

PATRICIA GRIFFIN: Yeah. And we do lack food testing data, but we will develop a model based on food testing and food consumption data, and part of what that model will do is point out the gaps and help us to develop ways to fill those gaps. And we are already talking with FDA extensively about how to get more data on eggs so that we can look better at changes in [*Salmonella*] serotype Enteritidis infections.

HAL KING: Hal King, Chik-Fil-A Public Health Innovations. One -- I'm going to quote -- I guess it was a news article on NPR Web, but it was actually based on FDA data, and it came out on February 16th. It basically was just listing the top five issues that were found in manufacturing plants during FDA inspections. I don't know if you're familiar with that, but two of the top five are pest control issues. And I don't know how much pest control contributes to these types of diseases, but one, I think it's important to what Caroline was saying, is that of the top five issues they see in these types of plant inspections, the critical limit wasn't well defined. Okay, so they did HACCP and they have HACCP supposedly documented, but they don't have a maximum or minimum critical limit in the hazard, so they're not really -- they don't really have any preventative control of the hazard.

And I just want to echo her comment and hear what your thoughts are on the FSMA? What's coming for these manufacturing plants is they're going to need to first identify the hazard. So many of these, we know what they are. They might be a pathogen, they might be an allergen or undeclared allergen, whatever it is, but then they have to have a well-defined preventative control to that hazard. And if they can't document that, the product can be recalled, so what's coming to them -- and their knowledge is that they're going to have to be prepared to identify and show the hazard and the preventative control, and how can we get to this faster with attribution data so we're combining attribution not just to the food category, but to how it actually happened, so that we can actually -- like Chris said -- use

industry data and preventative practices that are working in preventing these types of hazards to share with everybody in the industry.

So, I applaud what Walmart's doing with CDC. I think that's great. But if we don't know what they're doing, expect at a kind of high level, and can't apply it as buyers of our own suppliers and manufacturers, then we don't really get the benefit of that. So just a comment, but I also want to hear your comments on that related to FSMA.

SHERRI MCGARRY: Well, I'll start since you mentioned FSMA. A couple of things…one, as we're finalizing the rules, the Preventative Controls Rule, Produce Safety Rule, and some of the other rules, particularly with -- I'll abbreviate -- we have to use our acronyms -- the PC rule -- we'll be looking and trying to provide guidance on what does a food safety plan look like? What are some of the -- how does the science support identification of some of the hazards? So we very much are looking to give some guidance to industry on the science as well as what kind of the expectation would be as we move forward once we finalize and we issue guidance. So those are all things that we hope will support the industries efforts. That's one piece.

And the second piece -- again, I go back to what I said before in that we believe, you know, the industry is a partner here in ensuring the safety of the food supply and the food that they manufacture. So, whatever support that they can provide to research strategies that will help with building of the science for the hazard identification, for controlling the hazards once they're identified, I think it really, truly, is a partnership.

We are committed to providing industry as much guidance as we can, but I think the industry also can benefit and also provide some sound science to the foundation.

GREG DINAPOLI: Thank you, Sherri.

PATRICIA GRIFFIN: So a couple of things on that general topic is that to a great extent we operate without full data. We have data on outbreaks which are just part of the picture. We have data on some sporadic cases.

We have very limited data on product contamination that the regulatory Agencies gather, and there's more data on product and process level contamination that industry gathers that we don't have access to for various reasons that we understand. I mean, there's a nervousness on the part of industry about sharing that type of data.

But the more we can find ways to share that data in a way that would not result in anything punitive, then the better picture everybody will have, the easier it will be for industry to put their resources into the type of controls that really will make a difference, because within an industry there's often a problem that's found by an outbreak in one group, but it's often a problem throughout the industry. And so, if we can work out a way -- there is a way that's been started in collaboration with the CDC. It's called Voluntary Net and it's run out of the University of Georgia, but it's still in its early stages and we're still looking for more industry leadership in that. So, that's one thing that's starting.

Another thing that's happening now and could happen more is that in outbreak situations -- you know, we have more multi-state outbreaks that are identified every year, and they provide a really wonderful opportunity to look at problems that are often shared by entire industry. And so we're trying, in multi-

state outbreaks, to involve industry earlier so that they're part of figuring out the solution, both to limit illnesses during the outbreak, and then to sort of help get the whole industry on board to finding general solutions so that that contamination problem won't occur again, but we can still work on ways to do that better.

CHRISTOPHER ALVARES: This is Chris with FSIS. I think it's an important point that the attribution estimates that we have talked about today are really a measure, but there's a lot of work still be done to -- how do you effect changes in those measures? How do we drive down illness?

And the work of industry -- it's going to be very important to add the work of the regulatory Agencies, even the contributions of consumers, as well, can be important factors to that, and I think that's where work still needs to be done.

When we take a commodity like chicken, for example, how do we identify all the different types of chicken being produced, and is it -- are there particular products that need focus? What can we learn from those in terms of interventions and practices? Can they be applied to other parts of the food production chain?

And I think also it may be -- another way to look at it is when industry or Agency, or whoever talks steps to improve that process, where is that feedback? I think the ability to measure attribution over time and to be able to assess changes helps us to assess whether those changes and practices or those improvements in how food is being produced, are ultimately reflected in changes in illnesses. Attribution helps us really connect that to specific commodities and food types.

GREG DINAPOLI: All right. Chris?

CHRISTOPHER WALDROP: Chris Waldrop, Consumer Federation of America. Patty mentioned that outbreak data is the best data we have right now, but it has limitations, and *Campylobacter* is obviously a big limitation and a huge gap.

Whenever CDC puts out reports on new findings, whenever IFSAC puts out reports on new findings that just focused on outbreak data, it's got this big old hole in it where it doesn't really address *Campy* to the extent that we need it to.

So I'm glad to see that one of your planned projects is to really look at that and figure out other ways to bring in different data so that you can really start to get a handle on *Campy* and start to flush out this picture. So I just wanted to sort of flag that and say that I'm glad that you all are focused there and are going to be doing some work there because I think it's really necessary. Otherwise the picture is not really as clear as we need it to be.

GREG DINAPOLI: We'll take a short break and we'll be back at 2:30. Can we do that? What's that?

DAVID GOLDMAN: Fifteen.

GREG DINAPOLI: Fifteen? We're just running behind. It's up to you, Dr. Goldman, or what does everybody else want?

DAVID GOLDMAN: I think 15 is good.

GREG DINAPOLI: Okay. A 15 minute break.

(Recess.)
(Off the record.)

GREG DINAPOLI: Welcome back. I'm going to introduce Dr. Goldman here.

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Discussion by Panel of Outside Experts

DAVID GOLDMAN: Good afternoon again. I'm very pleased with the panel we've assembled for this particular portion of the agenda, and I will let you know that the full bios for all the panelists are in your packet so I'm not going to read them to you because that would take a little while.
But I hope you will be impressed with both the breadth of the panel in the aggregate, as well as the depth of each individual's interest in food safety.

We have broad perspectives here, from consumer advocates, from the industry, from academia, and all of these individuals here have spent a good portion of their careers, if not their entire careers, on food safety.

I also failed to mention we have a New York State representative, so we have a state health perspective. Sorry, Shelly.

I will just read the names of our panelists, but before I do that I want to let you know how we've set up this panel so that the audience here, both here in the room and those on the phone understand this. The panelists were sent the report that you saw featured in this presentations earlier today, as well as in your packets, about two weeks ago, so they could have some time to look at the report in some detail. And with that report in hand, we asked them to consider the following questions, which I'll read very briefly, as a way of preparing for their comments here today.

So, I'll just read these questions they were asked to consider:

1. Generally, how do you or your stakeholders use attribution data, methods, and results?
2. What other types of analyses or, you could say, approaches, have you used for attribution?
3. How do these new IFSAC attribution fractions and the uncertainty around these fractions inform your work?
4. What other types of data might you or other stakeholders use in source attribution related work and activities? For example, are you interested in data on microbiologic sampling of foods and other sources? And how would the availability of such data from other sources affect your own work on attribution?
5. What is your perspective on how the federal government should be using attribution estimates?
6. And what other types of analyses would you recommend as a priority for IFSAC?

