UNITED STATES DEPARTMENT OF AGRICULTURE

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FOOD SAFETY AND INSPECTION SERVICE

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INTERAGENCY RETAIL *LISTERIA MONOCYTOGENES* RISK ASSESSMENT PUBLIC MEETING

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SCIENCE AND RISK ASSESSMENT: *LISTERIA MONOCYTOGENES*

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May 22, 2013
8:45 a.m.

U.S. Department of Agriculture
South Building, Jefferson Auditorium
1400 Independence Avenue, S.W.
Washington, D.C. 20250-3700

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I-N-D-E-X

I-N-D-E-X (Continued)

I-N-D-E-X (Continued)

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

(8:45 a.m.)

MR. DiNAPOLI: Good morning. Welcome to today's FSIS/FDA Interagency Retail *Listeria monocytogenes* Risk Assessment Public Meeting.

I'm Greg DiNapoli with the Congressional and Public Affairs Office at the Food Safety and Inspection Service.

Before we get started, just a couple of things. Those of you who are on the phone, I hope you're on the phone, assuming you're on the phone, please put your phones on mute so there's no feedback.

It does say no food or drinks. So if I see food or drinks, I will try to look away.

We set aside some time for questions before lunchtime. Please hold them until then. For those of you on the phone, send your questions to Joan Lindenberger, joan.lindenberger@fsis.usda.gov.

The transcript for the public meeting will be up on our website in about 3 to 4 weeks. If you didn't sign up to make a public comment, and you'd like to do so, just let us know at the registration

table at the back during lunchtime, and we'll make sure that there will be time for public comment. Each person will be given approximately about 5 minutes to give a public comment.

So do we have folks on the phone?

So it sounds like we've got folks on the phone. I'm going to just mention to them again to mute their phones, and if you've got questions, for those of you on the phone, if you've got questions, please send them to Joan Lindenberger, joan.lindenberger@fsis.usda.gov.

Our first speaker, we're welcomed by Michael Landa, the Director for FDA CFSAN. Michael was appointed Director of the Center for Food Safety and Applied Nutrition at FDA January 2012. In 2004, he served as the Center's Deputy Director for Regulatory Affairs previously, as well as Acting Chief Counsel and Deputy Chief Counsel at FDA. You can read the rest of the bios in your pamphlet. Michael, please.

(Applause.)

MR. LANDA: Thanks, Greg. Can you all hear me? Yes, no, maybe?

UNIDENTIFIED SPEAKER: Yes.

MR. LANDA: Good. I'd like everyone to move all the way back please. It's just confusing to have so many people close to the front. Just kidding.

I do have some sort of I guess you could say prepared remarks, but I just wanted to make a couple of kind of off-the-cuff comments first.

The first is that the only other time anyone at FDA asked me to speak here or probably anywhere else and say anything about risk assessment was an IRAC meeting. I think it was a re-chartering of the group, and Sherri Dennis who's sitting in the front row here, will remember that I referred to risk assessment as a slog, s-l-o-g. I got a bunch of odd looks. I didn't get an opportunity to explain what I meant, so I thought I'd take that opportunity for about 30 seconds now.

What I meant is that it's just hard work. The more data you have, the better you can do, but if you have a lot of data, it's a lot of data to go through. The analytical work is intellectually taxing and because you're modeling reality, you produce a

document that more often than not a significant number of people will take issue with. So that's all I meant by the term. I meant it actually as a compliment, and in that context, I think the IRAC is something we should -- we do and rightly should highly value for what it's brought to improvements in risk assessment.

We need models, of course, when we don't know what reality is. If we actually knew what reality is, we wouldn't be doing modeling in risk assessments or other types of modeling which makes in the world we operate in, of foodborne illness in particular, which makes risk assessment a critical tool. I would just add that in my case, the virtual deli portion of this is of great benefit to my family since I can send my son there and he returns having spent not a nickel and having not purchased anything with which to make massive sandwiches on a 24/7 basis.

Turning just a little bit now to today's meeting, I just want to underscore, the focus is on the science and getting the science right and how it might be seen differently. The focus is not on policy. That's really for another day. So I would

encourage people to keep that in mind, encourage everyone here to keep that in mind and everyone listening both as you hear what is said and ask you speak for those of you who will be speaking as commenters if you will.

All that said, let me just remind you, remind all of us, that FDA and USDA have a long history of collaborating on microbiological risk assessments. This begins with *Salmonella* in egg, the risk assessment in 1998, and of course, ultimately FDA did publish an Egg Safety Rule which it's now been enforcing for several years and indeed reduction in SE as a result of that rule is one of the targets, one of the metrics for its success.

Then in 2003, there was a *Lm* risk assessment, the first quantitative assessment of the relative risk of listeriosis from consumption of a variety of ready-to-eat foods. More recently, the risk assessment of highly pathogenic avian influenza virus in poultry and eggs, that was completed in May 2010, about 3 years ago.

This current risk assessment of *Lm* in foods

sold in retail delicatessens represents yet another thoughtful and I think highly productive FDA/USDA collaboration. It's based on an extensive amount of information gathered through partnerships with other federal agencies, academia, and input from stakeholders, and I want to sort of identify them now.

Its collaboration with colleagues at CDC that led to an OMB approved study to gather retail food handling and preparation information for RTE foods prepared and sliced at retail, engagement of consumer groups, retail and food industry, to include Consumer Federation of America, CSPI, the American Meat Institute, the Food Marketing Institute, GMA, and the Association of Food and Drug Officials. The engagement was from the initiation to the completion of this risk assessment.

There was also collaboration with academia and researchers, including Cornell University, University of Maryland, University of Arkansas, Purdue University, Virginia Polytechnic Institute and State University. These collaborations were to fill specific data needs, identified in analyzing the

framework for this risk assessment.

There's also been scientific input and review through frequent presentations of the risk assessment model and data analyses at scientific conferences and through a rigorous independent peer review of the risk assessment.

It improves our knowledge, our understanding of *Lm* in the retail deli, and should encourage improvements in retail food safety practices and mitigation strategies to further *Lm* in ready-to-eat foods.

I think the whole process of developing this risk assessment, as well as this public meeting, reflect our commitment, our FDA and USDA commitment to transparency in Government and to involvement upfront and along the way, through, to and including completion of stakeholders in the process, in the entire process.

What you'll hear today is presentations on background information relevant to *Listeria monocytogenes* at retail and data commissioned to fill specific risk assessment data needs, the overall risk

assessment modeling approach and, of course, findings from the endeavor.

Time will be provided, as Greg noted earlier, for questions and comments from the participants.

With that, I thank you for your attention and participation today, and turn it back to Greg.

(Applause.)

MR. DiNAPOLI: Thank you, Michael.

I think we might have to take a brief pause as we await technology to keep up with us.

(Off the record at 8:57 a.m.)

(On the record at 8:58 a.m.)

MR. DiNAPOLI: -- Epidemiology Branch at CDC, where he is focused on the surveillance in epidemiology of listeriosis and other foodborne and invasive bacterial pathogens. Dr. Silk.

(Applause.)

DR. SILK: Good morning, everyone. Can you hear me in the back?

Good. Thanks.

To advance slides. Yeah, okay. All right.

Next slide please.

Listeria monocytogenes bacteria are commonly found in soil and water, and this pathogen is notorious for its ability to grow in refrigeration temperatures, and is transmitted to people through contaminated food. *Listeria monocytogenes* infection, also known as listeriosis, causes severe disease in vulnerable groups of people.

Next slide.

The groups at higher risk for listeriosis are pregnant women in whom illness typically manifests as a febrile illness with other non-specific symptoms but can cause fetal loss which includes spontaneous abortion and miscarriage.

Newborn infants are another group at higher risk, and their illnesses typically include blood stream infections and meningitis.

And persons with immunocompromising conditions and older adults, typical illness also includes blood stream infection and meningitis.

Next slide.

This slide shows the incidence of

listeriosis by risk group for the period 2004 to 2009. The incidence rate can be thought of as illnesses per 100,000 people. At the bottom of this slide, with the triangles, you can see the overall incidence rate of listeriosis annually in the United States and that incidence rate has fluctuated minimally around .25 illnesses per 100,000 people.

In older adults, age 65 years and old, the incidence rate is about 4 times higher or 1 illness per 100,000 people, and you can see from the line at the time, pregnancy associated listeriosis incidence is markedly higher.

Next slide please.

We think of listeriosis as a rare, but deadly, disease. This slide shows illnesses and death and case fatality rates for four pathogens commonly transmitted by food. *Listeria* as well as *Campylobacter*, *Salmonella*, and Shiga toxin-producing *E. coli*.

In the second column, illnesses linked to *Listeria* infection, the number of illnesses is relatively small annually, about 1600 estimated cases

per year, and by comparison, the number of illnesses annually for *Campylobacter*, *Salmonella* and Shiga toxin-producing *E. coli* O157, as you can see are much higher.

However, deaths attributed to *Listeria* are disproportionately high for these four foodborne pathogens, and that's because the case fatality rate in the right column, which is the proportion of infections that lead to death or fetal loss, is much higher, about 16 percent than these other pathogens.

This slide shows trends in the listeriosis incidence rate over time from 1986 to 2011, and we'll return to this figure throughout my talk to understand the milestones and progress of *Listeria* control in the United States.

So let's begin with progress in the late 20th Century which we'll use 1989 as the starting point in evaluating progress. In 1989, a case of listeriosis was linked to a turkey hotdog, and this really was a key event early in the detection of processed meats as a source of *Listeria* infections.

As a result, new regulatory policies and

industry efforts began targeting processed meats, and as you can see, a decline in the rate of listeriosis followed subsequently. And, in fact, there have been no outbreaks reported due to hotdogs since 2000.

The high number of cases and deaths in 1998 is noteworthy because that was when a large outbreak of listeriosis, a multistate outbreak in the United States occurred and many of you will remember that outbreak.

Similarly, the number of outbreaks due to deli meat have mostly been prevented, and you can see that there are far fewer outbreaks reported in recent years.

The 2010 outbreak is an exception because it occurred in a plant that was not federally inspected and distributed product only within that state.

Next slide.

The next milestone in progress with *Listeria* control from our perspective is the advent of PulseNet. PulseNet began with its implementation for *Listeria* in 1998, and this slide is a graphical representation of CDC's national molecular subtyping

network for foodborne disease surveillance or PulseNet.

Participating labs, such as state public health laboratories perform post-field gel electrophoresis or PFGE, and images of these PFGE patterns are then uploaded and compared among participating laboratories. And, this collaborative network allows for detections of clusters of illness that are dispersed in time and geography.

Next slide.

And you can see quite clearly in this side, that outbreak detection has increased dramatically with the advent of PulseNet in 1998. Many more outbreaks were being detected and importantly, many more multistate outbreaks, geographically dispersed cases have also been detected subsequent to 1998.

Next slide.

And now we'll consider new opportunities in the 21st Century for prevention and control of *Listeria*.

It's important to note first that since 2000, there's been a lack of progress with *Listeria*

control and as you can see, the rate of listeriosis incidence has remained above the Health People 2020 goal of two cases per million.

Next slide.

At the same time, however, advancements have occurred. We used the *Listeria* initiative which was developed in 2004, to conduct enhanced surveillance for all listeriosis cases nationally. This includes standard food history interviews and integration of epidemiological exposure data with data from PulseNet which again are the molecular subtyping results that I described previously.

And the *Listeria* initiative has been quite important in expediting identification of common food sources during outbreak investigations.

Next slide.

This was particularly true in the multistate outbreak of listeriosis in 2011 which we linked to whole cantaloupe. The *Listeria* initiative played a key role in expediting that investigation. Importantly also, this outbreak was really a wakeup call in terms of understanding that *Listeria*

infections can be transmitted through raw produce items.

Next slide.

And so you can see among these newly recognized sources in this table, that raw produce items have been implicated in several recent outbreaks including not only whole cantaloupe in 2011, the last row in this slide, but also sprouts, raw sprouts in 2008 and precut celery in 2010.

Next slide.

Mexican style cheese outbreaks in recent years have been a continuing problem as well. You can see that several outbreaks have been reported to CDC as recently as 2010 and 2011.

Next slide.

In fact, we believe that the Mexican style cheese may play an important role in explaining the higher incidence rate of listeriosis among Hispanic persons. In this slide, you can see a comparison of incidence rates, again illnesses per 100,000 people for Hispanics and non-Hispanics, and the rate of listeriosis among Hispanics is markedly higher.

It's important to note that this higher rate reflects cultural preferences in food and certainly not biological differences in susceptibility to listeriosis.

The 2012, last year's outbreak, that was caused by imported cheese went on to cross contaminate other cheeses, is probably the most relevant outbreak for today. Much of the cross contamination that may have occurred during this outbreak, which included 22 cases across the country, probably occurred in retail settings.

And so the outbreak began with the importation of contaminated ricotta salata which was implicated as the outbreak source, and that a pasteurized sheep milk cheese, and we have some evidence to indicate that cross contamination of other cheese subsequently propagated the outbreak, and notably, this was the first U.S. listeriosis outbreak reported to our knowledge that was linked to cut and repackaged cheeses.

Next slide.

And so, in summary, progress occurred in the

late 20th Century most notably through interventions that target processed meats including hotdogs and deli meats, and we've also had considerable progress in enhancing outbreak detection with the advent of PulseNet.

And I also reviewed new opportunities in the 21st Century including ways to identify sources of sporadic cases through continued enhancement of outbreak detection.

I described the *Listeria* initiative and it's also worth nothing that whole genome sequencing holds promise for better outbreak detection as well.

I showed you some data on newly recognized sources of listeriosis through the implication of certain raw produce commodities, particularly whole cantaloupe.

We also saw that Mexican style cheese has been a persistent problem, and importantly, this includes pasteurized and unpasteurized products.

And then we considered the ricotta salata outbreak of 2012 and how that provides an example of how targeting contamination and cross contamination in

retail settings may also be important for prevention of listeriosis.

Next slide.

And so another way to summarize my presentation is to understand that the regulatory successes in *Listeria* control with processed meats illustrate what we call a public health approach to prevention which essentially I have presented.

In this cycle, which begins at the top with surveillance, we monitor progress in controlled *Listeria* contamination by tracking annual incidence rates to see if incidence is falling and therefore progress is occurring.

We use epidemiological investigations, in particularly outbreak investigations at CDC, to better understand what causes outbreaks and importantly, by extension, what also might be causing sporadic illness which actually represents the majority of listeriosis cases.