So, again, the panelists were given the report in advance. They were asked to consider those questions as they constructed their comments here today.

What we'll do is we'll go just, I think, in order from left to right for the panelists, who will spend several minutes giving their perspective, and then if we have time -- and I hope we will have some time -- we'll

open the questions to the audience, both here in the room and on the phone, for our panelists, and then we'll go from there.

But just briefly, from left to right, we have Sandy Eskin, who is Director of Food Safety at the Pew Charitable Trust. We have Dr. Arie Havelaar, who is the Chair of the World Health Organization's Foodborne Disease Epidemiology Reference Group, and I should say a part of whose work has been on food source attribution. He's also currently at the University of Florida. We have Craig Hedberg. Dr. Hedberg is a Professor at the University of Minnesota. We have Dr. Scott Hood, who is Director of Global Food Safety and Regulatory Affairs at General Mills. Chris Waldrop is Director of Food Policy Institute at the Consumer Federation of America, and Dr. Shelly Zansky is Director of Emerging Infections Program at New York State Department of Health.

And with that, I will just turn to our panelists, and we'll call on Sandy first and we'll just go down the line. Thank you very much.

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SANDRA ESKIN: Thank you, David. Before I make my specific comments, just a couple of thoughts. When I spend a day like today hearing about things like food source attribution, I kick myself yet again for dropping that stat class in college. So, for all of you lawyers out there, you can perhaps -- or non-statisticians -- you can agree.

I think what I do want to say is two general points based on what I've heard today and some recommendations, I should say, to the group. And then I'm going to address, if not all of them, a lot of the questions that David just outlined.

Like others in the audience today, I think this process, this initiative, is wonderful because it does exactly what you would hope it would do. It moves more toward a risk-informed, science-based, food safety system. So, I join others in commending the people who are working at IFSAC for that reason.

My suggestion would be that it would be helpful if there was some way to make better use of outside expertise. Whether that means a standing panel or some kind of body, it's great to get comments today, but you are well into the process and I think going forward it would really be a good idea, whether it's people like the experts sitting to my left.

There are many people out there who could help you, inform you, and I think that will only result in a better -- in better food attribution estimates.

I do want to comment on Chris Braden's comment, and with all due respect, I think the group, the initiative – IFSAC-- needs to look at how this information gets to consumers because beginning with right now, there are some excellent reporters out there who are reporting on lots of food story issues -- food safety issues -- including issues like this.

Maybe it's a little technical, but this is going to get down to the level of the individual consumer, so it's something that you should, again, keep in mind moving forward because I know people want to know what they can do to prevent their family members from getting sick. The system is moving more toward prevention and this is an essential component of that.

So, again, in terms of general comments that I hope hit some of the questions asked, I agree with everyone that we need these other data sets -- contamination rates among products and consumption data -- to really inform these estimates, and I think it has to be an ongoing process.

I also, and I think you all have looked at, other types of food attribution sources. I know we've used them in our advocacy, whether it's the wonderful work that Caroline and her colleagues do at CSPI on OutbreakNet or the report that Mike Batz and Glen did a few years ago with pathogen product pairs. So there's obviously information out there. We've used it because it's solid and obviously is the IFSAC data continues to develop -- we hope to be able to use that.

And we use it for exactly the same ways -- exactly the same reasons that government policy makers do. Right? We “make asks” -- so, for example, PEW spends a lot of time trying to make sure the FDA has enough money to implement FSMA.

Well, if you look at the produce-related data, that reinforces the need for resources, so that's an example, and the same thing in terms of working on specific policies.

Obviously, *Salmonella*, and *Salmonella* in certain products like chicken, has been discussed and is an important issue, so whatever information we can get from the food attribution estimates to help us figure out what the priorities are, that's good. And then again, as some sort of a measure of the effectiveness of policies.

So, we're on the other side, or along with others who are making the policies, we want to make them better, so that's how we use the attribution data.

I will say that of the information that I was able to understand today in the actual report, the numbers -- the limitations are concerning, and some of the -- that -- I'll give you just a simple illustration which was already brought up today -- looking at *Listeria* in fruit, the certainty or uncertainty interval was, I believe, five to 77%.

I don't know what to do with that, so I think that back to the points I made earlier, getting some expertise helping you in looking at it, trying to find other data, just seeing how the data you have compares to other data, will hopefully address a lot of those uncertainties.

I'm just going to see here -- is there anything else? I think basically those were my major points and I look forward to hearing what my colleagues say.

Recording Timestamp=04:37:02

ARIE HAVELAAR: Thank you. I think you already said it, and I fully agree that attribution is a key source of information for any risk-informed decision making system, and the IFSAC initiative can only be applauded for taking this forward and also bringing the different Agencies towards one harmonized approach.

We already heard that there are different methods available. Each method for attribution has different data requirements, has different strengths and weaknesses, and it's very important to understand none of these approaches is unbiased in itself.

The data are biased, the approaches are biased, and they also attribute the food safety problems to different points in the food chain.

So, using any single method is not the best approach and we have to look at more methods. We have to look at the uncertainties in the different methods and acknowledge all the uncertainties.

The current report that we discussed mainly today is based on outbreak data as one basis for the attribution, and I think what IFSAC fairly transparently does is outline all the limitations also in that approach.

And some of the most important ones -- only 36% of the outbreaks were included, and 10% of these were institutionalized populations. So there is, I think, a big question about how representative the data are for the general population in the U.S., and then you don't even think about how heterogeneous the food consumption patterns in the U.S. are between states, but also between different ethnic groups in the states, so it is a very difficult problem to tackle.

Large outbreaks can affect the results significantly and I think apart from the fact that large outbreaks have large case numbers, they tend to reinforce themselves because the larger the outbreak, the more publicity there is, and the more active case finding there will be.
So, the sizes of the large outbreaks may even be upward biased because they get more publicity at some point, and I did not hear that discussed today.

I also realized that some of the most high impact, large outbreaks, they are resulting from what I would tend to call unusual situations, situations where hazard principals or regulatory needs have not fully been met, or where unusual practices have been done.

I was thinking back about the *Salmonella* Thompson outbreak we had in salmon in the Netherlands in 2012 that sort of almost doubled our regular number of reported cases of salmonellosis.

So, in that year, the attribution of *Salmonella* to salmon was close to 50%. Does that mean that we need to take that forward for the next four or five years? Or should we only use that large outbreak for that year?

And I think that depends a lot on how the industry has acted. Industry can certainly, in those big outbreaks, understand the sources and can take that risk factor away. And if they do that, and if you have evidence to do that, you could maybe discount that outbreak for future years.

So, I think apart from size of the outbreak, multi-state also, the circumstances under which the outbreaks arose and how far they were related to non-compliance issues, fairly unusual issues, might be taken into the picture to consider how long such outbreaks should continue to inform the attribution problem.

There are certain methodological aspects in our focus, particularly on the concept of uncertainty, because one thing I read in the report is that single food only was considered to minimize uncertainty, and I thought, that's a very limited definition of uncertainty.

That's only statistical uncertainty. In my book, uncertainty is all the limitations in knowledge that the analyst has in the moment that they perform the analysis, and any data that you have should be included as much as possible because they will help you to quantify and inform your uncertainty.

I was very happy to hear this morning that IFSAC actually has done a lot of scenario analysis to explore the uncertainties associated with their data. They have not yet been presented, and I think more can be done with those scenarios.

Methods like global sensitivity and uncertainty analysis might be very useful to apply to all those scenarios to formally quantify which of those choices are most influential -- and how is the full uncertainty, given all of those choices that the analysts had to make -- how can we quantify that full uncertainty beyond the concept of statistical intervals? And I'd be very happy to discuss those issues further with IFSAC.

It has already been discussed many times, so I will not go into too much detail. Some of the results that have been presented -- the face validity of those is also very low.