And from epidemiological investigations, applied research questions follow. Basically these questions relate to how we can make food safer, and

then we try to apply that research in terms of practices that can be implemented to improve food safety.

And so today we look forward to hearing more about the results of this applied research and how the work can be translated for prevention in retail settings. That's it.

(Applause.)

MR. DiNAPOLI: Thank you, Doctor. I understand there's some problems on the conference line. We apologize very much for that. We're having some issues transferring analog into digital. So it's going to be a little difficult. So the speakers, when you all come up, please just speak right into the microphone. My guess is that they can hear me pretty good right now. It's cutting in and out. So just if the presenters could keep that in mind. Thank you.

Our next speaker is our own Janell Kause, the Scientific Advisor for Risk Assessment at FSIS. In this capacity she provides leadership on the conduct and use of food safety risk assessment to guide policies and program decisions.

Ms. Kause has served on served on several national and international committees, provided oversight for the conduct and use of quantitative risk assessments to guide food safety policy development.

Welcome, Janell.

(Applause.)

MS. KAUSE: Thank you, Greg. Can everybody hear me just fine?

All right. Thank you. I will discuss the role of risk assessment and various risk assessments that we've conducted to guide decisions in our effort to prevent listeriosis.

Next slide please. Thank you.

Risk analysis plays an essential role in guiding food safety decisions. Risk analysis is a three part process. It involves the science which is the risk assessment, risk management which considers the science along with other factors including technical feasibility and/or statutes, and risk communication, that is communication among risk assessors and scientists, between risk assessors and risk managers and with the public and stakeholders.

Risk assessment is powerful public health tool. They integrate science and information to provide public health predictions of changes in policies, programs and practices. They're often thought of as the bridge between data and decisions. Risk assessment also provides a transparent framework that allows for improved stakeholder involvement and also ensures both scientific credibility and accountability.

As Mr. Landa pointed out, FSIS and FDA have developed a number of risk assessments together over the years. I'm going to talk specifically today about our *Listeria* risk assessments. We designed a number of those as well.

Each risk assessment was designed to answer a specific risk management question. These questions provide the framework and guide the type of risk assessments we're going to design. Each risk assessment is different in its design. It's what we call "fit for purpose." That is, it is designed to provide information specifically in response to a risk management or a set of questions.

In the risk assessment that we'll hear about today, we spent quite a bit of time engaging stakeholders to get questions in addition to getting questions from FDA and FSIS risk managers.

Answers to each risk management question leads to improvements in public health policies. However, answers to questions that we have also lead to new questions and further our effort to prevent listeriosis.

In the 1990s, there were various *Listeria* outbreaks as Dr. Silk talked about. Given a long incubation period from infection to symptoms, most listeriosis cases are not associated with an outbreak; that is, often we don't know what the food vehicle was.

At the time of the '90s, the risk managers wanted to know which ready-to-eat foods posted the greatest risk of listeriosis. To answer that question, FSIS and FDA partnered to conduct a quantitative risk ranking of ready-to-eat foods. This risk assessment was based on microbial contamination, predictive microbiology, information on industry and

consumer practices and dose response information.

This risk assessment identified deli meats as posing the greatest risk of listeriosis. About 67 percent of listeriosis cases were attributed to deli meats in that risk ranking. Other foods identified included soft cheeses and hotdogs.

These findings, released as a draft in 2001, provided the basis of the next question.

What processing interventions would be most effective in mitigating the risk of *Lm* from ready-to-eat meat and poultry products?

In 2002, FSIS developed a quantitative risk assessment to evaluate the effectiveness of processing interventions in mitigating the risk of listeriosis from ready-to-eat meat and poultry products. This risk assessment was developed, somewhat more unique than the first one. It had a dynamic cross-contamination model, and it included the growth of *Lm* while it was in commerce through consumer storage and handling, and it included national dietary consumption data as well as the well recognized dose response relationship.

This assessment provided information that formed the scientific basis for FSIS' interim final rule for *Listeria* which was published in June 2003.

While much of the focus prior to conducting that risk assessment had been on increased testing of product, this was kind of the consensus among our stakeholders as well as the Federal partners, that more testing is good.

In this graph that you see on the screen, these are the results, and what we found out was the use of post-lethality interventions and growth inhibitors led to a much greater reduction in risk and when used together was the ultimate *Lm* control during processing, both of which were much more effective than simply increased testing of product.

Next slide.

Industry's implementation of a policy and a risk-based program to match that policy did encourage industry adoption of more stringent *Lm* controls. Basically FSIS would sample all establishments producing ready-to-eat foods. However, it would allocate its resources based on public health risk.

What that means is, for example, those who had less stringent *Lm* controls would be visited more frequently and would receive more verification sampling.

The data that's shown here shows the adoption of policies. As you see in the graph shown on the slide, you can see the "before" and the "after." Before there was much more emphasis on preventing *Lm* through increased testing. The light green part shows you where there was a greater adoption of the use of growth inhibitors as well as post-lethality interventions.

This was considered a success both by industry and FSIS.

Next slide please.

So here's the results of that success. As you can see, this is a slide showing the *Lm* testing of ready-to-eat meat and poultry products that FSIS conducts. From about 2001 to 2011, there was about a 75 percent reduction in the percentage of product testing positive for *Lm*. We considered that the outcome of the success of those policies.

Next slide please.

Despite the decline of *Lm* in ready-to-eat meat and poultry products, however, as Dr. Silk nicely pointed out, we did not see a similar decline in listeriosis in this country.

We wondered why there was not further reduction. If ready-to-eat meat and poultry products comprised the greatest proportion of the listeriosis cases, and we saw the decline in our products, why were we not seeing further declines?

Next slide.

Well, we had a clue. One of the clues was from an industry survey. There was an industry survey produced by the National Food Processors Association and published by Gombas *et al.*, in 2003, that showed that there was a seven-fold higher incidence of *Lm* in retail sliced deli meats compared to prepackaged deli meats.

Go back please.

A subsequent study was conducted also by a group of universities including U.C. Davis, Auburn University, Michigan State University and the University of Tennessee, and they had similar findings

of a seven-fold higher prevalence of *Lm* in deli sliced products versus those that were prepackaged; and a higher concentration of *Lm* in retail sliced products.

Next slide please.

Using the data from these surveys, we translated using a comparative risk assessment, and what we found is about 83 percent of deli meat related listeriosis cases were attributed to those sliced at the deli counter.

Cornell University did a separate comparative risk assessment and had very similar findings. In most cases, the listeriosis was associated with deli meats sliced at the deli counter.

Next slide please.

So we began to ask the question, why would retail products be more contaminated?

The findings of those retail studies as well as the subsequent risk assessments by FSIS and Cornell led us to our current question. Why would ready-to-eat foods sold at deli counters have a higher prevalence and level of *Lm* than those from the manufacturer?

As FSIS and FDA considered the data and information, we hypothesize many things. We had a lot of discussions about cross contamination, temperature control, sanitary conditions and so on. We knew that there were a wide variety of studies already underway where people looked at compliance with the Food Code and other things. However, we did not have a quantitative link between retail practices and conditions and public health outcomes. We wanted to know the extent to which certain practices would contribute to listeriosis and which interventions…and how effective an intervention would be in terms of mitigating that particular risk.

Next slide please.

So we did what we normally do as risk assessors. We developed a risk assessment based on the scientific data. This is not to say the scientific data that's developed isn't useful. It's highly useful. We needed data on retail behaviors, interventions, the effectiveness of those interventions, transfer coefficients, and so on. And, we went out and obtained those data, either through

review of the literature or collaborating with academia to garner those specific data to meet those data needs.

But what's important to know about data is data provides us a specific set of information. It does not provide us information on exactly how that's going to impact public health. What the models allow us to do is to not only integrate that data and link data to the public health outcome, it allows us to create a place where we can make predictions, where we can go ahead and ask a myriad of "what if" scenarios.

What if we change our gloves more frequently? What if we sanitize more frequently? What if we control the deli case temperature? What if we don't control the deli case temperature?

So, we had all these different types of questions. This "virtual deli," as we often call it, allows us to explore that and relates it to public health.

And with that, I will turn it over to Dr. Sherri Dennis to tell you about the model. Thank you.

(Applause.)

MR. DiNAPOLI: She deserves an introduction. Janell, thank you very much.

Dr. Dennis is the Acting Director of the Division of Risk Assessment in CFSAN's Office of Analytics and Outreach. She oversees the development of mathematical models and risk assessments to support science-based risk management decisions.

Dr. Dennis has been invited to serve on numerous Agency, interagency and international workgroups addressing a wide range of scientific and technical topics.

With that, again, Sherri.

(Applause.)

DR. DENNIS: Thank you and good morning, everyone and thank you for being here today and your interest in this work and participating in this public meeting with us.

I'll be picking up the story from where Janell left off, from her very good introduction of the background and the studies that led us to conduct this risk assessment. I'll focus a little bit more on

the scope of the risk assessment and our process that we used for conducting it.

So on the slide here, you see the stated objective of this project, and I'll just read it. It is to ascertain the impact of public health of current practices and potential interventions that reduce or prevent *Listeria monocytogenes* contamination in ready-to-eat foods, sliced, prepared and/or packaged in retail facilities.

So the scope of this work is focusing on *Listeria monocytogenes*. The foods that we're focusing on are ready-to-eat foods, and this would include items such as sliced deli meats, sliced cheeses, and deli type salads like potato salad, that are purchased in the retail and then consumed in the home.

The range of retail types that we looked at included delicatessen departments in large major retail chain supermarket facilities and other types of groceries such as multipurpose, independent, small or local facilities. And you'll hear this afternoon how that is translated, those conditions in those deli departments, are translated and taken into account in

the model.

In the risk assessment process, the first key step is to identify the risk management questions that the risk assessment will undertake. And so these questions really flow from that stated objective in the previous slide.

There were posed three questions initially from our risk managers to this interagency workgroup. So the questions were, first, what's the exposure to *Listeria monocytogenes* from consuming ready-to-eat foods prepared in retail facilities? What are the key processes that increase ready-to-eat foods contamination at retail? How much is the relative risk per serving reduced according to specific risk management options?

From those three risk management questions, we further refined a list of what we refer to as "what if" scenarios. And in developing this list of scenarios, we involved not only our Agency policymakers and scientists, but we also involved our stakeholders, both industry and consumer groups.

The scenario analysis is how you really put

a model to work, and the results of the scenario analysis are generally expressed as relative to a baseline estimate. So you'll see that this afternoon.

They're conducted by changing one or more of the inputs into the model and then simply measuring how that is translated into the outputs and how that change will change the output estimate.

We had a large number of scenarios that we looked at, but they can really be grouped into five broad areas: those that deal with sanitation; worker behavior; growth inhibition; cross contamination; and storage temperature and duration.

The "what if" scenarios are typically posed as a question and this slide shows three examples of that. I'll read these out for you to give you an idea of kind of the scope of them.

So, for example, what is the public health impact of temperature abuse in deli cases? What would be the public health impact of separate slicers for foods that support growth versus those that do not? And what is the public health impact of the use of gloves?

So this afternoon, you'll hear more about the findings relative to these scenarios.

In conducting a risk assessment, there's lots of activities that have to be undertaken, and these can be loosely grouped into five steps.

So first is to commission the risk assessment, and during that process, we refine the scope, those risk management questions and we form teams.

Second is to collect and evaluate the data, and typically the data would be obtained from the literature, the published scientific literature as well as government surveys, but often we may also issue a *Federal Register* notice to solicit data that may be unpublished that we could also use in the risk assessment.

The third is to build and validate the model, and then prepare a report that describes it.

Fourth is review, and this includes external peer review required through the Information Quality Act and OMB, the Office of Management and Budget's peer review bulletin. It also would include the

various Agency review and clearance processes.

And then the last step is issuing the risk assessment, and we would do this first as a draft for public comment, and then a revised document takes into account the public comments.

So this interagency risk assessment included all of those various steps and activities and where we find ourselves now is the last step. We issued the risk assessment for public comment earlier this year.

Now I want to highlight a few things that really make this project special.

So really this project sets a new bar for us. In planning and conducting this risk assessment, we actively set forth a unique partnering of government agencies, academia, industry and consumer groups, and many of the activities that are described in the previous slide were undertaken but we really went a step beyond that.

Our goal in doing that was to improve the transparency and to obtain and use the best available science and information in the conduct of this risk assessment.

So what makes this risk assessment special? First is interagency partnership to share resources, collaboration with academic researchers to collect data specifically for the risk assessment, frequent engagement with our stakeholders, and then taking all of this into account, a truly innovative project.

So I'd like to elaborate a little bit on each one of those.

FDA and FSIS formed an interagency workgroup with experts from both of our Agencies in consultation with CDC. We truly worked together. We worked together to commission the work, to develop those risk management questions that I showed you, to collect and analyze data, obtain our stakeholder and public input, develop the model, refine the model, validate the model. We did this altogether within our workgroup.

And we not only shared staff and expertise, but we shared financial resources. And so, for example, we co-funded the peer review that you'll hear about.

We worked together to put presentations together. We worked together to develop all of the

technical and communication reports associated with this risk assessment.

So the value of this interagency approach really goes beyond that sharing of resources, of staff and financial resources. The value of it is the inclusion of a variety of perspectives, and I think you can see that, as you view the options, that we looked at and the scenarios that we looked at, it's very broad to fully explore this issue at hand, *Listeria monocytogenes* in the retail deli.

So the second thing that makes it unique is collaboration. You'll hear later this morning about studies that were undertaken to collect data specifically for this risk assessment. A number of universities mentioned previously, but I'll mention them again, have collaborated in this effort including Virginia Tech, University of Maryland, Cornell University, Purdue and others.

Our stakeholders from industry and consumer groups also had a role to play with this and, in particular, trade associations such as FMI and AMI, contributed tremendously to the planning and conduct

of these studies.

So on this slide, you'll see a list of some of the studies that were undertaken, and you will hear a lot more details about these studies later this morning, and then this afternoon, you'll hear how that information was translated into the model.

Our engagement with stakeholders began when the study initiated in 2009. We issued a *Federal Register* notice call for data, and we held a public meeting to help clarify what our plans were and to solicit input and some of the data that we needed.

But we didn't stop there. Our engagement with the stakeholders continued actively through the conduct of this study. This included making presentations about the model and the methodology and the approach at scientific meetings to get additional input from risk assessors and other scientists on the actual approach of the model development.

We held a vast number of briefings. I started doing a tally of each of the briefings. I stopped at 56. There's probably more than that over the five year period, or over the four year period.