*Campylobacter* attributed mainly to raw milk consumption has been mentioned I think also. *Listeria* in produce, based on this one huge cantaloupe outbreak, is an issue where maybe the outbreak data did not tell you the true problem and the only thing to really address that is to use other types of data. I'm thinking for *Campylobacter*, in particular, about MLST-types of data.
Many countries who have typed *Campylobacter* know that the types in humans are more related to chicken than to cattle, so getting that kind of information, and I understand it has already been collected, will help to inform the attribution estimates and take those further.

Another aspect is the credibility intervals. There was a statement in the summarizing slide that the uncertainty in the *Salmonella* attribution estimates is lower than for the other pathogens, and I dare to challenge that, because normally you don't look at the absolute value for an uncertainly interval, you look at a coefficient of variation. and it was not easy to deduce that from the published graphs, but when you look at, say, the range of published intervals divided by the midpoint of the interval, the *Campy* for dairy estimates, for example, is less variable than *Salmonella* for pork, which actually has a higher coefficient of variation and just because we are chopping up *Salmonella* to small numbers doesn't mean that the statistical uncertainty is less because the absolute values are less.

So, I think looking in a broader concept that uncertainty is something that might be very helpful.
The last point I'd like to make is the approaches that have been presented, now and also in the future plans, they're mainly top down approaches. They start from diseased humans and try then by mainly epidemiologic methods to figure out what could have been the causes of those illnesses, and the level of resolution you can get from those approaches is limited.

In that sense, having an ever-expanding set of food categories may be dangerous because you end up with less and less data points in every category.

For *Listeria*, I think the uncertainty is related to the fact that you have far too many categories to get enough data, and collapsing, particularly for *Listeria*, the categories more so that you get at least some data, might have been helpful.

And I think if you want more resolution, considering bottom up approaches, risk assessment approaches, where you include data on occurrence of pathogens and consumption of particular foods, on how consumers handle particular foods, might help you to get the level of resolution that in the end you will need.

And I think even IFSAC has particular strengths because it's not only CDC who has the epi data, it's also FDA and FSIS who have the risk assessment capacity, who have the regulatory data.

There was a very interesting discussion about access to industry data, so at some point I think blending top down and bottom up approaches might be more productive in providing the level of resolution that you would need. So, thank you for the opportunity to comment.

Recording Timestamp=04:45:06

CRAIG HEDBERG: I'll reiterate a lot of what Arie and Sandy have said.

You know, I think that the goal of having a single robust method is very attractive, but, you know, I think what we can see from the *Campylobacter* data, in particular, is that the result, you know, can't meaningfully inform FSIS policy around one of the major categories of foods that they're regulating, and I think that that's a key issue.

You know, I have spent most of my life in the world of outbreak investigations, and at the University one of the things I'm most engaged in is working with our public health system to understand how outbreaks are conducted, how we can improve the investigations to make them timelier, more thorough, and more useful for purposes like this.

So I like having an attribution model that starts with outbreaks and builds around that, but we need context, really, to understand how those outbreaks fit into these models, and much of that context is really subject to research that still needs to be done.

And the one concern I have sort of with the very ambitious plans that are ahead of IFSAC is that, you know, in the first three years we've identified a lot of areas where we need research, and we're identifying new areas to move into.

And my concern is that we're going to move on and not fully address those foundation pieces that we need to understand before we start locking in new elements on to this food -- IFSAC food attribution modeling piece.

You know -- because I think one of the key issues for me is this relationship between sporadic cases and outbreaks, and clearly, that's pathogen-specific. So, *Campylobacter* behaves very differently than does *Salmonella*.

It also seems to be food specific, so when we look at the shiga-toxin producing *E. coli* O157s, we've seen sort of the rise of outbreaks associated with leafy green vegetables, so that they're about as common now as we see outbreaks associated with ground beef as a vehicle.

But despite that, leafy greens haven't really been established as a significant source for sporadic infections, and in fact, you know, in limited case control studies that have been done, and in some work

that the Minnesota Department of Health is doing in just aggregating food histories from sporadic cases of infection, it looks like leafy green vegetables are underrepresented as dietary components of our cases.

So there's complexity there related to this product category that we really need to begin to understand if we are going to make sense of this in any kind of holistic manner.

And Patty talked about the need for having more food testing data, and I think produce is the big black hole of information relating to food testing data.

You know, it's a major component of our diet. We're continuing to promote fresh fruit and vegetable consumption, and yet it's the area where we have the most unknowns in terms of what is coming through that part of our food supply with respect to our foodborne pathogens.

You know, I think a lot of what I do is -- and to try to work with public health agencies to improve outbreak investigations -- it's really clear to me that one of the potential hazards in having attribution models out there like this, is that they could actually send reinforcing signals to public health agencies. So if we expect that *E. coli* O157 is from ground beef, then ground beef is the first thing that many public health agencies are going to look for as they start an investigation occurring.

And so, you know, we as Epidemiologists at state and local health agencies, do respond to what we expect to see. And so in the past 20 years we've seen a lot of *Salmonella* in tomatoes. You know, before those first outbreaks were investigated, it wasn't viewed as being a biologically plausible vehicle for *Salmonella*.

Once we broke down that barrier and we started to regularly encounter this as a vehicle, you know, then we start creating an expectation that it's going to be there, and sometimes we can get led astray by having expectations that sort of preclude our broad search for possible agents.

And so that's something that as we work with the public health system on training and education, we really need to keep as part of -- a core part of our training, and sort of explore, you know, these areas, but also just to prevent this from being sort of the top five likely sources for this outbreak, that then are the ones that are really going to be looked for. And that, I think, is a significant concern.

The other piece of this is that if we want to have attribution models that incorporate the size of outbreaks as part of it, then I think we need to create a clear expectation for our public health agencies that that's something that's a valuable source, because right now most outbreaks aren't investigated with the idea of trying to estimate how many people were actually affected by the outbreak.

Depending on the setting in which the outbreak happens, that may or may not occur in a rational way, but it really hasn't been a design element, I don't think, in terms of how we approach outbreak investigations generally, and I think it's something that we can do a better job of if it's really clear that that's a valuable piece of information.

And in terms of improving outbreak investigations, generally, I think the key issue is in demonstrating to the Agencies doing these investigations, that the data are being used.

And so, you know, I think the models being developed here actually do provide incentives to the public health system to do a better job of investigating outbreaks, and I think that that can lead to improved data yields down the road, you know, if we plan that appropriately.

And my last -- well, two final points. One is that ultimately, I think, we want to be able to spin these models into looking at attributions that follow transmission pathways and get us to points of control. The commodities don't really matter as much as where we can control the contamination and break that transmission cycle, and so as we think about where we need to go down the road with this, you know, I think that really needs to start to become part of the focus of where we want to go.

And in that last regard, I really concur that IFSAC is off to a great start, but it really needs outside ideas as part of the core functioning of the group.

Recording Timestamp=04:53:16

SCOTT HOOD: I'll start by saying thank you for the invitation. It's a pleasure to sit here with this group and kind of listen to the whole process during the day.

I'll also start by saying I understand your concern with statistics. I did not drop out of statistics and I probably should have because it certainly brought my grade point average down.

SANDRA ESKIN: That's why I dropped it.

SCOTT HOOD: You know, as I sat here today -- and we did have the opportunity to see the summary report previously -- but the summary report was pretty high level, and I think, you know, finding ways to really get way more into the details of how the group got to where they did, to me was interesting, because the summary report kind of tells this top line story, but it doesn't go into the details of the thought process and how you got there.

And I realize that's hard to do in a publication, but it almost feels like that part of the story is important -- is to say that there's lots and lots of questions -- and I think in many cases you had really strong answers to those questions because the group had thought about those things and gone through the different models. It doesn't necessarily play out in the paper as I saw it.

It was -- you know, as I think about from -- you know, I work for a company, but I don't really represent industry, I represent my company -- I just want to make that clear -- and I think attribution data, as we look at it overall, it helps inform us as we do risk assessment, and so clearly as we do ingredient hazard analyses, as we do HACCP plans, we use this kind of data to help inform, where should we put energy? What kind of preventive controls and critical control points do we need to put in place? And so I think any time there's new attribution data, it helps us inform what those risks might be.

But I will say that, you know, from our perspective, you know, risk is really that sort of probability times severity. Well, we think all of these pathogens are severe, and any probability above a certain threshold, we have to take action.

So whether we're seeing more outbreaks in one commodity, or another product versus another, it's really kind of saying, well, does it reach the threshold to say we need to take action to put some controls in place to prevent it? And that threshold is pretty darn low.

And so, from our standpoint, we would look at this kind of attribution data -- it helps inform, but we're also trying to see -- we follow outbreaks.

Outbreaks give us information. We see what recalls are happening. I mean, if -- for the last two weeks, as much as this has been focused on microbiology, we've spent a lot of energy on things like peanut contaminants in spices.

And so following what's going on in industry is, you know, how we make better informed decisions, and do we need to change things? I'm not sure that there's anything in this report -- you know, we've talked a lot about the *Campylobacter* in dairy, and we know that if we drill down that's kind of in the -- maybe in the raw milk or unpasteurized milk area, so I don't know if there's anything here that changes our thinking today because mostly these are categories of foods we already associate with some sort of foodborne illness -- and let's put things in place.

I would say, you know, as being somebody who works in industry and hearing this, you know, "Hey, we want to get a hold of some industry data," -- and I would really like to find ways, and I think for some of you people here I've talked to before -- and we're going to look at ways that we can share data. But I would be cautious about it because when it comes to pathogens, for the most part, on the microbiology side, we're doing, you know, qualitative analysis. We're doing, you know, a 375 gram sample. It's either positive or negative.

And so, if it happens to be positive, we're not shipping product and we hope our vendors aren't shipping product, but the level of *Salmonella* or other pathogens that may be there would be so low, do we really understand -- would that cause foodborne illness?

And so I think if our goal is to prevent foodborne illness, we just have to have that watch out as to say just the presence of low levels of pathogens, while we generally agree that's not a good idea, that doesn't necessarily translate to causing illness out there.

And then, you know, I'll echo on what Craig had said. I sort of look at this, you know, and parts of what he said -- you know, that this is part of a longtime journey.

We're really in the -- you know, what's going on? We're finding out what foods are involved, but we need to move to the next level of where that contamination occurred. You know, what's going on there? And finally get to the how. How did this occur?

Because if we're really going to make changes -- you know, once we know what we have, we can start to implement some changes. If we have more information about where that's occurring, what the point of contamination, you know, then we can take additional actions.

And if we really know exactly how that's occurring, hopefully then we can put plans in place to say, let's -- if we can prevent this from occurring ever, you know, then -- you know, my goal is to put these epidemiologists out of business -- is to make sure that they have nothing to investigate.

But I think until we get to the point where we know how this stuff happens, you know, that is the point that which we'll be able to kind of bring it down to a solution.

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CHRISTOPHER WALDROP: So, second to the last panelist of a very long day. I've already had a couple of turns at the mike, so there's probably not much more to say, but I will reiterate a few things just because I have the mic.

First of all, congratulations to the Agencies for the work you've done so far, and putting on this public meeting. I think it's clear that public engagement is critical, and you've seen a lot of interest from stakeholders just today in terms of comments here on this panel, and then during the question and answer period. So this idea of finding some way to get that outside expertise in at various points along the way I think is a good one, and one that I would suggest that IFSAC take a look at and figure out how they can do that and how that might work.

I'm very pleased to see the Agencies are collaborating on this type of work. That's not something that I saw when I first came into food safety. So working on this -- developing that single method, in this case, that the Agencies can use, I think is a good step forward, and it's good that they are kind of collaborating on this type of work.

As I mentioned earlier, I do think IFSAC should make -- and the Agency should make -- the full data, the full model, and the methods public, so that everyone can take a look at it and can build on the work that's been done and continue the effort that we've seen on attribution so far.

You know, attribution work shouldn't be just the domain of IFSAC. We need a whole lot of people looking at this and working to improve it.

Again, as was mentioned before, that sole reliance on outbreak data is an issue. It's continuing to be an issue, and I think it's really limiting. So it's only -- it only shows us a little bit of the puzzle and the picture, and it doesn't give us that full picture that we need, especially for pathogens like *Campylobacter* that are rarely linked to outbreaks.

So we need to figure out a way to incorporate sporadic illnesses into this mix, as well as address things like the multi-ingredient foods, which was mentioned, or other pathogens, in addition to the four that have been focused on. It makes sense that that's where you started, but obviously I think we need to go beyond that.

I think we also need to figure out ways to pull together different data sets and figure out how they start coming together, and painting that fuller picture. And if they say different things, or point us in different directions, how do you reconcile that?

And I think that's something that IFSAC could serve a very useful purpose in putting forward sort of a vision in terms of how you start reconciling those different data sets, and specifically when they say different things. You know, what's the method? What's the means of pointing a way forward on that? Just looking at the specific report today, the estimates on *Salmonella* and *E. coli* seemed a lot more robust, or had less uncertainty than the estimates around *Campylobacter* and *Listeria*, and I think that then starts to point towards ideas for different data collection or additional data collection, where CDC can play a big role there, working with the states to figure out, you know, what is the current data telling us and what does that mean in terms of additional data or different data we need to collect, or collect in a different way?

So I think there's a good role there for CDC, the states, and other stakeholders to start looking at that and rethinking maybe our data collection that we do currently.

Finally, a question for FDA that I should have asked earlier that I didn't this time, but in regards to how FDA plans to use this. FSMA has -- uses the term, "known food safety risk." They use that multiple times throughout FSMA, so how does this then play into the way FDA is thinking about that and then developing sort of what is a known food safety risk, and how that gets applied then throughout implementation of FSMA?

Finally, again, great work that the Agency has done so far. I encourage you to continue to move faster and quicker on this. We all need this information. We need it yesterday, so to the extent that you can get the data, get the work done, and then reduce the amount of time that you get it out to folks. So if that review process is too long and needs to be shortened, think about ways that you can also do that so you can begin to get this data out on a more regular basis. So thanks again for the opportunity.

Recording Timestamp=05:02:52

SHELLY ZANSKY: And last in a very long day, thanks, Dad, for Zansky, in the alphabet.

Anyway, again, it would be a great time to have somebody who could really synthesize everything into a few things. I'm not that person, but a few comments.

Again, I would like to thank the Interagency Food Safety Analytics Collaboration for inviting me to participate today.

I wear sort of a couple of hats. One of is to oversee the Emerging Infections Program for New York State Department of Health, and of which of course FoodNet is a major component, as well as work in the surveillance unit in the department for the 60+ communicable diseases that are under our purview. So it's sort of with those two things.

I think FoodNet has contributed greatly and will continue to do so in terms of attribution. It's one of the main principle objectives of FoodNet when it was in its first inception, and in fact a special attribution work group was developed about ten years ago to address many of those issues.

We've conducted through FoodNet, for the last 17 or whatever -- 18 years -- many case control studies, and those were discussed briefly today -- some of those.

I would like to see that data used in maybe a new light. Bring it back -- resurrect some of that -- all those studies that we used. They weren't, you know, publications, of course, but look at it maybe in a new way to be able to inform attribution as well. There's a lot of information there. I think it's been underutilized and it's -- it was a lot of work for a lot of folks to get.

Likewise, more recently -- and Patty mentioned it and others -- that we've been working on -- starting last year, I believe -- for *Salmonella* enteritidis -- a case exposure ascertainment project -- so asking cases of *Salmonella* enteritidis in the ten FoodNet sites -- to ask more extensive questions so that we could get, again, a handle on some of those sporadic cases and attribution.

More recently, in 2015, we started to expand that to *Campylobacter*, so some of the sites have initiated that as well, so I think that, again, will help inform issues around sporadic cases.