So we put a lot of effort into engaging with our stakeholders and getting the input that we needed, and I think this really helped us to develop a very good risk assessment model.

And lastly, the model structure was formally evaluated in a peer review in January of 2011. This peer review focused very much on the model structure, the framework, the approach, data, assumptions, how the components of the model fit together, how we are planning to evaluate the scenarios and how we would handle uncertainty and variability. And the peer reviewer comments as well as our response to those comments, and how we took those into account into the current version of the model, is available on both FDA and FSIS websites.

So I show you this diagram really to give you a little better sense of the extent of the outreach and engagement that we underwent to help frame the risk issues that are addressed in this project. This is not an exhaustive list of events. It goes through May 2010, but I hope what it does help to convey the engagement aspect that really makes this

project unique.

And lastly, this project is about innovation. This model is really the first of its kind. It allows us to link all of those events that happen in the retail delicatessen with public health outcomes, and it allows us to do this in a way we could not do previously because this gave us some quantitative estimates to help us understand the impact of deli conditions and retail practices and help us move forward to our goal of minimizing listeriosis.

As you'll hear this afternoon, this model is really quite complex. There are a lot of components to it, and one of the other innovations that I want to mention from the diagram is that we used a high performance computer, and this was parallel 2,000 cores working simultaneously. This allowed us to essentially virtually serve 1 million customers in our model in 1 minute. So that's a huge progress in the technology that we were also able to incorporate into this effort.

So again, thank you for joining us today. I

hope that with Janell's presentation and my presentation, that we've helped set the stage for you, the context of this risk assessment and an understanding of the next presentations on data, the model and the findings. Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Sherri. We're running a little bit ahead of schedule. So I'm going to take this opportunity to invite folks to ask any questions before we take a break. I believe there's a microphone there that should be on, but if you want to just go ahead and raise your hand for a question for any of the presenters that we just had. Clarifications? No?

Okay. We'll take a 15 minute break. Be back here at about 5 to 10:00 or a little bit sooner than that, that would be great. Thank you.

(Off the record at 9:40 a.m.)

(On the record.)

MR. DiNAPOLI: Okay. Welcome back. I'm just going to remind everyone on the phones to mute your phones please. We'll do our best to speak

clearly and closely into the microphones so folks on the phone can hear us.

Our next speaker is Dr. Karin Hoelzer.

Dr. Hoelzer is a, I'm sorry, that's ORISE, O-R-I-S-E --

DR. HOELZER: ORISE.

MR. DiNAPOLI: -- fellow at FDA's Center for Food Safety and Applied Nutrition, where she conducts qualitative as well as quantitative risk assessments.

Before becoming a fellow, she was a research associate in Cornell University's Department of Food Science. Welcome, Dr. Hoelzer.

(Applause.)

DR. HOELZER: Can everybody understand me okay? Great.

Much of the research I'm presenting today was actually performed while I was still at Cornell University and under contract for FSIS. FSIS funded this research primarily to gather data for the interagency retail risk assessment.

Next slide please.

The goal of all the research that is

presented today is really to leverage science in order to prevent or at least minimize contamination of *Listeria* at retail.

My talk will in particular focus on four questions. First, which environmental sites are of greatest concern for cross contamination? Second, what is the likelihood that *Listeria* will be transferred from these sites to food if it is present? Third, what fraction of the bacteria will be transferred during cross contamination events? And, fourth, how effective is cleaning and sanitization in reducing environmental contamination of *Listeria* at retail.

Again, the objective is to minimize or even prevent cross contamination of *Listeria* at retail.

Next slide please.

I will start the presentation with a very brief introduction. After that, I will walk you through the establishment of a risk map of *Listeria* at retail to address the first two questions, which environmental sites to focus on and what is the likelihood that *Listeria* will be transferred from

these sites to food.

After that, I will walk you through the establishment of the coefficients for *Listeria* transfers, and then I will review the efficacy of cleaning and sanitization, hopefully leaving you with a few unifying conclusions.

Next slide please.

This slide is just to remind you that listeriosis is a very serious public health concern, and I'm sure after Dr. Silk's excellent presentation this morning, there's no doubt about this.

Next slide please.

This slide is just to remind you cross contamination at retail is a very serious concern. I'm sure many of you are very well familiar of the FSIS risk assessment of the *Listeria monocytogenes* in deli meats that found that of the deli meat associated listeriosis deaths, more than 70 percent attributable to deli meats that are sliced at retail and manufactured without growth inhibitors. So this is a very serious concern.

Next slide please.

This slide is to hopefully convince you that environmental contamination of *Listeria* in retail delis is a very common occurrence. The data I'm showing here is from a cross-sectional study of *Listeria* in the environment of retail establishments in the State of New York that we performed a few years ago. I will not go into too many details in the interest of time. You can find expert elicitation on the slide, but basically what the study showed us environmental contamination in retail delis is very common. Non-food contact surface sites are significantly more likely to be contaminated than food contact surface sites. And when I'm speaking about food contact surface sites throughout my presentation, I'm referring to accidental as well as intentional food contact surfaces.

We also found that there was a great variability in the prevalence of *Listeria* at different sites for food contact surface sites ranging from 2 to 3 percent for slices to up to 10 percent for some other contact surfaces.

And we found certain stores are more likely

to be contaminated than others.

Next slide please.

So why would we develop a risk map of *Listeria* at retail?

If you think about it, risk can be thought of a product of two factors. First, the likelihood that an event occurs and second, the expected impact if the event really occurs.

Risk maps plot risks based on these two factors and if multiple risks are plotted on the same map, naturally things will occur, and this can help us to guide actions. If you look at the risk map on this slide, risks that would be located in the upper right-hand quadrant have both the high likelihood of occurrence and a high expected impact. So they are very high risk and you probably want to take immediate action.

Risks that are located on the lower right-hand quadrant have a lower likelihood of occurrence but the expected impact is still very high. So we probably want to detect and monitor these risks.

The risks located in the upper left-hand

quadrant have a high likelihood of occurrence and a lower expected impact. So it might be sufficient to monitor these risks, and risk located in the lower left-hand quadrant pose a lower likelihood of occurrence and a lower expected impact. So resources might be better spent on risk in the other quadrants.

Next slide please.

If we want to establish a risk map of *Listeria* at retail, we need to know two things. We need to know the prevalence of *Listeria* in different environmental sites and we need to know the probability that *Listeria* will be transferred from these sites to food if that site is contaminated.

When we set out to create the risk map, we have fairly good information on the prevalence of contamination at different sites, based on the cross-sectional study of *Listeria* in retail establishments in New York that I mentioned earlier, but we had very limited data on the probability of transfer from different sites to food.

So we decided that we needed to conduct an expert elicitation to fill this data gap.

Next slide please.

In the next two minutes, I will walk you through first the expert elicitation that we conducted and then how we used that data to create a map of *Listeria* at retail.

The first question we needed to address for expert elicitation was which environmental sites to include. We started with a literature review but we also sought very active dialogue with industry experts, academic experts and regulatory experts at the federal and state level, to make sure that we really captured all the sites that were important.

In the end, we ended up having 31 environmental sites which are shown in this slide plus hands and product. So this is a very large expert elicitation.

Next slide please.

For expert elicitation we use what is called the Delphi method, which is a structured, iterative forecasting method, meaning we provided a questionnaire to our panel of experts, analyzed the results, invited experts to an anonymous telephone

conference to discuss the results and then gave experts the opportunity to revise their estimates in light of what had been discussed.

We enrolled a total of 45 experts in this expert elicitation, 20 employed in the retail industry and 20 what I call state experts. Those were employees at state level regulatory department with oversight over retail delis.

In the interest of time, I will not go too much into the expert elicitation. You can find this expert elicitation on the slide, but we decided that in addition to the questions, we really needed to address our data gaps for the risk mapping, and we would include other questions as well.

We would first include questions about transfer dynamics in retail establishments to get a better understanding of what experts thought about what was going on in the retail deli.

We also included some questions to address cognitive bias that we were worried about, and we incorporated some questions to get an idea of how good individual experts performed in forecasting.

What we found, as expected, was that certain experts were better at forecasting than others, and there were some quite interesting demographic depicters of how experts performed. But if you look across the diagram, which is shown on the left, on the slide, you see that if you look at how all the experts responded to the questionnaires, we had three statistically significant clusters in our expert elicitation and all three clusters contained state as well as industry experts. So this gave us good confidence that it was okay to combine everybody's responses to obtain summary methods.

Next slide please.

In the next two slides, I will just highlight a few things from the expert elicitation before showing you how we used that date to create a risk map.

When we asked experts about transfer dynamics at retail, experts always, always, always pointed toward the role of hands and gloves. So even though my talk here primarily focuses on transfers from hard surfaces to food, we really cannot

underestimate the importance of hands and gloves.

Next slide please.

Experts always exhibited very high probabilities to transfer from food contact surfaces to food. There was a lot of consensus among individual experts on the likelihood of these transfers and the self-rated level of confidence was high.

Next slide please.

Experts usually also attributed a fairly high probability of transfer to transfers from hand contact surfaces to hands, but there was less consensus among individual experts and the individual weighting of self-confidence was lower.

And the primary reason for the expert elicitation was to fill our data gap to create a risk map.

And here is a risk map. On the "X" axis, you see the transfer probability from a given site to food if that site is decontaminated based on our expert elicitation. And on the "Y" axis, you see the probability that the site is contaminated based our

cross-sectional study of retail establishments in New York.

When we enrolled stores in this cross-sectional study, we enrolled stores of different size, and we have the problem with not every store had all the sites that we were interested in. For instance, not every store we enrolled was big enough that it had the produce preparation area. So we had different numbers of observations for different sites, and we felt that it was very important to incorporate this in our risk map.

So what you can see is that the bubble sizes shown is representing how much data the prevalence estimate is based on, with larger bubble sizes representing more data.

As I showed you before, experts also seemed to have more confidence in predicting certain transfers than others, and we felt that was important to show this in our risk map as well.

So the font legend size is representing how much consensus we saw among the experts based on how similar their predictions were and what their self-

weighted level of confidence was and lighter font sizes represent more confidence among the experts.

If you look at this risk map, the first thing you'll see is that there are no sites located in the upper right-hand quadrant which is good. That was the quadrant of highest risk, but there are a number of sites in the lower right-hand quadrant meaning that even though the probability of contamination in these sites is relatively low, it is definitely not zero as you can see based on our cross-sectional data. And if the sites are contaminated, there's a high probability that there will be transfers from these sites to food.

As you can see, all of the sites that are located in the lower right-hand quadrant are food contact surface sites.

You also see that the number of sites in the upper left-hand quadrant, meaning the probability of transfer from these sites to food is lower than for the other sites that I mentioned earlier, but the probability is definitely not zero, and the probability of contamination is very high. So we do have to worry about these sites as well, and these

sites, as you can see on the map, non-food contact surface sites.

So now that you know what sites you have to worry about, next slide please, what fraction of bacteria will be transferred from these sites to food?

To address this question, we performed a systematic review and meta analysis of the available literature. So the data I'm showing now are based on experimental studies performed in laboratories.

I'm only going to go into a few details here in the interest of time. You can see the expert elicitation on the slide again, but basically what the diagram is showing are mean transfer coefficients and surrounding 95 percent confidence intervals for different transfers.

The first thing you will probably notice is that different transfers have different transfer coefficients meaning some transfers are more efficient than others, and you see that the confidence intervals are often very wide. So from replicate to replicate we see a lot of variability.

And while reviewing the literature, we found

a lot of factors that can have an impact but basically the take home message here is there's a lot of variability in transfer coefficients and we need to make sure if you want to model this, that we are accurate and that we account for this in an accurate way.

We also see that in certain circumstances, you can have high transfer coefficients which means that a large fraction of bacteria will be transferred from a site to another site to food, but in many cases, transfer coefficients are low which means that only a very small fraction of bacteria will be transferred, for instance, from a given site to food.

The problem is that this can mean that contamination can become very widespread. Many different foods, for instance, handled on a cutting board can become contaminated at low levels and especially if that product subsequently supports *Listeria* growth, this can be a very serious concern.

To estimate the efficacy of transfers during slicing of food, it's more difficult than to estimate the efficacy of transfers from hard surfaces to food,

but you use basically a similar approach by just reviewing and analyzing the available literature and the data are basically showing the same thing. Transfer coefficients range from less than 1 percent of bacteria being transferred to almost 30 percent of bacteria being transferred at any given time. So we have again very large variability in the efficacy of transfers and high efficiency transfers are possible but in many cases the amount of bacteria transferred seems to be relatively low.

So how effective is cleaning and sanitizing in removing *Listeria* from the environment?

We use the same approach of reviewing and analyzing the available literature. So again this is based on laboratory studies.

What you can see here mean reductions in $\log_{10}$ *Listeria* contamination after treatment with different sanitizing compounds showing 95 percent confidence intervals. The first thing to see that the efficacy differs across compounds and that the confidence intervals are very wide. So from replicate to replicate we see a lot of variability, and we found

a lot of factors that had an impact including exposure, time, temperatures, sanitizer concentration, et cetera.

But what we found that had a tremendous impact was whether the compound was used in a clean or soiled surface. When used on soiled surface always led to lower efficacy.

So what this is telling us, first of all, it is very important of cleaning and sanitization are performed, that they are performed correctly according to label instructions, et cetera, which means among other things, to use them on clean surfaces.

We also see that cleaning and sanitization can be very effective at removing contamination from environmental sites, but especially if these procedures are not performed adequately, the efficacy can be very low.

We also see that there's a lot of variability and we definitely need to account for this if we're ever going to model cleaning and sanitization.

So in conclusion, next slide please, food

contact surface sites are certainly a major concern in retail deli. Even though the probability of contamination is lower than for non-food contact surface sites, we do see that the prevalence can be relatively high, and we have a very high probability of transfer from these sites to food if the site is contaminated.

The amount of bacteria that will be transferred is highly variable. In certain circumstances, it can have high efficiency transfers where very large fractions of bacteria will be transferred, but it seems that in many cases, we only have low efficiency transfers in which case contamination can become very widespread at low levels which can after subsequent growth pose a considerable public health concern.

We also see that we cannot neglect non-contact food surface sites. Even though the probability of bacteria transfer from these sites to food is relatively low, it is not zero, and we have to be worried about things like contamination of hands from non-food contact surfaces that can then

subsequently lead to contamination of food. And we have to be worried about these sites because the prevalence of *Listeria* in these sites is quite high.