And I'm not going to belabor -- everybody has said many times what some of the deficiencies have been in using outbreak data. We keep using it as the standard, and yet today we saw over and over again that there are incredible limitations to utilizing that, and it's not surprising that *Listeria* and *Campylobacter* came up real short in terms of the modeling, because we don't have a lot of outbreaks with those.
With respect to the sort of -- in terms of utilizing what we have here today -- the model and so forth -- and the state level, or even at the consumer level, Sandra, I take some issue with your issue with Chris. What Chris said earlier with regards to -- that it's not -- and even with the best writers and translators of this very complicated issue, and the modeling and all of that -- all the caveats -- is that it's not so easy to translate that, even at the state level, and utilize that information.

I mean, how do you do that? You know, what's your message? You know, let's go out there and make sure that all ground beef is cooked, or you know -- you know, we have a lot of messaging already, and what do we -- how do we translate that into consumer messages?

And I think we're still a long way from that. I would certainly not take the model today back to the state and really try to push, you know, this as the attribution model now for the four major organisms we see. For the very reason -- in New York, I wrote down the data from the last five years as our data, and we've had approximately 1,900 *Campy* cases a year in the state. This is exclusive of New York City, they do their own reporting, and less than 2% were associated with outbreaks for *Campylobacter*.

Similarly -- not quite -- over 1,300 *Salmonella* cases, 33% were listed as outbreak associated, and so on -- 44% of the O157s, 29% of the *Listeria*.

So, very small -- you know, relatively small percents, and that's -- on top of that -- that's of course -- most of those outbreaks don't have a food associated with them.
So, over 50% of those alone never have a food association determined, so you know, what's your message? What can you actually say about that with those kind of -- you know, the disparity between what you have in terms of cases?

We're still trying. We get calls and it sort of takes Scallan's burden of disease. We'll get a call, and say, of the nine million, how many of those cases are in New York State? Or even more, you know, how many are in Oneida County in New York? Things like that.

It's sort of -- you know, they want us to translate that to a very specific situation, either at state level -- what is the meaning for the state? Or even at a local level. And so that becomes very difficult.
So I think, you know, we have to sort of -- you know, it's important to get these things out there and to continue the work, but I think we also have to be very careful in our messaging for that and how we proceed with that. I think that's as important as the models themselves in the way we supply information.

And, again, I think this really -- part of my -- you know, from where I sit with FoodNet is I wanted to just come back with, where do we get this additional information?

And while -- Craig, I think -- you know, I really do hope that feedback to local health departments -- New York State is a "home rule" state, so our investigations take place by the local Health Departments.

Multi-state -- of course, the state steps in assists, and the state assists with others, but you know, they're burdened tremendously and feedback is very important, and I think it does improve quality. We see it with FoodNet all the time, that feedback makes -- improves the quality of our data constantly, so I think that is important to get that, but I think that for some of the future -- for data collection activities in terms of getting at those sporadic cases, particularly for *Campylobacter* and *Listeria*, and other pathogens, that we really need to rely -- I mean, in terms of at CDC -- for a combination of programs that are supported to do those sorts of things, like FoodNet, like the CDC, the Epidemiology and lab capacity grants, Centers of Excellence for -- what is it, Integrated Food -- Centers of Excellence and Food CORE programs -- I think that they need to meet more regularly, or meet, and actually start discussing in a much more clearer way of what we can each contribute, and how do we prioritize our activities, and what can we do to advance the attribution?

And that would help, I think, a lot, but I don't see putting it -- in New York -- putting it on the local Health Departments to obtain data like our case exposure ascertainment that we're doing through FoodNet to really add - asking them to do more at this point in time is -- of limited resources -- would be very difficult to do.

So I think it's beholden to the programs that are functioning -- paid for doing things like that -- to advance that. Thank you.

Recording Timestamp=05:11:50

DAVID GOLDMAN: I want to add my thanks to each of the panelists for your insights. I think you gave us a lot to think about, and I'm sure, both from the Steering Committee perspective as well as the Technical Working Group, we've got lots of substantive things to consider as we move not only Project 13 forward, but just the broader projects that we've got under consideration, or underway in IFSAC.
I think you, as a group, covered all the questions except one, and maybe you touched on it a little bit, but I'm interested to know if you have anything further to add to the question about how the federal government should be using these estimates, whether these particular numbers or not?
We told you throughout today's presentations how we thought we should be using them. You know, priority setting for resources in terms of policy development to measure our progress.

And I'm not pressing you, but if you have other ideas about how we might be using this -- certainly the regulatory Agencies have one perspective on use of data, and then the CDC has a different use perhaps of the attribution estimates.

So any of you -- I just invite any of you to add comments along that line, if any.

CRAIG HEDBERG: Well, you know, one of the things you could do is allocate more resources to state and local agencies that provide the raw material that you use for the estimates.

But actually, I just wanted to make one other comment that actually -- something that gets lost in the way the attributions are being done -- which is that, you know, part of the reason we have trouble with *Listeria* is because actually *Listeria* rates in this country have dropped fairly significantly over the past 20 years, and better control of *Listeria* in the food supply is a huge public health success, and that isn't reflected in sort of the ways that we're going about compiling this.

And similarly, with the *E. coli* O157 rates, on a population level, that control isn't always reflected in sort of the attribution estimates that are coming in here.

And, you know, right now, we have like the lowest rates of *Listeria* in the world, which I think is a great tribute to the integrated work of the federal Agencies to both do surveillance and then follow through on that surveillance activity.

SHELLY ZANSKY: Well, do you think that's highlighted in the analysis today, where we don't see sliced -- you know, meats, et cetera -- in there in the last few years so that they're -- they kind of fall out? Because I remember when you started with foodborne in '98 and '99, we were having all those outbreaks, and I think that is part of that story.

CRAIG HEDBERG: It's part of the story, although you have to sort of dig in and tell the story for it to emerge, and that's -- you know, that may just be an inherent limitation of the process, and it might be why we need to use this information in the context of other things that are going on.
But, you know -- but I think where we actually have had success -- you know, we should have a framework for acknowledging that as well.

SCOTT HOOD: I mean, I think that it's always great to build on successes. I think the other way -- you know, the alternative is that people have been working on *Salmonella* forever, right?

And *Salmonella*, when we look at all of the data that got analyzed, I think that the data points for *Salmonella* was, you know, twice as much as everything else.

And so, as much as we've been able to find sources, or you know, figure out *Listeria* to some extent, and *E. coli* O157:H7, to some extent, how do we -- you know, how do the three Agencies use the data, say -- I mean, *Salmonella* is the one that, you know, if you talk to anybody from my generation -- the professors that they learned from their generation were working on *Salmonella*.

It won't -- you know, it hasn't really changed and we haven't been able to move the dial on *Salmonella*, and what is it going to take? You know, how do we use this data? Is there a way to use this data to get more to where is it occurring? How is it occurring? What's going on there? So that, you know, another generation of microbiologists is talking about something else.

DAVID GOLDMAN: Okay. Thank you. Any other comments on how the federal government might use this?
(No audible response.)

Recording Timestamp=05:16:47
Question and Answer Period

DAVID GOLDMAN: Okay. We have a few more minutes before we move to public comment because we only have a small number of public comments, so if -- with agreement of the panel, we'll open it up to some questions from the audience, perhaps questions to ask the panel about something you've stated, or ask you to elaborate. If there are any questions for the panelists?
(No audible response.)

DAVID GOLDMAN:: No? Okay, we have one.

CHRISTOPHER BRADEN: So there are two panelists who took up this issue about the use of this data for consumers, and I -- my comment that I had before -- this is Chris Braden from CDC -- but I'm thinking maybe I'm missing something and it's not really about trying to explain the complexities to the consumer.

But maybe there's something else about -- as I think about this more, the consumer's role in making changes in the industry -- not necessarily what they can do in the kitchen. And maybe -- and I just bring that up -- is that, Sandy, what you're thinking?

SANDRA ESKIN: Hi. Sandy Eskin, again. I think two different points -- what I was trying to say and probably wasn't clear on is whether or not this information, at whatever level, is intended for consumers just by trickling down.