Cleaning and sanitization clearly can be very effective at removing environmental contamination of *Listeria* but there are other factors that need to be considered. There's a lot of variability that we need to take into consideration and if you talk about the net efficacy of cleaning and sanitization, we need to take into consideration what the levels of bacteria in the environment are.

The data that I showed you before from the cross-sectional study were just looking at -- data. They did not incorporate enumeration. Dr. Oliver will be presenting new data later this morning that do contain some quantification, but we need to consider that the levels of bacteria at retail are definitely -- at this point.

With this, I would like to thank everybody who contributed to the study. There were a lot of people, a lot of different institutions that contributed, and I would like to acknowledge my

funding sources which are listed on here. Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Dr. Hoelzer.

Our next speaker is Dr. Haley Oliver.

Dr. Oliver is an Assistant Professor at Purdue University's Department of Food Science. Her areas of research include investigating foodborne pathogen transmission in retail food environments and the use of molecular methods to understand how foodborne pathogens survive stress and cause disease.

Welcome, Dr. Oliver.

(Applause.)

DR. OLIVER: Good morning. I'm here to introduce really only Phases 1 and 2 of what we have finally come to know as four phase longitudinal study, and really the hypotheses of this particular study were that *Listeria monocytogenes* does indeed persist on food and non-food contact surfaces in retail delis, and that cross contamination can occur between these surface types.

Our four phase longitudinal study really has been an evolutionary process in its design. Initial

Phases 1 and 2 were initiated under the Food Safety and Inspection Service, Office of Public Health Science, to specifically address some of the data needs in the risk assessment.

So briefly to describe what this study is or what it has become, in the initial phase we did monthly food and non-food contact surface testing for *Listeria monocytogenes* and *Listeria* species in 15 stores, and those stores were represented in three different states, and that was conducted once a month for 3 months.

In Phase 2, we conducted monthly sampling, and this was during operation, daily operation of the deli. We were testing for *Listeria monocytogenes* as well as other *Listeria* species in 30 stores. We increased that number from 5 stores in 3 states to 10 mainly just because we found that we have the laboratory capacity to continue to do so and was done over 6 months time.

I will address mainly the data in Phases 1 and 2 today, but just to comment a little bit on how this study has continued, Phase 3, we engaged

stakeholders through the Food Marketing Institute and the American Meat Institute to develop interventions that could be practically and hopefully successfully implemented in retail delis to control *Listeria monocytogenes* and *Listeria monocytogenes* transfer to food contact surfaces.

So really Phase 3 was simply intervention development and application into these retail delis, and in then Phase 4, we essentially repeated Phase 2, testing both food and non-food contact surfaces for *Listeria monocytogenes* and *Listeria* species once a month for 6 months.

So to jump immediately to results, our pre-operation sampling which we also referred to as Phase 1, we collected 315 samples in 15 delis over 3 months time, and found that 21 of 315 samples were positive for *Listeria monocytogenes*, so 6.7 percent of samples tested were positive.

Also, to note that 2 of those 315 were positive for non-*Listeria monocytogenes, Listeria* species. So, *Listeria innocua* as an example.

This was our first opportunity to quantify

Listeria monocytogenes on these surfaces and these would be quantified as CFUs or number of microorganisms per sponge, and we found that on the surfaces of drains, we were not going into the drain, but on the surface of the drain and the floor, we could have numbers as high as 10^4 *Listeria monocytogenes* cells per sponge. The surface area of that sponge did vary by site, but a typical surface sample for a drain or a floor would have been 10 inches by 10 inches.

As you can see, we have an overrepresentation of non-food contact surfaces in these seven sites that were initially selected in the design of this study, but as you can image, it's a challenging interface to actually be testing for a pathogen. So, testing for *Listeria monocytogenes* in a functioning retail deli. So this is actually in the environment sampling during operation.

And so what we did find, notably on trashcans we found *Listeria monocytogenes* positive as well as one *Listeria* species positive over that three month sampling period.

Not surprising that our non-food contact surfaces were more likely to be positive for *Listeria monocytogenes* where we found, using the example, the floor/wall juncture which was also under the 3 or single basin sink, 8 out of 45 samples tested were positive for *Listeria monocytogenes*.

This was our first insight into persistence, however, of *Listeria monocytogenes* on these contact surfaces. So on the left are the list of sites, the seven sites that were tested over the three month period, indicated by April, May and June. Each of the numbers represents a blinded unique identifier for a store.

So if we look at the floor next to the drain, we found that on that particular site, it was positive for *Listeria monocytogenes* in store 2 in all 3 months. This didn't necessarily mean that it was the exact identical *Listeria monocytogenes* based on molecular subtyping data, but certainly it was our first insight into *Listeria monocytogenes* being routinely recovered from these surfaces and suggesting persistence.

So, really the bulk of the data in this study comes from what we call Phase 2 which is our longitudinal testing of up to 28 sites in 30 stores in 3 different states across the country. There were a total of a little over 4500 samples evaluated for *Listeria monocytogenes* and cumulatively there was 9.4 percent of those samples testing positive for *Listeria monocytogenes* specifically.

Not surprisingly, we did find higher percent positives in non-food contact surfaces, but 4.5 percent of food contact surfaces as defined in this study were positive for *Listeria monocytogenes*. 3.3 percent of what we considered transfer points, for example, the slicer knob or the deli case handle were positive for *Listeria monocytogenes,* and then perhaps a challenging number 14.1 percent of non-food contact surfaces positive for *Listeria monocytogenes*.

And this is the breakdown again as type of food contact surfaces defined in this study, but to highlight some of the challenging contact surfaces at least as I defined it here as a food contact surface, the interior of the single basin sink, we found that

18.3 percent of those samples tested were positive for *Listeria monocytogenes*. If you're not familiar with this surface, it can be used for different purposes, depending on the deli, but it is a stainless steel surface that should be relatively easy to clean and sanitize if it's in good working condition.

Again, the transfer points as we define it in this study, slicer knob, case handle and scale top, an average percent positive of 3.3 percent.

Addressing your attention to the non-food contact surfaces, some of the highlights or some of the more challenging areas as far as *Listeria monocytogenes* is concerned, the floor/wall juncture under the single basin sink is one example, almost 28 percent of samples tested were positive for *Listeria monocytogenes*. Not surprising that drains, floor drains or those areas were positive for *Listeria monocytogenes* but still at numbers that were somewhat surprising, 25 percent and higher in some instances.

We also looked at standing water, if it was present in these delis, finding that, you know, almost 18 percent of those samples were positive for *Listeria*

monocytogenes.

What becomes important to understanding the dynamics of *Listeria monocytogenes* in these environments is looking at them at the by store over time resolution. I'll get to the PFGE data in just a moment, but we have stores where we don't have challenges and we have stores that we have larger challenges, and so this really is a heat map representation of positive samples by major sites, again as defined in this study, over time and by store.

So if you look at store number 1, which would be on the far left by month and segregated by food contact transfer point or non-food contact surface, we really didn't see that many *Listeria monocytogenes* challenges in this store. Only one site was positive for *Listeria monocytogenes* in month 11, and that was on a non-food contact surface.

Perhaps a much more and more obvious challenging store would be store 7, for example, where we found *Listeria monocytogenes* on food contact surfaces over time, and we would find those also on

our non-food contact surfaces. At that point, we knew we needed, and it was anticipated in the design of the study, PFGE, pulsed field gel electrophoresis, DNA fingerprint typing, to know whether or not it was the exact same *Listeria monocytogenes* persisting over time.

All right. Next slide please.

And this is just a continuation really of that data. It's the further 15 stores that were enrolled in the study that were only enrolled in Phase 2, so stores 16 through 20, again showing you examples that we have stores in a variety of situations, stores with limited *Listeria monocytogenes,* some with moderate challenges and some with more significant challenges that we're still trying to really get to the root cause of why this particular environment might support *Listeria monocytogenes* as opposed to another retail deli.

So looking at our 30 stores and focusing on the subtype, again PFGE conclusions, we found that 12 of our 30 stores enrolled in this study really had low *Listeria monocytogenes* prevalence, and we defined that

in the context of this study as less than 4 positive samples or less than 2 percent prevalence.

What we did see, however, were 4 of 30 stores that showed low *Listeria monocytogenes* prevalence with a single high prevalence contamination event. So on the next slide is an example of what that might look like.

So we'll set these out. These are going to be -- it sounds like we have a marching band in the background. It's pretty exciting. I know this data is exciting, but geez.

MR. DiNAPOLI: Folks on the phone, if you could mute your phones. We'll try to speak into the mic and slowly.

DR. OLIVER: I did enjoy the marching band though.

MR. DiNAPOLI: Sorry.

DR. OLIVER: So we will repeat the image of this slide a few times or the set up. So I'll only go through it once, but on the left are the main classes of food contact sites. So food contact, non-food contact and at the bottom, transfer points. And then

on the "X" axis would be times. So each one of the month it was sampled for this particular store. This represents a single store in this study.

So you'll see in the month of August that on such as the slicer, deli case trays, and the countertop, every color represents a single PFGE subtype, and so we found that PFGE fingerprint, everything represented in blue, on all of those sites in that month in that store. Again, this is one cross-section of time. This was one day in August in one store, but you can see that, cleaning and sanitation, in its routine performance in this store, managed *Listeria monocytogenes* after the month of August.

And so just to show you, if you haven't had a chance to look at PFGE data or what those fingerprint bands might look like, there was significant evidence that it was the same strain of *Listeria monocytogenes* being isolated from these surfaces as demonstrated here.

In 14 of the 30 stores, however, they showed evidence for persistence, at least in our preliminary

classification of those, and so I'll show you an example of some of the unique situations that we observed in these stores.

On this slide is *Listeria monocytogenes* persistence on non-food contact surfaces with maybe a sporadic case of a transfer to a food contact surface. So again every color represents a single PFGE pattern or single DNA fingerprint, and you'll notice the abundance of that microorganism when positive and when identified as, of course, I can't see it from here, my eyes I guess they're going, Purdue's winning, that there was a transfer to the single basin sink, for example, one month or a one time event. We sample again in these stores once a month and so this is just one snapshot of time in the month of July where we observed that incident actually occurring.

So this is an example of where we found persistence on non-food contact surfaces with the same subtype found on multiple food contact surfaces. It's also important to note that we only DNA fingerprint a single isolate from positive sample. That would be due to time and cost restrictions that we don't PFGE

subtype multiple isolates from a single sponge, but you can see that we have evidence of potential persistence on both the food contact surface, at least as defined in this study, persistence on food contact surfaces as well as on non-food contact surfaces and an instance where we only have persistence on non-food contact surfaces.

So again, we only look at one single isolate for PFGE typing but this suggests that *Listeria monocytogenes* in this particular store has not transferred from a potential niche on a non-food contact surface to a food contact surface.

Again, this is a particularly challenging event where we have persistence on non-food contact surfaces and possible short-term persistence of a second subtype on food contact surfaces. So, a challenging environment. We have multiple *Listeria monocytogenes* fingerprints existing in these environments with some evidence that there is transmission between our food contact and non-food contact surfaces.

Again, as Dr. Hoelzer mentioned, the

important part of this study is the quantitative side or trying to actually understand how many microorganisms were on a given surface or a given surface area.

We did see occasional high numbers on non-food contact surfaces. As I mentioned in the pre-op study, we found numbers as high by NPN and selectively for *Listeria monocytogenes,* numbers as high as $4X10^4$ CFUs per sponge, and sometimes as high as 10^5. So numbers that were surprising to us but again these are on non-food contact surfaces and a good deal of evidence suggesting that there is preventative measures to control transfer from non-food contact to food contact surfaces.

During operation, we could still see these same numbers on a surface such as the floor/wall juncture under a 3 basin sink where our numbers could be as high as 10^5 CFUs per sponge.

It's important to remember in this study that what we are actually testing for *Listeria monocytogenes* and other *Listeria* species, and so of our 4500 plus samples that we tested, 3,980 were

negative for both *Listeria monocytogenes* and other *Listeria* species.

In 291 of those samples that were positive, they were positive for only *Listeria monocytogenes.* So we did not co-recover another *Listeria* species in addition to *Listeria monocytogenes.*

And 131 samples were positive for both *Listeria monocytogenes* and other *Listeria* species. So, potentially *Listeria innocua*, for example, and 108 where we recovered only *Listeria* species non-*monocytogenes*.

So, really what these data suggest, if you are doing *Listeria* testing, and whether that would be, if you're not testing down to the resolution of species, you really should have a high probability of actually testing for *Listeria monocytogenes.* So focusing on actually testing for *Listeria monocytogenes* in this environment is probably the best way to actually manage the hazard.

So what we've concluded so far looking again, the data focusing here on Phases 1 and 2, that *Listeria* contamination in retail does occur and that

there is a high proportion of *Listeria monocytogenes* found on non-food contact surfaces compared to food contact surfaces, and that finding it on non-food contact surfaces is not uncommon.

We do see a wide variation of *Listeria monocytogenes* prevalence among stores and, of course, that means one of our big objectives is to understand what are the characteristics of those stores or practices in those stores that are either preventing *Listeria monocytogenes* persistence or that are contributing to its persistence, and that's some of the continued work that our laboratory continues to investigate, to understand and to help manage the risk in the most challenging stores.

We do know that *Listeria monocytogenes* does persist widely in this environment, and we could have some stores, up to 35 percent to 40 percent of samples, test positive for *Listeria monocytogenes* but that doesn't necessarily reflect the food contact surface.

And again because we recover *Listeria monocytogenes* in greater proportion compared to other

Listeria species, really at this point we would focus on *Listeria monocytogenes* testing from a management standpoint if testing were warranted in retail.

It's important to remember how many people are actually involved in this study. Phases 1 and 2 were funded by USDA, but the time and energy put in by the American Meat Institute and the Food Marketing Institute by way of intervention and then subsequent testing, really has helped move this study forward. We can have data that say where *Listeria monocytogenes* is, but really at the end of the day we want to be able to manage it or remove it from these environments.

It's really collectively with all those stakeholders involved that are on our way to actually achieving some of those goals.

Ecolab and Neogen also are significantly involved in these studies as we've tried to come up with management tools in these environments that again are effective at controlling this pathogen.

It's also a multi-institutional, from an academic standpoint engagement activity from Cornell,

North Carolina, and Purdue University really that were able to help make this study continue to be possible. Thanks.

(Applause.)

MR. DiNAPOLI: Thank you, Dr. Oliver.

Our next speaker is Dr. Renee Boyer. She is an Associate Professor at Virginia Tech's Department of Food Science and Technology. Her areas of research include investigating methods to remove foodborne pathogens from food and food contact surfaces and pre- and post-harvest interventions to enhance the safety of fresh and fresh cut produce. Welcome.

(Applause.)

DR. BOYER: Thank you very much. I'm going to have to bring the microphone way down, way down.

Okay. So today, thank you very much for having me and allowing me to speak about the study that I will be talking about which involves the cross contamination transfer dynamics at retail, and this was all done as part of a mock deli that we established at Virginia Tech.

So the objective of our study was to

identify any sort of significant cross contamination pathways throughout a retail deli that may occur when contamination is introduced from different sites.

So what we did was we introduced contamination from a variety of different sites separately and then performed deli operations in order to see where that contamination transferred.

We used an antibiotic fluorescent surrogate which we chose to use the Glo Germ lotion, and we did this for a couple of different reasons. One of the reasons that we did this was because it was going to be very difficult to have a space large enough to set up a mock deli within a BSL-2 facility at Virginia Tech, and then even if we were able to do that, it would be difficult for us to identify where to sample, if we were then sampling after some deli operation activities.

So, we chose to use the Glo Germ because then we could use that and then turn the lights off, turn UV lights on to see the fluorescing compounds, and then we could ultimately see where contamination had spread after a series of events.

This study was funded by FSIS in order to provide data for the risk assessment that will be talked about later this afternoon.

And I also want to mention that the results have been published in a peer review journal, in the *Journal of Food Protection*, and the citation is listed up there.

Next slide. Thank you very much.

Okay. So this slide just depicts the layout of the mock deli. Basically what we needed was we needed a space where we could turn the lights off and completely get it to be pitch black. So we didn't have any windows or anything, and so we found an old large walk-in cooler that we used, and then we brought in all of the equipment into the space in order to set up the mock deli.

So you can see if you look at the slide that we have the table up along the back wall and that was a large stainless steel table with one sink, and we sort of used that one sink as being a hand washing sink for the space. The other large table is a three compartment sink, again stainless steel table, that

included a preparation area.

Then we have the large or, sorry, the smaller stainless steel table which housed the deli slicer and that table had a backsplash on it as well. And then you see that we did the deli case, and we had it set up such that, and I don't have a pointer, but such that if you walked into the space, you would be entering the deli case. If you walked in from the left-hand side, you'd be entering the deli case as a customer, you would order your meat chub over the counter, that person could then reach into the case, take it out, slice it, weight it, and then hand it back over the counter.

Along the perimeter of the space there are one, two, three, four black lights -- oh, okay. I get a pointer. Oh, good. Okay. Thank you. So there's one here, one here, one here and one here, and those are large four-foot long black lights that we had mounted on the walls, and then we also had two free standing black lights right here and right here, that were sort of mounted and hanging so that we could get a good illumination of the floor, and there were two

floor drains. There was one floor drain there and one floor drain there.

I'm going to show this slide again a little bit later in my talk, and we'll actually show you where some of the spread moved throughout the deli.

Next slide.

Okay. So in each experimental trial, what we did was we contaminated one of six locations and then we went through a series of standard deli operations, and it was about 10 minutes worth of work. So we had an individual come in and work as if they were working in a retail deli.

After we did that 10 minutes worth of work, we turned off all the lights, turned the black lights on and witnessed where the contamination had spread, took photographs of all of the contaminated sites and then we used a sensory panel, a trained sensory panel to quantify the level of contamination that we then saw.

So the sites that we started with included the deli slicer blade, the floor drain, the surface of the deli meat chub, an employee's bare hands, an

employee's gloved hands and then the preparation table surface.

Next slide. Thank you.

And so here's the slide to depict the deli operations that we performed and these operations were taken from the study that you're going to hear about next from the Lubran study, where she conducted some observational work and came up with a series of actions that commonly occurred.

So basically what we started with was our initial site inoculation. Then we washed hands, put on new gloves, opened the case, removed the chub, closed the case, unwrapped the chub, sliced, weighed on the scale, rewrapped the chub, opened the case and replaced the chub and closed the case, and then we threw out old gloves and replaced them with new gloves.

So we went through that series several times, and then we went through some other operations where we walked to the back of the storage room, brought a cart out from the storage room or from a freezer, and then we went through and did some more of

the same series of actions before then returning the cart to storage. So we went through all of these for about 10 minutes worth of action.

Next slide.

So to continue on with the materials and methods, we used a trained sensory panel to quantify the presence and level of contamination that was witnessed on the photographs that we took. So after doing some troubleshooting, we realized that we really needed to get a rating or a ranking for coverage, and that would be the total area. So if we saw that there was an area that was contaminated, we would want to rank the coverage of that area, and then we would also want to rank the intensity of that area because in some instances, there was more contamination in smaller areas than widespread coverage.

So once we got the panel to evaluate those and rank those, and I'll talk a little bit more about that in the next slide, we then came up with a ranking. So if someone rated the intensity as slight, but the coverage as moderate, then we ranked that as a slight contamination event, and so we went through

that way.

And I've got a couple of pictures here. This is some bologna slices which for the purpose of this study, we used deli bologna for all of the actions. So you can see here where we may have a slide here or a slice here where we would have a large coverage, that might be heavy coverage and also heavy intensity, whereas something over here might be more moderate coverage and heavy intensity. So, just to give you all kind of a depiction of some of the images that we were looking at through this study.

Next slide.

Okay. And this is a picture of what a panelist, what one of our sensory panelists would have seen. So when they came in to evaluate the contamination, they would have looked at clean surface to give them a baseline of what that surface would look like with nothing on it, and then they would then look at what the experimental data that we collected looked like.

Okay. So, for example, in this slide, we have the clean slide, and then we had our sensory

panel review it and eight of the panelists ranked that 460, that number as having heavy contamination.

So, as I mentioned before, the panelists were asked to rank the contaminated surface compared to the clean surface which I just showed you, and then they were also asked to rank controls. So, we set up a lot of controls to make sure that the experimental data that we received from them was actually accurate. So, we had controls that included the initial inoculum levels, the surfaces after cleaning, and then we also used duplicate photos to ensure that we got similar results depending on the photo that they were looking at.

So, the sensory panel then gave us a one word ranking and that was either slight, moderate or heavy -- none, slight, moderate or heavy, excuse me. And then what we did was we converted those rankings into numbers. So, none was 0, slight was 1, moderate was 2, and heavy was 3.

And then we averaged them all and came up with a mean contamination score and then we translated that back, and that was in order to run statistical

analysis, and then we translated it back to a descriptive value where we rounded up whatever that average number was. If it was, for example, 2.75, we rounded that up to having a descriptive value of heavy, and if it was 2.25, we rounded that down to having a descriptive value of moderate.

And when I show you the results, you'll see both the descriptive as well as the numerical number.

Next slide.

Okay. So this is the first slide that I'm going to show you, and I'll get you a little familiar with it. So what we have along the top here was the source of contamination. So, where did we initially start the contamination out for that site, and then along the left-hand side, you'll where the recipient, what site was the recipient of the contamination following all of the actions.

So, if we started with the floor drain, gloves, blade, meat chub, prep table, hands, for example, we then had locations that received contamination, including floor drain, gloves, blade, meat chub, prep table and then door handle. That was

one of the large ones that we identified as continually becoming contaminated throughout our operations.

And then also just to set you up with the slide again, so if we have gloves here, and gloves were the recipient of contamination, we have here a heavy because we started out with something that was contaminated and we ended with something that was contaminated, so just to set you up with that.

So, if you go down this diagonal here, you'll see that this was where, for example, blade started and blade ended, and there was a heavy contamination.

So, I'm not really going to talk about those sites. I'm mainly going to talk about the sites where we identified new heavy or new moderate contamination.

So, for example, for the floor drain, there was no transfer throughout any of the activities of contamination to the floor drain. Now with the gloves, if you look at the gloves becoming the recipient of contamination, we found that gloves became contaminated from prep table and from hands.

So if someone had contaminated hands, didn't wash them, and then put gloves on, they then contaminated the surface of the gloves, for example.

Some other things I wanted to mention here include the fact that if the source of contamination was gloves, we had meat chub was heavy, and then moderate contamination onto -- I'm sorry, sorry, gloves and then door handle was heavy. Sorry. I got confused what I was doing.

So if the source of contamination was gloves, we had heavy contamination to meat chub, prep table and door handle.

And really the gloves were the primary transfer of contamination where we saw the most contamination spread.

Next slide.

So here's a slide that depicts the contamination spread from the floor. So when we started with the contamination on the floor drain, we saw little to no contamination spread anywhere else throughout the deli with the exception of across the floor.

So we broke the floor into panels and we actually took pictures of where the contamination had spread on the floor and ranked those as well. So if there was one diamond, then that contamination would be slight. If there was two diamonds, then that contamination would be moderate.

So basically for these activities, someone would have been walking around in a space, had a cart and moved the cart throughout the space as well. So that just sort of shows how the initial -- most of the contamination still remained around the floor drain, but it did spread to other areas throughout the deli.

Next slide.

So I showed you all of the locations that we ranked, and there were some additional locations that we saw that varied from experimental trial to experimental trial. So we didn't rank some of the more sporadic contamination that we saw. We only ranked the things that we saw consistently.

And again, I'll set you up. The source of contamination here, floor drain, gloves, blade, meat chub, prep table, hands, and then we've got the

recipient of contamination.

So some of the other key areas that we saw where contamination was transferred to include the hand washing sink faucet knows, the top of the glove box, and by glove box, I mean, you know, when you're taking the gloves out to change the gloves, the cart handles, the scale face, the surface of the interior deli case shelf, bottom of the prep table sink near the drain, slicer table near the slicer, and then also the bottom of the employee's shoes and the cart wheels.

And so when the source of contamination was the floor drain, the only chance for contamination that we saw again was along the floor, and we saw a transfer of contamination to the employee's shoes and then also to the cart wheels as the cart, you know, moved throughout the space.

For the source of contamination for the gloves, obviously we saw contamination to all things that the gloves would have touched, hand washing sink, top of glove box, cart handles, scale face, those sorts of things, and so again when we looked at some

of the more incidental locations that we saw contaminated, it was primarily the gloves that was transferring that contamination throughout that space.

Next slide.

We also looked at the transfer of contamination to meat slices from each of those spaces. So what we did was when we sliced the chub, we sliced the third and then the ninth slice, and we had our sensory panel evaluate those slides.

So here again if we see the floor drain, we have no contamination transferred to the meat chub, but if we have gloves, we did have moderate contamination transferred to the third slice, but then it reduced as it went to the ninth slide.

If the blade started out as the contamination source, we always had heavy contamination on the meat chub. Now we didn't continue to slice it. We only sliced the first, you know, nine slices. So, you know, I don't know if that would have reduced in contamination as you went through the entire chub.

And when the meat chub started out as the

contamination site, again we have heavy contamination but then that contamination reduced as you moved through the chub and there wasn't as much contamination.

Next slide please.

The other location that we evaluated specifically was the slicer and the different components of the slicer. So again we're looking at the same type of table with the source of contamination along the top, and then recipient of contamination along the left-hand side where we broke the slicer apart and evaluated the blade, the bed of the slicer, the shelf, the handle and the carriage of the slicer separately and here's just an image to show you what we stated all those things would be.

So again if the floor drain started out as a source of contamination, there was no contamination transferred to the slicer.

However, when the gloves started out as the contamination site, we saw that the handle and the carriage had heavy contamination, as well as when the meat chub started out, we had heavy contamination

transferred to shelf and handle and also when the prep table started out as the initial contamination site.

I know it's a lot of data and it might be a little confusing to read up here on the slide as I go through it. So I certainly would suggest if you wanted more information to go to the publication that we had.

Okay. So in conclusion, we saw that the six originating sites were also generally the six that became most commonly contaminated from other surfaces. However, again as I mentioned, there was no contamination seen spread to the floor. We did see significant contamination spread to the deli case door handle, and again as I mentioned previously, the majority of the spread we saw came from contaminated gloves.

And then I just wanted to mention a little bit about some of the future research that we've done is where we're actually taking some of the components of the mock deli where we did the Glo Germ work and we're moving that into a BSL-2 lab, and we're actually running -- we're co-inoculating with *Listeria*

monocytogenes and *Listeria innocua* currently to try and quantify that a little bit better as far as real time what the pathogen would actually act like.

Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Renee.

Our next speaker is Dr. Régis Pouillot.

Dr. Pouillot is a visiting scientist at FDA's Center for Food Safety and Applied Nutrition. He provides expert scientific and technical support in the development of quantitative risk assessments for the Division of Risk Assessment's Office of Analytics and Outreach. Welcome, Doctor.

(Applause.)

DR. POUILOTT: Actually, I'm doing this talk in the name of Meryl Silverman who is currently with FSIS -- and I will present the studies that she did when she was in the University of Maryland, the studies she did for the Joint Institute for Food Safety and Applied Nutrition, and that was an observational study of food practices in retail deli departments.

Several studies have assessed food employees' behavior in food service settings, but very few have taken place in deli department, at least when we started working on this project.

In the study, in the literature, various methods were used. Some included self-reports in which employees report past or future behavior on what they did when they faced some particular situation.

Other study designs were observational study in which actions were recorded as they occurred.

Next slide please.

I provide two examples of these two methods. So, for example, in 2005, Green and collaborators used a telephone survey and they asked food workers their behavior facing some specific situations, notably regarding the recommendation from the Food Code.

They found that most of the food workers reported that they washed their hands between touching raw meat or poultry and ready-to-eat food, but a significant proportion of them didn't change their glove or wash their hands in this situation, and that was reported to the facts.

Another study design that can be used is an observational study, and that's what was used by the FDA for their report on foodborne illness risk factors in 2004 and 2009. In this study, they observed employees during 90 minutes and recorded specific behavior regarding the Food Code and they classified the behaviors either in or out of compliance regarding to the Food Code.

So, for example, in this slide, you can see that they observed about 23 percent of the observation were out of compliance for the personal hygiene or the avoidance of cross contamination.

In order to build our risk assessment model of *Listeria monocytogenes* in deli department, we had to specific data gaps. We knew that we had to consider the food worker and the various objects that were in this environment just like deli foods case or sink, but we had no real data on the specific interaction between all these objects and all the details and essentially how all these retail deli departments was working. So we needed a very specific method to evaluate all these details.

Actually in 2004, Clayton and Griffith used a very clever study and very clever methods. They transferred this method from the study of -- in sports and in football, and this method was noted as Notational Analysis, and this method allowed them to track for cross contamination in catering establishments in South Wales.