You have an active news media -- all different types of outlets that are interested in food safety, so I think I was just wanting to make sure that IFSAC was aware, or at least thinking about this. I wasn't suggesting consumer-facing message, per se, but just figuring out how to present this information, whether it's talking points when people are interviewed about it. Whatever. That was one.

Number two, I would distinguish individual consumers from consumer advocates, like myself and my other colleagues.

And I think I said initially that we do use attribution issues. Yes, we all have concerns about it. We shared –what is being expressed today -- but we think this information is absolutely essential to be effective advocates for sound public health policy, efficient government use of resources, et cetera -- measuring progress, establishing priorities, et cetera.

So, I would distinguish, number one, individual consumers -- yes, this is very complicated for even relatively educated consumers. We have to just be aware that this information trickles down and perhaps it gets changed like that game of telephone, but that's something just to be mindful of. But, yes, the consumer advocates, public health groups, et cetera, find this information as essential to our job as it is to the job of the regulators.

CHRISTOPHER BRADEN: Anything to add, Chris?

CHRISTOPHER WALDROP: No. I'd agree with that. I mean, we use this type of analysis and data all the time when we are trying to make the case for changes in public policy, or why we should be focused on a particular commodity, or a particular area of the industry, and that's when we're talking to either the Agencies themselves or to policy makers, or to the press, whomever. We use that all the time, so it's used in that way, for sure.

I do think, though, you can use this type of information to -- because individual consumers are going to learn about this through the press, or learn -- you know, CDC -- a new report from CDC says this -- and then consumers want to know how to act on it.

So, not necessarily this report itself, but this type of work needs to then inform -- you know, tools and messages to consumers in terms of what they need to do when they're preparing certain foods.

CHRISTOPHER BRADEN: Case in point, Reuter's already has a story on it today, so --

SANDRA ESKIN: Yeah. I think they quoted you.

CHRISTOPHER BRADEN: They did. But, yes -- and I must say, too, that, you know, when you talk about -- it's consumers of the information, besides the Agencies. Obviously, people involved in food safety policy on the consumer side --

SANDRA ESKIN: That's right.

CHRISTOPHER BRADEN: It's very important. But they're also -- people are making decisions in the industry who are getting through the news.

SANDRA ESKIN: Right.

CHRISTOPHER BRADEN: And especially trade publications and so forth. That's important.

SANDRA ESKIN: Yep.

CHRISTOPHER BRADEN: Thank you.

DAVID GOLDMAN: Any other questions from those in the room, or even those joining by webinar, for the panelists?
(No audible response.)

Recording Timestamp=05:22:09
Public Comment Period

DAVID GOLDMAN: All right. Hearing none, please join me in thanking the panel.

GREG DINAPOLI: If you've registered for public comment, I believe we only have two at the moment. If I'm mistaken, please let me know, but first up, Caroline Smith Dewaal, CSPI.

CAROLINE SMITH DEWAAL: Thank you. First of all, thanks to the Agency -- Agencies -- for hosting this day where we could really dig in to the new IFSAC data.

It would be, I think, useful to get the data in advance so we can really dig into it before the meeting instead of trying to follow the slides, and I do hope you post all the slides on IFSAC's website so we can see them.

I really have two observations. I know I've asked a lot of questions today, and I appreciate your tolerance. I have two observations that I want to share with the steering committee as you move forward. One is on data going in to IFSAC, and one is on data coming out.

With respect to data going in to IFSAC I guess I want to do an early warning, and I think I've mentioned this already today, but you are facing -- well, let me start with the fact that the key data that you need to do this work on food attribution is what we at the Center for Science in the Public Interest called "solved outbreaks."

And solved outbreaks are those where state or local public health officials have identified both a food and a pathogen.

CSPI is working on finishing up our second report called All Over the Map, where we analyze outbreaks reported by states to CDC over a ten year period, and the news is not very good.

We analyzed 10,000 outbreaks reported by states to CDC, 3,600 of those were solved. So, that's the 36 figure we've heard earlier today. But the news is even worse because in the last five years of the data we're looking at, which ends in 2012, the percent of solved outbreaks had declined from 44% down to 29%, a 15% fall in solved outbreaks, and the total number of outbreaks being reported to CDC has also declined pretty significantly from the first five years of the ten year timeframe to the last.

The range is 1,300 outbreaks reported annually to 700, so it's nearly cut in half. That means the data coming in to this system is really going to become even slimmer than what they've been using so far. We do the extra step of actually looking at reporting practices by 50 states and the District of Columbia, and we give each state their own page in the report. Thirty-four states receive a "D" or "F" rating, which means they're reporting three or fewer outbreaks per million.

I mean, this is really dramatic that the best reporting states are reporting -- like Minnesota and Oregon, and those that have a history of really solid outbreak reporting, are reporting eight outbreaks per million or more, and yet, so many states, 67%, are reporting three or fewer, and really about 20% are reporting one or fewer outbreaks per million, so this is also very bad news.

We have a few observations, one is that FOODNET states do appear to be doing slightly better than non FFODNET states. They're reporting about 21% of the outbreaks coming in when they're covering only about 15% of the population. And also, urban states, not surprisingly, are reporting larger numbers of pathogens through their outbreak reporting.

So, those are some of our findings. We have a number of recommendations, but I think for the federal agencies involved, you're not going to have the data to run this analysis, and we really think we're leaving valuable information on the table if you -- if we can't get the resources to the local and state health departments to complete these outbreak investigations and feed better data into this system. So that's my observation on data going in.

I have, hopefully, a couple of minutes just to give observations on data coming out of the system -- and we talked about Goldilocks earlier in the day.

Well, now I'd like to take Patty Griffin through the looking glass and see if we can't look at the data maybe a little bit differently in order to come out with some -- what we believe is more valuable data. So, the question that we've been tackling today seems to be, what commodities are implicated in *Salmonella* outbreaks, or *Campylobacter* outbreaks, or *Listeria* outbreaks?

So the question I would ask IFSAC to think about is whether you could give us the top pathogens linked to beef outbreaks, or leafy green outbreaks, or nut outbreaks, or herb outbreaks, or tuber outbreaks. Give us the top pathogens.

I believe that information would feed more easily into a hazard analysis, which is going to be critical for the implementation of HACCP and FSMA, and for aiding industry in doing the work it has to do in the next few years.

So, with that, thank you very much for giving me the time.

GREG DINAPOLI: Thank you, Caroline. I'm not sure if I've ever heard applause to a public comment, but that's a good thing, I think.

PATRICIA GRIFFIN: So, I also want to ask if there can be any reply.

GREG DINAPOLI: This is just a comment period, unfortunately. Brad Goskowicz?

BRAD GOSKOWICZ: I'm here. Can I just go from this microphone?

GREG DINAPOLI: You got it. Actually, I think it's this one.

BRADGOSKOWICZ: Oh.

GREG DINAPOLI: Yeah.

BRAD GOSKOWICZ: So, it's been a very good day for me. I want to thank you all for this opportunity to comment. My name is Brad Goskowicz. I'm the CEO of Microbiologics. We're based in sunny, Saint Cloud, Minnesota, and we are a leading global provider of highly accredited biological reference materials that are used for validating methods and quality control processes for food laboratories, as well as other industries.

I really enjoyed today hearing about the IFSAC project to produce these harmonized foodborne illness attribution estimates. I think that data based on sound, statistical methods, should help clarify outbreak analysis and risk assessments for these pathogens that are under study, and I certainly want to commend the three Agencies for their cooperation and collaboration. It's very impressive to see that happening, so thank you for that.

So, I'm going to give you a little bit of an example of one of the things that I wanted to talk to you about. There's really three things. One is, while we appreciate IFSAC conducting these public meetings such as this one, there is also a need for additional engagement with the laboratories and laboratory companies. IFSAC states its goals to share analysis and interpretations and use them to guide policy decisions from its three participating Agencies. Well, we respectfully ask that IFSAC also engage private sector laboratories, and food laboratory-related organizations in its continued deliberations.