And the basis is to record action related to al the various facts, all the different movements that are done by the food worker to record that systematically and then to analyze this data later on.

So the objectives, the primary objectives of this study, was to identify the realistic range of frequency and sequence of contact between the food worker and any object and the considered produce in deli department. The frequency and sequence of objects were needed to be used in the *Listeria monocytogenes* in the retail delicatessens model.

Next slide.

We had secondary objectives, too. These were to identify routine cleaning, storage and preparation practices in deli operations as we as

average daily and weekly throughputs.

And the next objective was also to develop and validate this notational analysis.

The participants were nine retail facilities which sell deli meat, cheese and deli-type salads and they were selected based on the various criteria. They were all situated in Maryland and Virginia and the D.C.-Virginia area. And we had six chain stores and three independent retail stores.

I will introduce this Notational Analysis method. This is a two-step method. It consists first of the development of a coding scheme. This method was developed based on common food preparation behaviors and the Food Code requirements.

So for all object of the deli departments and all kind o foods, we developed a kind of code, for example, you have here DIS for the dish, SCL for the scale, FRT for the fruits. So we had all this kind of coding scheme. Also a coding scheme for all the action, food on, food off, remove, wash and so on, and we tested this coding scheme in a pilot test in one retail deli department before doing the actual

observation.

So once in the deli department, an observed watched a food worker and recorded each of his actions during a certain period of time. The food worker, of course, agreed to participate, and we first observed the food worker during 15 minutes without any records, just to give him the time to acclimate to our presence. And actually we did this observation during rush time. So they forget very quickly that we were here.

So, for example, in this situation, at 10:00 a.m., the food worker washed his hands, he put on gloves, he opened the case, he pick up the salami, he closed the case, he put the salami on slicer number 3 and he sliced the salami onto his gloves. So this is the kind of findings that we did and we ended with a pile of these sheets where we actually noted every action that the food worker did to serve the customer.

We were also able to put some additional notes, for example, here he washed his hands without soap. So the washing action was needed, was required, but it was just considered as attempted and not done

adequately. That was for the -- that's for the results.

So we accept 25 employees in chain store, 8 employees in individual store, for total time of 885 minutes in chain store and 266 minutes in independent store. We recorded thousands of actions.

Okay. The first striking result was that a very, very regular sequence of actions were required to serve a customer. So in most of the case, I would say about 80, 85 percent of the cases, the sequence was regularly like that. So the food worker wash his hands, put on the gloves, opened the case, pick up the product, close the case, put the product on the slicer, slice the product directly on his gloves, put the product on the deli tissue, put the deli tissue on the scale to weigh it, wrap the product, give it to the customer, pick up the chub again, open the case, put the product in the case and close the case.

So this is the kind of sequence of actions that we noted, and it's very important because this is the core of our model. Most of the servings that we are doing use this sequence of actions.

Interestingly, we were also able to identify some alternatives to this sequence of actions. As an example, here you can see that from time to time, of course, the food worker has to open a new chub, and we observed that he might open this chub either on the food contact surface, he could open the chub over the sink, but we also observed food workers open the chub over a trashcan and even one food worker that opened the chub with the slicer, cutting the plastic with the slicer. So this is the kind of alternatives that we were also able to identify and to quantify, and we put this kind of separate alternatives in the model.

Next slide.

So our first objective to be able to build a sequence of actions for this retail deli model was completed.

We also get some very interesting information on hand washing. So as you will note, the FDA Food Code provide some recommendation on when to wash hands, and the food worker should wash his hands, for example, when he touch bare body surface or where he touch soiled equipment. So here I reproduced the

part of the Food Code that provides these recommendations.

So once we have our sheets of observation, we were able at the lab to check when this hand washing was required, when they were performed and if they were performed adequately. So you can see here that most of the time, before donning gloves, the food worker washed their hands. After touching body, they touched their hands in 50 percent of the time but you can see here that after handling soiled equipment as defined by the Food Code, we observed 295 times that the hand washing was required and it was never performed in this situation.

If we get further into details, we can see that the food worker frequently touched the deli case handle and the scale and never washed their hands after that.

So this analysis allowed us to evaluate a hand-washing benchmark, that is the number of times that the food worker should wash his hands within this current sequence of tasks. So we reached a very high number of 30 times per hour. That means that the food

worker with the sequence of events should have washed his hands 30 times per hour.

So it's very important here to understand that it doesn't mean that the Food Code recommends that the food worker wash their hands 30 times an hour, but it means that with the current sequence of events, they would have required 30 hand washings to be in compliance with the Food Code. And actually an effective reconfiguration of job duties or an effective sequencing of the work tasks would have reduced dramatically this benchmark.

Actually in our observation, most of these hand washings were needed just because the food workers sliced the product directly on the gloves rather than on the deli tissue. So the hand washing was needed because of this unneeded contact between the gloves and the food. So should they have used the deli tissue, then the washing benchmark would have been dramatically reduced.

The protocol was also able to evaluate the frequency of cleaning and sanitation actions that were needed, that were required but because of the short

period of time of observation, this was less -- with these settings, but we eventually conclude that each time that the food contact surface needed to be washed, it was washed and this action was performed adequately.

Moreover, we observed that there were lots of additional cleaning and sanitation actions that were engaged by the food worker that were not needed. We found, for example, that in 100 observations, there were -- attempted food contact surface cleaning actions that were started even if it was not really adequate.

If we get further into detail, we can see that the food worker keep on wiping the slicer whenever they serve a customer, whenever they try a new product, they wipe the slicer. So that leads to very frequent action of cleaning even if this is not adequate because it's not a complete washing and disinfection, but just a wiping. In the model, we considered this wiping action, and we have a lot of wiping actions, wiping of the slicer.

So as conclusions, notational analysis

enabled us to record and identify all the common sequences of actions, as well as deviations that we needed to build our risk assessment model.

Next slide.

So this is a slide that I will introduce more in the next talk. This is the actual core of the deli model, risk assessment model, and you can see on the right, the different sites, the utensils, the slicers, the food contact surfaces, the scales and so on.

You have on the right the products, incoming products, on the top, the products that are sold, and at the bottom, the food worker, and each of the arrows show a contact between one object to the other, and these are the contact that are currently modeled in the risk assessment model. And all these contacts, all these arrows were derived from this observational study.

You can notice, for example, that we have no arrow from the floor to the food worker or to any kind of food, because during this observational study, we didn't find any interaction between the floor and any

kind of other sites.

The second set of conclusions concern the results that demonstrated that food employees engage in a large amount of contact between objects, gloved hands and ready-to-eat food, and this highlighted a potential risk of cross contamination if one of these products or one of these sites was contaminated.

To be understand the variability in actions, we would set up a larger study but this study allowed us to really build the core of our model and because of the very, very regular sequence of actions that are done by food workers when they serve customers, we were able to build the core for our model from this observational study.

Okay. So you'll find all the details from this study in this paper from *Journal of Food Protection.* It was published in 2010 with Meryl Lubran as the first author, and I would first like to thank her because she did almost all of the work for this observational study, and this study was supported by the Joint Institute for Food Safety and Applied Nutrition, the University of Maryland, and the ORISE

Fellow Programs.

We'd like to thank the Food Marketing Institute for the help in the selection of the retails and Caren Kieswetter from FDA's CFSAN for her work with the IRB. Thank you very much.

(Applause.)

MR. DiNAPOLI: Thank you, Doctor.

We're going to take this time to give you an opportunity to ask some questions. There are some -- do we have hand mics. There is that mic back there.

MR. O'NEILL: Just a question about clarification. When visiting the independent retailer types, could anyone elaborate on the types of retailers that they were visiting? Were they typical full-service delis? Were they -- did they include things like cheese shops, any elaboration on that would be helpful. Thank you.

DR. OLIVER: So to address the question of types of delis that were used in the longitudinal study, they were all large retail stores that would have had -- I think almost every one of them had prepared foods also or close to or -- well, let me

think, let me clarify it, that two-thirds of the delis had prepared foods in the environment as well. So they were a large footprint, large retail type store.

DR. POUILLOT: The observational study, these were from small independent stores with a deli department inside the store, a kind of mom and pop deli that were present in Virginia and Maryland. Yes, we had three independent stores and six larger chain stores.

MS. KLEIN: Hi, I just have a couple of quick questions about the Virginia Tech study. First, I'm wondering if you could tell us a little bit more about the difference in the spread of contamination between gloved hands and bare hands or whether -- if you could just kind of unpack that a little bit.

And then the second question is who staffed the deli? Was it a scientist or actual deli employees that you brought in to staff the mock deli?

DR. BOYER: Okay. Sure, I can answer those. For the barehanded study, what we did was we applied the Glo Germ to the bare hands and then put gloves on. So we didn't actually do anything with bare hands in

the space. We then put gloves on to see where, if you started out with contaminated hands without washing your hands, where that transfer may occur once you put the gloves on.

And then the folks that staff the deli were Virginia Tech researchers but they had been trained by deli employees.

UNIDENTIFIED SPEAKER: Don't go too far. I've got a question. My question has to do with you, in your deli, you showed the actions. Did you also do a mock up of sanitation? I know there would be inherent challenges in cleaning such an environment, but I'm curious if you, based on our experience in the processing side, that if you're cleaning drains and how that impacted that? Did you rate that?

DR. BOYER: Right, we went into the study with a plan of including a sanitation component to it, but we had a lot of trouble with removing the Glo Germ adequately enough to where, you know, it just really wouldn't be correlated to a pathogen necessarily. So we felt that that just didn't link up very well. So we didn't end up doing the full portion of that study.

Oh, the other question was about the drains. We didn't do any cleaning of the drains. So certainly I understand that that could be a pathway of contamination as well. We did not do that.

UNIDENTIFIED SPEAKER: Hi. This question pertains to the observational study relating to the slicer. You know, you mentioned, I think we heard that, you know, there were frequent wipe downs between every slicing incident. Were wash clothes disposable, non-disposable at play? And what was the tracking action after wiping down the slicer, disposal or, you know, it's just something if you could elaborate on. Thank you.

DR. POUILLOT: So your question was about additional action when they wipe the slicer. We didn't observe the complete washing and disinfection of the slicer during this observational study, and we just chose this kind of action, really quick action of wiping down the slicer, but that's all what we observed in this observational study.

MR. DiNAPOLI: I'm going to ask that you go ahead and identify yourself and who you are affiliated

with before you ask a question. Please go ahead.

MS. ECHOLS: My name is Marsha Echols. I'm an attorney here in Washington. My question is about the relationship between some of your observations especially concerning sanitation and the Food Code.

So several of the points that you're saying employees did not do, sanitation steps or other measures are covered already by the Food Code. So it sounds as if you're saying employees aren't complying with rules that already are in place and how does that figure into your analysis?

DR. POUILLOT: You might want to refer to the paper, but we really checked whether or not the food worker was compliant with the current Food Codes, and what I presented today was really noncompliance to the Food Code.

MS. ECHOLS: And how does that affect the results of your analysis? I mean there are already rules there.

DR. POUILLOT: For the general model or just this observation?

MS. ECHOLS: This observation.

DR. POUILLOT: Here we just noted and counted the number of times it was compliant or not compliant.

MS. ECHOLS: All right. Thank you.

DR. POUILLOT: But it didn't change anything.

MR. RAPPIER: Good morning. Thank you for the very good presentations.

MR. DiNAPOLI: Can you -- I'm sorry. Can you --

MR. FRAPPIER: Bob Frappier with Ahold USA.

MR. DiNAPOLI: Thank you.

MR. FRAPPIER: My question has to do with determining whether an observation was compliant or not compliant. As I look at the data, especially with the wiping, if a program would be washing slicers, sanitizing, per the Food Code, every four hours, and then they would be doing an activity in between to remove soil using a sanitizing cloth, whether it be in a sanitizing solution or let's say using a wiping cloth that would be disposed of, how would that be observed as being ineffective? Because it looked like

many of the observations on wiping were ruled as ineffective.

DR. POUILLOT: There was a misunderstanding. I talk about the compliance with the Food Code regarding to hand washing. The fact that they wiped the slicer, we don't consider that as being out of compliance of the Food Code. It's just additional actions, sanitizing and washing actions that were done completely independently of the Food Code. So we didn't consider that as being out of compliance, just additional actions and we noted that there were some additional actions, cleaning and sanitation actions.

MR. FRAPPIER: So they weren't described as ineffective then if somebody wiped the slicer down?

DR. POUILLOT: We don't say that it's --

MR. FRAPPIER: Okay.

DR. POUILLOT: -- ineffective. We just say that it's not considered in the Food Code as a recommendation.

MR. FRAPPIER: Okay. Thank you.

MR. DiNAPOLI: Any other questions for our morning panelists? Janell, I think you're going to

get off the hook and, Sherri, I think you're going to get off the hook, too. Go to lunch without any questions.

If there's no more questions, I believe -- let's meet back here at 10 to 1:00, if that's good with everybody. 12:50, right here. Thank you very much. I appreciate it.

(Applause.)

(Whereupon, at 11:40 a.m., a lunch recess was taken.)

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

(12:53 p.m.)

MR. DiNAPOLI: Okay. Thank you all for coming back. We're going to get started in a few minutes.

Thank you all for coming back. We're going to get started. I'm going to ask Dr. Pouillot to come back and give another presentation.

(Applause.)

DR. POUILLOT: Thank you very much. I'd like first to do a small precision on my previous talk, where I said that the wiping actions were inadequate for our observational study, and I wanted to make the precision that these wiping actions are not required by the Food Code. So I shouldn't have used the word inadequate. What I meant is if it had been considered by the food worker as a complete washing and sanitation of the slicer, that could have been inadequate, but they are not considered, of course, by the food worker as a complete sanitation action.

Okay. That being said, this afternoon I

will introduce the designs and data sources and modeling approach and the verification of this interagency *Listeria monocytogenes* in retail delicatessens risk assessment model, and I will do that before Part 2, where Dan Gallagher from the Virginia Tech will introduce the results of this risk assessment.

So I'll start with a brief recall of the objectives of the model. So the study have shown that the prevalence and the level of contamination of products that were sliced at retail were higher compared to those sliced by the manufacturer.

Our major hypothesis was at retail, we have additional cross contamination and maybe temperature abuse that will lead to an increase in the contamination level.

So we were charged to evaluate what were the key processes that lead to additional *Listeria monocytogenes* contamination at retail, and more importantly, we had to see how much this relative risk per serving could be reduced according to specific risk management options, and for that, we developed a

model that we call the virtual deli model.