As an example -- and this may be a little bit off the mark, but one example is in Europe. If you remember in 2011 there was the emergence of *E. coli* 0104H4, and that's an example of a pathogen that had become suddenly more prevalent. It really hadn't had many outbreaks before that.

According to the Morbidity and Mortality Weekly Report, this outbreak afflicted more than 4,000 people, was associated with raw fenugreek sprouts. I'm not sure what fenugreek sprouts are, and evidently a lot of the patients that were infected did not recall the consumption of this product either.

Laboratories need to respond in a timely manner to find these pathogens that are of public health significance, and we're often called upon to provide controls and materials for new and emerging pathogens, and we have to respond rapidly.

The public is best served if there is better public/private coordination of source attribution data and potential emerging pathogens. It helps the laboratory community to respond accordingly.

Second, insuring the availability of these new pathogen strains is also critically important. As a producer of nearly 1,000 microorganism strains in many different configurations, we strive to respond to the needs of those laboratories, public and private, in providing reliable biological reference materials in a timely manner.

Availability of these new strains and new biomaterials is a serious concern we have in responding to public health needs.

An example of that here in the U.S. is Shiga-toxin-producing *E. coli* was an important policy directive, namely a verification testing of raw beef manufacturing -- trimmings for these STECs and was issued in advance leaving the laboratory community's ability to respond.

You know, typically a laboratory manufacturer will seek biological reference materials because they have to validate their new methods, they have to be able to assess the quality and reliability of their testing, and they need proficiency samples to make sure that their operators can do these tests correctly. These materials were not available in advance of these regulations taking effect.
While we absolutely agree with the FSIS determination -- we think this was good and needed testing -- but ensuring the strain availability from the beginning would really have improved implementation.
So, finally, as part of the IFSAC goal to identify foods that are an important source of illness, it's also important to recognize the limitations of the data. While outbreak illnesses are the source of only a fraction of foodborne illnesses, other new emerging pathogens may appear from familiar food sources. This information will assist in testing surveillance and risk assessment planning, but hazards change and subsequent policies will need to be able to adapt to those changes.

Laboratory testing plays a significant role in foodborne illness detection and identification, and we look forward to partnering with CDC, FDA, and FSIS, and I want to thank you all for your hard work and collaboration on behalf of furthering food safety.

GREG DINAPOLI: Is Barbara Pope here from Vie de France?
(No audible response.)

GREG DINAPOLI: No? Okay. Since we do have a little bit of time, if anyone would like to make some comments -- Dr. Griffin I want to give you this opportunity now to make your response. I think that mic is still on.

PATRICIA GRIFFIN: Is it on?

GREG DINAPOLI: Yeah.

PATRICIA GRIFFIN: Yeah. Caroline, thanks for your comments, and I agree with your bottom line, I just disagree with some of the details.

And so I think it's very true that many outbreaks are not detected or investigated and there is a really wide variation by state in how many outbreaks they investigate, and that's a concern because we know that there's a lot more that we could learn if those states went out and investigated those outbreaks and found them in the first place, and we know that this is a resource issue, and we're worried that it could get worse, especially as laboratories begin to use culture independent diagnostic tests and we don't have sub-typing information any better.

But I'm not convinced that it's worse today than it has been in the past. I don't have the data at my fingertips, but just a couple of things to mention was that several years ago, as we've improved our outbreak reporting system, we used to have standard reporting of foodborne outbreaks and water borne outbreaks, and outbreaks that were traced to animals or the environment, or that were spread person-to-person, weren't collected in a systematic way.

Those are now being collected in a very systematic way in the surveillance system and it turns out that some of them that in the past -- that were classified as foodborne, when we asked the states, "Would you classify that now as foodborne?" they say, "Well, no. We'd probably list it as either person-to-person or undetermined."

So, there's been some shift and improvement, and that's been part of the reason why we've had a decline in the number of foodborne outbreaks.

And when we look -- again, I don't have the data -- I haven't looked at it in the past several months -- but I think that there's not been a decline in the number of bacterial disease outbreaks. I think there's been decline in the number of viral foodborne outbreaks because some of those norovirus outbreaks are now ascribed to person-to-person transmission.

The other thing is that I think it can be a little bit dangerous to look only at solved outbreaks as successes. I really, really, want states to report an outbreak if they know what was the pathogen that caused it even if they don't know the food, because then I know that that pathogen is causing an outbreak and it's causing an outbreak at home or in a restaurant, or associated with a catering service. It tells me something that helps me to understand the foodborne illness better.

Similarly, if there's an outbreak and it's caused by a particular food and we don't know the pathogen, I also want to know because then I know that there's still outbreaks from sprouts even though I don't know if it's *E. coli* or *Salmonella*. I know that that food is still a problem.

So, they're not completely solved outbreaks and it would be better if they solved it. Sometimes they could be solved -- sometimes because of issues like accessibility of people to interview, we can't get that information.

And the other thing that's a little bit dangerous is there's some states that have told us that they've gotten bad ratings as far as numbers of solved outbreaks, and so then they only report to us the ones that are completely solved, and then we lose that richness of information in which we get information on the ones that aren't completely solved.

Is she allowed to have a rebuttal to my rebuttal?

CAROLINE SMITH DEWAAL: I do have the data right here if you want to see it.

As you know, we are in complete agreement that outbreaks are valuable whether they're solved or unsolved, and we are in complete agreement that states should do everything they can to report both types.

But we can test the allegation that maybe they're only reporting their solved outbreaks because we did a previous report in 2011 -- published then of ten years of data. So we can look at all those inquiries. We have the data, we have the analysis.

I think you would agree, though, that the total number of outbreaks being reported to CDC is going down. I mean, it's coming off of your food outbreak database, so I just -- I understand I'm now over. But I think we're in complete agreement. I think that the states and locals need the resources to do their job if you guys are really going to do the food attribution work and continue it.

GREG DINAPOLI: Okay. Is there -- one more. We'll give one more. Going once, going twice.
(No audible response.)

GREG DINAPOLI: Okay. I'll hand it over to Dr. Goldman who is going to give our closing remarks. Thank you.

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Closing Remarks

DAVID GOLDMAN: Thank you. I won't take an hour.

This has been a very interesting meeting to me personally, and I wanted to harken back to a meeting that FSIS hosted about ten years ago. I know Mike Batz was there, and that was several jobs ago for him.

So, I don't remember all the other folks, but the point of this is that there are two recurring themes in this meeting that we spoke about at that meeting almost ten years ago.
What are the data sources available to inform attribution work, and what are the methodological approaches that should be taken? I mean, that debate continues and will continue, I'm sure, for another ten years. So I think -- I think it's important to maintain perspective about where we are and where we started on this.

I also wanted to mention for those of you who came to our meeting three years ago when this room was about twice as full as it is here -- do keep in mind that there are over 200 people on the webinar, so because we've advanced in our technology we have been able to create the webinar and I think it's very good for people who couldn't make it in to D.C. to have joined us. So, I did want to mention that there are about 200+ folks registered via webinar.

I hope that I'm speaking for the entire Steering Committee, but I want to say that I hope you're impressed by the complexity of this issue. I think that is rather obvious given the technical details presented to you by our presenters as well as the questions, the very good questions and comments that you, the audience, have raised here.

I did want to say that despite the complexity, we march on. I think the creation of IFSAC, kind of moving ahead from ten years ago in a public meeting and the various efforts that occurred since that time, till the creation of the IFSAC, shows both the level of commitment and the level of effort that's necessary to undertake this work.

Again, we heard very important comments from our audience here which speak to the complexity of this topic. For example, the requests to see the model and the data. We heard that several times. That will be a topic I can assure you of the next Steering Committee meeting.

You asked very specific and knowledgeable questions about some of the assumptions made in the work that was done for Project 13 that was the feature of this public meeting.

You asked questions about how this data will be interpreted to the wider audience, the public. We had several questions about that and I think very good questions as well.

And we touched on this, but I think -- and I'm going to come back to this in a minute -- but questions about how attribution can be measured over time and therefore take on a different level of meaningfulness, especially for the government and for industry who need to use the data over time to adjust ourselves, both our activities as well as specific interventions.