So as I said, I will start by the design of the model. So here is our retail deli area. So we have some food, meat, cheese and deli salads. We have food workers, various sites, slicers, cases, food contact surfaces, non-food contact surfaces and utensils that have potential niche.

And in this environment, *Listeria* may be introduced. It may die. It may be washed. It may grow. It may be transferred, and we have to evaluate all the various patterns followed by this potential *Listeria* in this dynamic environment.

So we designed what is called a discrete event model. So I take a basic example of how model behave when the food workers have customer. So I introduce you these sites before. So the sites are on the right. The products, the incoming products on the left, the products that are sold on the top and at the bottom, you have the food worker and his gloves.

So, for example, the food worker might start by wiping the slicer and for us in the model, this would correspond to remove or at least reduction of

the number of bacteria that were present on the slicer, if any.

After that, he would wash his hands and change his gloves. So that, in our model, corresponds to a reduction of the number of bacteria present on the hands of the food worker, and we would have no bacteria on the gloves because they are new gloves.

Then the food worker will open the case, remove the chub, and close the case. That could considered in our model as a potential cross contamination between gloves and the case. So if ever there was some bacteria on the case, it might be transferred to the gloves during that step.

Here is the most complex or basic process of the model. This is when the food worker slices the product on his gloves as was observed during the observational study, and we can see that we have complex interaction here between the slicer, the incoming product, the product that is sold and the food worker. So if ever we had some bacteria in these settings, either on the incoming products, on the slicer or on the gloves, there might be a transfer of

the bacteria from one object to the other.

Then the food worker would touch the scale and similarly we would have a potential cross contamination between gloves and scale.

You could rewrap the chub and here you would have contact between the product and the food contact surface and the potential cross contamination.

And you would open the case, replace the chub and close the case, and that would lead to a potential cross contamination.

We also have to consider in this model the growth of bacteria. So we monitor bacteria growth on products, and we currently don't consider any bacteria growth on the sites because of gap of data.

I introduced this previous slide. These are all the various cross contaminations of various contact that we have between all the various objects of our virtual deli. For example, you can see that the gloves are, of course, a major actor of this transfer that can touch the utensils, the slicer, the food contact surface, the scales, the cases, the sinks and so on.

So the model mimics an operating deli and leads to a collection of products sold to the consumers amongst which some of them are contaminated with *Listeria monocytogenes*. So from the contamination of product when sold, we consider then the potential growth that can occur during home storage, and we know that this have a big impact on the predicted risk of listeriosis. We consider the serving size and with the dose response model, the dose of bacteria that is ingested to the probability of getting an invasive listeriosis.

Okay. I'll get to the data sources. So this is a slide that Sherri showed this morning, and all these studies were introduced and the results were introduced. So I won't spend a lot of time on this one.

I will just show you how we interpret the data and translate that in the model. This is the basic observation of sequence of actions to serve a customer as observed in the study by Meryl Lubran, and in the model, those that are directly translated as process and you can see here the basic process,

bacteria inactivation, cross contamination, partitioning and all the various objects that are involved in the different set of actions, so a direct transfer of data to the model.

We used additional data, additional model. So we have also a growth model. It's a growth model that was published in 2009, and this growth model considered the presence of growth inhibitors. It also considered, of course, temperature, pH water activity, and this was important for the model because you have more and more product that incorporates growth inhibitors in them. So we have to consider this impact of growth inhibitors in the growth of *Listeria*.

We have also some data on temperature in deli case, time and temperature during transport at home and this was study performed by EcoSure in 2007, a study that was founded by FDA. We had the consumption data that came from what we eat in America from USDA. It's based on the NHANES study from 1999 to 2006. And we had the dose response model. It's a very classical dose response model that was developed by FAO and WHO in 2004.

As for the implementation, so Sherri talked about it this morning. It was a technical challenge because you have to understand that it's a discrete event model. We have to simulate working deli department, but most of the time there are no or few bacteria in the system. So we model a lot of zeros.

And this lead to a process of slow convergence meaning that we need a large number of servings to get some robust statistics.

So then we introduce you the results and each number I will show you correspond to 100 stores that are serving 1 million servings. And currently we have 126 scenarios. So a lot of servings, of virtual servings.

So as Sherri said this morning, we have the opportunity to be able to work on the high performing computer and everything is coded in a language called R, and the code is available from the FDA or the FSIS websites on request.

Thank you. I'll go to the modeling approach. So we still have some data gaps, and we'll have some data gaps that we'll probably have for a

long time. For example, as for the sources of *Listeria monocytogenes*, we know that have basically the following studies from Cornell about the frequency of contamination of non-food contact surface. Nevertheless, we will need a better quantification of the relative contribution of the incoming food compared to the environment.

Similarly, for the transfer event, following the study made at Virginia Tech with the mock deli or even the data from Cornell, we have a better qualification on the non-food contact surface interaction. We know the qualitative impact of drains, the impact of *Listeria* in sinks but for this model we would need a better quantification, for example, with the frequency of occurrence of transfer in deli setting, transfer from the drain to the food contact surface. We would also need the number of bacteria transferred per transfer.

Same thing for niches where we have sporadic data, but if ever we know that there's a niche in the deli department, we don't know the frequency of transfer from this niche to the food contact surface

or the number of bacteria itself transferred. So these are long-term data gaps.

So we define modeling approach that let us make some conclusion under risk mitigation scenario despite these long-term data gaps. Their approach was to define some baseline conditions. Let's say that we have regular environment contamination that occur in the store, in the given baseline. In the second baseline we would say that the store has no environmental contamination that occur in the store, and we will run all the values mitigation scenario within the different baseline conditions.

So that's what we did, and we developed six baseline conditions. They are provided here, and it's important because then we will provide a lot of slides and graph with these baseline conditions.

So our first baseline condition is a set of stores with regular *Listeria* transfer from the environment or from niche and, for example, we decided here that we used the transfer of 100 bacteria weekly on average on various food contact surface, and this will be used as a baseline condition for store with

environmental transfer.

Our second baseline considers that there's no environmental transfer and so all the incoming bacteria come from incoming products. Some of the products are contaminated obviously, and we don't have additional bacteria in the system from the environment but only bacteria from the product.

The baseline 3 and 4 are very interesting because we consider that they are stores without transfer from the environment but for some reason or another, we have a highly contaminated incoming product. So an incoming product that is highly contaminated that enters the deli department regularly. And in the baseline number 3, this incoming highly contaminated product support growth and in the number 4, it does not support growth, so that we have to evaluate the impact of the incoming growth chub, whether or not it supports the growth of bacteria.

Our fifth baseline condition is a baseline condition where we consider that the store don't have any regular transfer from the environment and they are

all compliant with the Food Code temperature control. So this would be the lowest level of contamination, and a good compliance to the temperature, and this baseline condition was developed to try to better evaluate the impact of the temperature in this setting.

Lastly we evaluate the sixth baseline condition with niche and temperature control. So we have some niche, some regular transfer, but we have a temperature control.

So these are the six baselines that we developed, and then within each of these six baseline conditions, we evaluate all the basic what if scenarios, the risk mitigation scenarios.

So the model currently answers to the question, given that there's a niche in the retail deli, what are the best mitigation strategies, but it does not answer to the question, what is the probability that there's a niche in the store because this is a long-term data gap.

Okay. So to sum up, we'll be able to evaluate all the impact of the risk mitigation in the

various sets of stores, and we will be able to see if one risk management scenario would have an impact in increasing the risk for all different set of baseline or would have various impact according to the baseline.

So now we are at the risk management question. We have a large number of risk management questions, and we have to translate them in the model.

So this is where all the flexibility of the discrete event model helped us a lot, and that's also why we developed this kind of model, is that once you have a virtual deli, you can test all the risk mitigation or risk management questions that you are asked, by just changing a small part of the model.

For example, if the question is what is impact about separating slicers and the counter for growth versus non-growth products, we would have to model more than one slicer in our setting and we would select the slicer to use each time a customer is served based on the product type.

If the question is what is the impact of the use of gloves in the retail environment, we would just

set the probability of wearing gloves to 100 percent.

If the question was what if we consider frequently touched non-food contact surface as food contact surfaces, we would change the classification to food contact surfaces. For example, we would put the scale, at least the pad, as a food contact surface, and we would need additional washing and disinfection for this object.

So that's the flexibility of this model, and that's how we were able to evaluate these 126 scenarios.

So lots of different "what if" scenarios. We classified them in five categories. We have some what if scenarios about sanitation. For example, one where we consider no sanitation, one we consider some non-food contact surface cleaned as food contact surface, one where we considered an increase in the effectiveness of cleaning.

We tested some what if scenario on the worker behavior. This is a worker behavior related scenario. For example, what if the food worker does not use gloves?

What if we avoid all the contact between the glove and the case because in the observational study, we have observed a lot of contact between the glove and the cases and we will be able to check if this has an impact on the risk.

What if we pre-slice the product in the morning? So the food worker would come in the morning and just after washing and disinfection of the slicer, would pre-slice the product in the morning and would just serve them in the afternoon.

What if they did not slice the products on the gloves?

We have some other sets of what if scenarios on growth inhibitor. We tested some scenarios where all products would have some growth inhibitors and other one where no product would have some growth inhibitors.

We tested some scenario on cross contamination. What if we separate slicers? What if there's no cross contamination in the retail deli?

And the last set of what if scenarios are linked to storage temperature and we reduced the

temperature as observed from the Cornell longitudinal study and tested "what if" the temperature was always in compliance with FDA Food Code, and we also did a test to put the temperature where no growth could occur.

Okay. So then we'll basically introduce you all these results. I will just leave the podium just to show the results. I will just tackle what we did for the verification of the model. It's not completely feasible to validate this kind of complex model, but we took all the tools we had to check that the model was correct and that it may be used to draw some general conclusions on the behavior of -- and retail delicatessens.

So, for example, we confirmed the correspondence between the frequency of contamination of our objects compared to the ones that were observed during the Cornell longitudinal study and we saw that we were in line, and we were also able to check as Haley showed you this morning, that from time to time you have a path of contamination in the retail that disappear after some washing. So this was very

interesting because we were able to reproduce this kind of behavior. We were also able to reproduce behavior where we had some chronic contamination of much of the non-food contact surface during a long period of time. So that was our first check.

Our second check was that we considered the important source of contamination as observed in the risk mapping and the mock deli study. So we build in part the model but we also checked the -- that the major source of contamination were reproduced from the risk mapping and the mock deli study.

We, of course, and this is an engineering trick, did a control of the mass balance, the fact that all the *Listeria* that come in the system were disappeared, were put out of the system one way or the other, either washed or trashed, sold to the consumer or just died.

And last of all, this is what I show on this graph. We check the correspondence between the simulated bacterial density distribution versus the one that was observed during the NAFSS study.

So on this graph you can see the community

distribution as observed in the NAFSS study in blue, and in red and green, we have the continuous distribution function of what we simulate from the virtual deli. So we can see that we are in line and we are not simulating too high a level of contamination or too low one, but we are in line with what was observed in this study. So we were ready to do this control.

Okay. So that's it for this introduction to the model, and I will leave this podium for the results.

(Applause.)

DR. GALLAGHER: Thank you, Régis. Nice job.

Well, thank you, everybody.

Next slide.

I'd like to go back in time, 4 years ago, when we first had our public meeting on this project, and remember what we were facing at that time. We had two studies, observational studies at retail, that found that the prevalence of retail sliced product was about seven times higher than prepackaged product. What was causing that?

So this is the slide we used 4 years ago as our working hypothesis. If you have an incoming chub that's uncontaminated, okay, it's sliced at a slicer that's uncontaminated, leaving in the customer's hands, it is an uncontaminated sale. That's unusual. That's not unexpected. That's by and large what happens most of the time in the retail delis. There's a lot of zeros as Régis pointed out.

But watch what happens if we get a contaminated chub coming in. Okay. So in this case, the chub is contaminated. There's cross contamination to the slicer. The sale leaving is also contaminated. That's not unusual but now that slicer now has some *Listeria* bacteria cells on it, all right, and they're going to persist for a little while over the next couple of sales.

Next slide.

So even if we go back to an uncontaminated chub, there's no *Lm* on the chub, but it's now put in contact with that slicer. Some of the bacteria transfer from the slicer to the chub, and the sale leaving in the customer's hands has *Lm* on it, and that

can continue for a little while.

So next slide.

All right. So what we're seeing is coming in the store. We don't have a lot of chubs that are contaminated, but leaving the store the prevalence can be higher. So the bacteria are spread across more servings and -- next slide -- some of those servings can grow out, okay, which leads to the risk.

So that's a four-year-old slide, four-year-old graphics. We've now got a computer model with lots of numbers and lots of quantification. Let's look at that same kind of scenario.

So I want to do a tracking of Listeria from retail almost to a listeriosis case in four graphs, but let me show you the first one.

All right. So they're all going to look like this. Remember, each one of these scenario baselines has 100 million servings. What I've done is take a snippet of about 40 of those servings, just to illustrate the point. So the earliest one on the bottom here, I don't know if you can read it, it says cured turkey, and there's no pejorative allegations to

any of the products. I'm just naming them, all right. I can find this for any other products that you want.

But the first customer that comes in is ordering a cured turkey. The next customer coming in is the potato salad without growth inhibitor. So we're down in this portion of it, and then we just work up the list.

Now during this time, one of the chubs was contaminated. My "X" axis is the concentration of *Listeria* on the chub or in the salad, and one chub at this time was contaminated. It happens to be a cured ham. Those are the red dots out there. It was contaminated about a level of 12 CFU/g. So we see what we've got. This is what's in the store, as the customers are coming in and placing their orders. This is what's on the chub to begin with. I see some puzzled faces. Is that roughly okay? You want to try it one more time?

Okay. So we're all coming across as a different customer coming in the store. I know they're hard to read, but what you see over on the left is the product they ordered and then the "X" axis

is how much *Lm* is in that chub as it comes in out of the case.

Next slide.

Exact same graph but I need to fit more on. So the exact same thing that we saw before. Same sequence of sales, one chub contaminated but sold twice.

Next slide.

If you can get these next four slides, you've got a real good understanding of what's happening with cross contamination in the retail deli.

This is the same sales sequence but now we're looking at the number of bacteria in the bag leaving the store in the customer's hands. So not the chub concentration, but what's the customer have.

All right. The two contaminated chub sales are off in the thousands of CFUs. They're way off scale, 2,000 for the first one, 6,000 for the second one, all right. So as we expected, the contaminated chubs lead to a lot of CFUs.