You've already heard very nice summaries of the projects completed, the projects that are underway, the projects that are planned, and the projects that are being contemplated, so I'm not going to repeat any of that in this brief summary here.

I think in particular Patty Griffin did a very nice job of summarizing all of what you heard, so you can go back and look at the webinar if you want to refresh yourself on that.

I did want to say a few things about the Project 13. Recall that we used 15 years of data, and there was a very purposeful effort to extend the work of the Painter project, which used data from 1998 to 2008. We added four years' worth of data, so we had 15 years of data.

And so there were quite a few questions early on about how we decided to use the five year window, and then to -- and then the decay function -- and all of that was predicated on this 15 years which we happened to have available. Had we had ten years of data, we'd have come up with something probably quite different.

So I just wanted to make the point that we had 15 years of data. I'm not sure that that commits us to using 15 years of data at a time as we move forward, although one of the projects is going to consider how we might do that. That is, take a new years -- an additional years worth of data and drop the oldest year of data, and how that might look by way of reporting trends over time. So that's at least one of the possibilities that will be discussed and contemplated in the IFSAC.

So, back to the 15 years. It's in essence just a big snapshot with a wide angle lens. Again, to reiterate, there's no trend analysis embedded here, so -- there are lots of questions that came up in today's discussion which I think are very good questions and suggest to us in IFSAC that there's obviously more work to be done on trends in particular.

Ultimately, attribution changes over time are what's very important to the regulatory Agencies in particular. Again, to repeat what's been said several times, we use -- we all use the public health cycle and for those who may not be familiar, it's assessment and then you develop policy based on your assessment. That is, the data that you have in front of you.

And then you do assurance work to make sure that your policies are effective, and then you reassess, you re-measure your efforts. So we all sort of subscribe to that policy in one form or another, so we really do need this data over time to tell us whether our policies that have been set forth are effective in reducing exposures to a particular food product that we know causes a significant proportion of illnesses.

So, again, I think the specific numbers that you see in the report are not as important as trying to look at the relative differences between different commodities on a pathogen by pathogen basis. And we heard many times the importance of bringing in other tools.

I wanted to come back just briefly to the Hald model, which is the work that's underway and we hope will come to some conclusion soon. This is a very important and different way of looking at attribution for *Salmonella* in particular, and does bring in other data sources.

So I think we've heard you. We are engaged in other analytic projects that do incorporate other sources of data.

I also want to go back to something that Caroline said earlier, and that is, all these attribution trends aside, when there is an outbreak, each of the two regulatory Agencies work that outbreak up completely and we engage with the industry, whatever the industry is, or the company, or the corporation, very considerably over that particular outbreak, and we all are trying to learn from any given outbreak as much as we can about the root cause and whether this is symptomatic of some broader systemic issue, which is a very important feature of any given outbreak investigation.

Is it just something that happened in one plant on one day? Is it symptomatic of something that needs much more attention by way of a policy change?
So, despite the efforts put in to developing attribution estimates, and in particular measuring trends over time, we'll never get away from the very important work of each and every outbreak investigation and the work that's done with the industry at the time the outbreak occurs, so I just wanted to make that point.

Similarly, if there's a brand new food vehicle that's been identified as a source of an outbreak, that gets a lot of attention, obviously, and we don't -- none of the regulatory Agencies wait until the next year's trend data to jump into action.

So I think it's very important for the audience here to understand that the regulatory Agencies use other data and other ways of getting at policy development that is necessary.

I'll just use one example quickly. At FSIS, we're aware of the difficulties with using outbreak data for *Campylobacter* attribution so -- but we've known about and we all have on our shelves that special issue of the Clinical Infectious Diseases from more than ten years ago now which really pointed to chicken as a major source of *Campylobacter*iosis, especially chicken consumed outside the home.

So we didn't wait for IFSAC to be developed. We have -- as you all know-- we've recently published performance standards for the industry. We had published them in 2011 to set performance standards for *Campylobacter* in chicken and turkey. We published new standards -- proposed new standards just less than a month ago looking at *Campylobacter* in ground turkey and ground chicken.

So there are other mechanisms for the regulatory Agencies to take advantage of to consider the appropriate policy development that's necessary when we're confronted with this sort of data.

The last thing I'm going to say about the Project 13 in particular that also was echoed in some of the comment is that this is a point of consumption attribution so it really does lack many of the sorts of data and information about what we call contributing factors, which are very helpful, particularly to the industry, but as well to the government in targeting interventions or policy.

We did hear you kind of looking to the future and next steps. We did hear you about the -- how we might share both the model and the data for Project 13 in particular, but more broadly share and engage with the public.

I want to go back to something I said this morning. We are very committed to public engagement and we realize, based on today's comments, it doesn't just mean us getting up every couple of years and telling you what we've done.

We hear you say that you'd like more than that, so again, something for the Steering Committee to take up.

You also realize that -- if you are familiar with the Painter estimates, that this is an advance from Painter in several respects. I won't go over those, but the point is that attribution, even using a particular approach, is an iterative process. It takes a lot of effort. I can tell you, from the Steering Committee perspective, and I wasn't in the trenches, the Technical Working Group spent really two years in the trenches on this. They did a lot of work and had a lot of debates, very fruitful debates I think, and yet we hear concerns raised about some of the limitations and the assumptions that were made, all of which are things that we have considered as we've gone along.
Again, just to echo something that's been said many times, finding a way to incorporate sporadic illness is a key goal of IFSAC is the blending projects that you heard mentioned really relatively briefly -- are very important efforts in that direction.

Sporadic illnesses are difficult to deal with. I directed a local health department, and if you've got a single *Salmonella* case come in and it lands on the desk of your infection control person, or your Epidemiologist, they've got other duties to do and they may not call that patient for a few days, and by that time, as we all know, the food history is fraught with some concerns in terms of recall.

And so individual cases are very difficult to get a fix on, so it requires some analytic approaches and techniques that have been shared a little bit here and have been shared in other publications, and how to incorporate those illnesses into a bigger attribution product will be very important, as well as the use of product contamination data, which was also mentioned.

And I just want to make one more comment about outbreak data versus sporadic case data, sort of harking back to something I said earlier.

An outbreak may signify something -- I'll use the term "catastrophic" -- that happened in a plant on a given day. So they had a good food safety system. Everybody might agree that that was the case, but something happened. A switch was flipped or a dial was turned the wrong way, whatever the case may be, so outbreaks may tell us something about that.

Again, they may also tell us about more systemic problems that need to be investigated and for which a policy change is necessary.

Sporadic cases, on the other hand, may be what we might see from a fully functioning safety system that is never going to be perfect. That is, that food safety system is functioning well to prevent the big outbreak. It doesn't malfunction in the sense that a big outbreak may occur, but the sporadic cases may still get through that otherwise well-functioning food safety system.

So it's just a different thing to keep in mind when we think about what sporadic cases and outbreak cases may tell us.

Finally, we're interested in your input and we have been soliciting it all along about how to engage with you. What's the appropriate frequency of these sorts of public meetings, which obviously take a lot of effort versus a webinar.

We've posted a couple of webinars which were highly attended -- and then other venues for communicating our efforts and engaging with you, so we're interested in continuing this sort of thing. I want to end by thanking all of you for attending and for sitting through a long day of a lot of technical detail, but your input has been highly beneficial to us as we move forward. Special thanks to the panel who came and contributed their expertise and years of experience in food safety.

I also want to thank the organizers and those who set up all of the logistics for this. You can see a lot of people who have been helping out -- set up the slides and the webinar.

I want to thank Greg DiNapoli for moderating today's event, Juanita Yates from FDA for really being the person organizing much of this, and as well as many of the Technical Workgroup members who pitched in to help out with organization.

With that, I think we have concluded a bit early, so if you have flights you may be able to get on the earlier flight.

Again, thank you for your attention and your attendance, and please look forward to further communications from us. Thanks.

(Whereupon, the meeting of the Interagency Food Safety Analytics Collaboration was concluded.)