But, watch what happens on the subsequent sales that are coming off this same product

processing. All right. So see that one at about 80 CFUs. It's an uncured turkey, and then the next one after that, the uncured ham at about 20 CFUs.

Okay. So we get this exponential washing off. It's a really odd way to think about it, but think about it as you're cleaning the slicer which has gotten contaminated by washing it with clean product, with uncontaminated product. So you get the slicer clean, but you've contaminated the product that's then going to leave with the customer. All right. So the risk is going to go up.

So we have this kind of exponential drop off in terms of the number of CFUs leaving with the customers.

Now you might look at that and say, but wait a minute. There's some zeros. There's some things that don't seem to follow that trend. Well, they're further verification of how the model's working. So see that zero right there, it's the one just above the 2,000. That's a zero. Okay. But that's a cheese. That's a Monterey Jack cheese. That wouldn't have been put on the same slicer in this case. So it

didn't get that cross contamination event. The other zero towards the top of the red ones is a potato salad, not involved with the slicer at all.

So what you're seeing is one chub, two sales coming in. So we have two sales that started off contaminated. Leaving in the customers' hands, we've got one, two, three, four, five, six, seven sales that are contaminated with *Listeria*. So we've increased the number of servings that could potentially cause disease from what the original incoming chubs were.

Next slide.

All right. This is the exact same sale sequence but now what we've got is the dose at the time of consumption in terms of total CFUs. And, yes, if there's modelers in there, I'm using an arithmetic scale because I want to highlight that one point. They're not all exact zeros down there. They're just really low numbers. All right.

But of all of those seven sales, in this case, only one of them grew up to be a high enough concentration, high enough dose, that might actually cause disease, all right. The other ones weren't

stored at the wrong temperature, stored for too long. They weren't abused in the customer's house that might have allowed for growth, but the takeaway on this one is that one that's so high, it's not either of the original contaminated chub sales, right. It's not the ones that left the store with thousands of CFUs. It's actually like the fifth highest one, one of the actual low concentrations. Once it got contaminated leaving as it left the store, then it had the potential be abused by the customer and go out to a high enough dose.

Next slide.

Our dose-response model treats the population as two separate populations. There's a susceptible and a non-susceptible population, okay. And there's about a factor of 100 difference between those two in terms of the exposure that would cause disease. So there's red and blue dots over there, and in this one case, that high dose goes to a blue dot, a non-susceptible person. So the percent, the chance that that would cause a disease is about a .02 percent. It would be about a two percent chance if it

was a susceptible one. So this is very unlikely to have actually caused any kind of disease.

But you see the sequence of events now with numbers because we've got 100 million for each one of these baseline situations. We can see how often this process tends to occur.

Next slide.

So let's look at the steps that are required for a listeriosis case to occur. We've got to have a contaminated product at the time of sale. It might be coming because the product was contaminated. It might be because of cross contamination, but at the time of sale, it's leaving the store contaminated.

That product has to be growth supporting. We don't see concentrations that are high enough to cause disease in a store itself. So the growth has to occur out in the consumer home. It's got to be a growth supporting product for that to occur. There has to be some consumer mishandling. It's got to be stored too long at too warm a case to get up to those kinds of high numbers. And then generally it's got to hit a susceptible consumer.

Anything you can do to break that chain will cut down on disease cause from retail sales.

Next slide.

All right. So what we do tend to think is that this retail cross contamination, at least the sporadic cases, not outbreak type cases. The Batt's article has suggested that there's about 44 cases of sporadic listeriosis for each outbreak case. This would explain some of that discrepancy.

Next slide.

All right. Régis talked about the different types of baselines. So I just want to show you the kinds of risks that arose from those different baselines.

So what you have on the "Y" axis here is the mean susceptible population risk per serving times 10^{-7} and what you've got across on the "X" axis are the six different types of baseline stores that we've wanted.

And as you saw from Haley's talk earlier, we see different kind of stores out in the real world, right. There's stores that are fairly clean, where you might occasionally see *Listeria*. There are others

where there's some persistent niches, some persistent environmental contamination, and we're trying to capture that range and for at least five of those, you do see some kind of variation by about a factor of 2 in terms of the risk.

The one that's very, very different is this growth supporting chub. So if you let a chub come into the store that's growth supporting, it's a much, much higher risk than any of those other categories.

One more point I want to make on here. For anything that says a niche, so a niche there, a niche there, or anything that says an incoming chub that's contaminated, we pick certain levels of a niche transfer in a contaminated chub, right. There's nothing magical about those numbers we pick. They're reasonable. They're representative, but we could have picked other numbers. But niche, for example, it's multiple niches at 100 coming in per week. We could have picked 10 per week. We could have picked 1,000 per week. The risk result would be different from there, and we'll some of those in the sensitivity analysis a little bit later.

Next slide.

All right. I am not going to go through this slide, even an academic wouldn't, but this is in your interpretative summary back there, and a lot of the results are incorporated in this table. So I want to make sure you know how to read it, okay.

In this case, that first row all the way across the top is the graph that we just saw. It's the risks for each of the baselines. And then coming down a column, we looked at those 22 different scenarios, potential risk mitigation approaches, to see how effective they might be, and these numbers in here, going down the multiple niche column, are the percent change compared to that absolute risk.

All right. So, for example, that 41.3 in red there means there's a 41 percent increase in the risk if you do this activity over the 1.7 times 10^{7}. Okay. So keep in mind, this table represents 12.6 billion, with a B, servings analyzed here. All right. There's a lot of data getting compressed into one table, but what we're looking for is across the different kinds of stores that might be out there, and

again the deli department does not know which of those six baseline situations it falls under, which activities tend to be good, they're going to show up in green here, which activities tend to be bad, they're going to show in red, and which activities really don't make a difference, they're going to show up in black. And how consistent are they across those stores.

So this one, for example, the no growth inhibitor, is a really bad idea because it always makes things much worse across any kind of baseline store. There's a green one. Here, this green one here, transfers to zero, okay. That's a really good idea if we know how to do it because it always decreases the risk across all baselines, and then there's a few where, let me find one, here, okay, sometimes they're red, sometimes they're green. That means the kind of response depends on what kind of store you're trying that activity in.

Okay. So that's how to read that one. Let's go look at some of the actual questions.

So one of the risk management questions we

had was, how effective is sanitation? All right. Compared to the observed sanitation practices that Régis talked about from Meryl's observational study. So one of the things that we did is, because it's a virtual deli, we can do it, again what Meryl saw was that most people were following the Food Code, cleaning everything well at least every four hours, with lots of additional low level of wiping down things more often. That's our baseline for comparison.

If we stopped all of that, right, and did no sanitation at all, the risks across every single baseline went up sometimes quite substantially. So what we've got on all these next couple of slides, there's a 0, plus 60 to minus 60. Positives mean an increase in risk. Negatives mean a decrease in risks. I've got the six baselines across here.

So this says if we did not do sanitation, no matter what store type it is, the risk goes up sometimes quite a bit.

Okay. The other problem though is we looked at a lot of other different things. What happens if

we clean more effectively? What happens if we clean more often? None of those activities led to a significant reduction in the risk compared to the baseline. So it seems like that activities you're currently seeing are capturing most of the benefits. We don't have a strong recommendation for do additional cleaning because the predicted values here and for listeriosis only clearly, you know, don't seem to buy you any more benefit beyond what you're already doing.

Next slide.

Similar situation, kind of with glove use. Meryl observed that about 65 percent of the time the workers would change gloves between each customer. Okay. So that's our baseline.

If we turn that off, if we said never use gloves, okay, gloves are a removal mechanism, right, if they get some *Listeria*, when they take the glove off and throw it in the trash, that's removing it from the food chain. So it's not cross contaminating from there any further. If we stopped that, we say never wear gloves, again for all of the situations the risk

gets worse, not as dramatic as for the sanitation, in a few cases it's not significant, but it clearly is getting worse. So we want to ensure that they're using gloves.

But, on the other hand, if we drive it up to 100 percent, okay, there there's no difference from our baselines. We're not getting any additional benefit from going from 65 to 100. We've already captured a lot of that benefit already. Now there might be other organisms, there might be other diseases. This is only for listeriosis, and it's only a predicted risk situation. But again, we're capturing a lot of the benefits with the sanitation and glove use that we currently see in practice.

Next slide.

All right. Sometimes we get these situations where it's good in one type of store and not in another. So what we see here is pre-slicing. We had thought maybe going in, if you pre-slice everything in the morning, that would reduce the potential for spreading out across a lot of different types of foods, and that it might be a good idea.

Well, by and large, it's a bad idea. For all but one situation, pre-slicing increases the risk. So it's not something you want to do. The one exception to that is that incoming non-growth chub, where the pre-slicing seems to prevent the cross. So now you have a chub that won't grow at all, okay, if you pre-slice that one, it tends to prevent the cross contamination out to other growth supporting chubs. So that value actually goes down. But again, a store is not going to know which category it’s in here. So pre-slicing becomes something that generally we would not, without stating policy statements, sorry, pre-slicing would increase the resulting risk.

Next slide.

All right. The one that I had to change the scale on, the one that gave us the most dramatic improvements, was the use of growth inhibitors. So in this case, before it was always plus or minus 60, here it's 200 to minus 100 on both ones of these.

Now I realize that not all products can incorporate growth inhibitors, but we can in our model. So if we set all the products to have a growth

inhibitor, basically the entire risk of listeriosis almost disappeared. You can't go below negative 100, right. That means it's all gone, and you see from that top slide, if everything had a growth inhibitor in it, basically there's really no more resulting risks.

On the other hand, if we did away with the current baseline uses of growth inhibitor and said nothing has a growth inhibitor, the risks almost doubled in almost all of the cases except for the incoming growth chub where it's already such a high risk to begin with.

All right. So growth inhibitor usage is something that we strongly encourage wherever it's feasible for the particular product. It really makes an enormous difference in the risk.

Next slide.

Okay. The other one that we could do on a virtual deli type model is, what happens if we cut the concentrations of *Listeria* entering the store? We're using the FSIS observed data at the plant as our incoming data. So it's observed data. But what

happens if we cut that in half? What happens if we reduce that level by a factor of two?

And what we saw for all of the store types is that the risk went down, okay, generally about 20 percent. The one difference again is the incoming growth chub where even cutting it in half, it's coming in so high already, it's just overwhelming that kind of reduction.

So reducing the concentrations coming in is something that we would also want to keep working on. The retail processors have done a nice job. You saw the slide that Janell showed earlier but it's something that we want to still keep pounding at.

Next slide.

All right. Cross contamination is an interesting one. So I'm going to start on the bottom slide first. So what we can do here is turn off the transfer coefficient, basically for the modelers, set them to zero, non-modelers think about we hermetically seal every sale as it's going through the store. So it's still held in the store, it's still being transferred each space and at the same temperature,

same potential for growth, but it's hermetically sealed. So it doesn't transfer any bacteria in or out of the product. That's a transfer coefficient to zero, and that's what we see on the bottom on.

If we turned off cross contamination, the risks all dramatically reduce, most particularly for the non-growth chub that's coming in contaminated because it can't grow, and with no cross contamination, it can't move out of there. So the risk drops dramatically.

That's for all of the sites. If we turn off all the transfer coefficients.

If we turn them all off except for the slicer, so now we allow transfer to occur at the slicer, we get the top graph, and none of those are significantly different from the baselines.

So what that is telling us is the slicer is the nexus for most of these cross contaminations that actually occur that have an impact on the risk. All right. It's the slicer that long term we need to think about how to design slicers so they're easy to clean, so we get less cross contamination if we want

to reduce that risk.

Next slide.

All right. Temperature, okay. We use the observed EcoSure data in our temperature baseline models. We could do an analysis, and that showed over 50 percent had cases that were above 41 degree Fahrenheit, 5 degrees Centigrade. Okay. If we removed those, and that's not recommended by the Food Code, the Food Code sets 41 degrees Fahrenheit or lower, if we only use the distribution that was from 41 on down as observed, that's what we get here. Okay. Always a fairly strong reduction in risk, roughly about 15 percent by doing temperature control as recommended by the Food Code. Okay. Low hanging fruit. There's no reason we shouldn't be doing this already. All right. This reduces the in-store growth and that reduces the resulting risk.

Next slide.

All right. This is a virtual deli model. So what can we learn that we can't do with any kind of real experiment?

One of the things Régis touched on briefly

was this mass balance approach. We can keep track, we can count where ever bacteria starts, okay, so we have a “from” column over here on the "Y" axis, has all the sites and the products as well. Where do bacteria arise from? And then on the "X" axis, where do they move to? The sites and trashing and things like that.

All right. So each one of these has a block that counts up over 100 million servings, the total number of bacteria, that moved from this site to this site, okay, and then we're going to color code it. It's a log scale over there on the right. The darker the red, the more total number of bacteria transferred.

All right. So let's look at gloves. We have strong evidence both from Régis' model where all the arrows came to the worker, from Renee's talk where the gloves tended to contaminate everything.

Next slide.

Let's look at gloves. What you see is they touch a lot of different sites, okay. They're touching everything, a lot of the “from” and “to,” but the colors are all fairly muted. They're all fairly

light. So while they're involved in the cross contamination, they're really not transferring a lot of bacteria, okay. They're getting disposed of, often enough, that really it doesn't seem to be one of the nexuses, unlike the previous slide, where controlling transfers from gloves leads to much of a benefit. They do touch everything. It's consistent with what we've seen.

Next slide.

There's also a lot of growth occurring in the retail deli that add new organisms inside the deli, okay. That's where temperature control and growth inhibitors would help that process. Okay.

Next slide.

Okay. The sanitation and the glove use does dispose of a lot of bacteria from a lot of different sites, and that's what we're seeing here. So it's washed, basically cleaned off the surface or trash, something like a contaminated glove thrown in the trash. Okay. A lot of different sites, removing a lot of different organisms. That's why not using sanitation would increase the risk significantly. Not

using gloves would increase the right a bit.

Okay. And then the ones we are most worried about then are the ones that are leaving in the customers' hands, the ones that are sold. Those are the ones that could potentially grow out and potentially cause disease.

All right. Five minutes, I want to try to get through two more. Go ahead. Next slide.

All right. I want to try and show something that we've learned talking about the impact of cross contamination. So they're all going to look like this, a given baseline graph. I've got a baseline absolute risk that we've seen before, and then look at some of the other scenarios, the susceptible risk per serving on the "X" axis.

So for the baseline where there's no niches, no environmental contamination, the only *Lm* are from what's coming in for the observed levels of chub, I get a risk of about 1.4.

Next slide.

If I turn off cross contamination, if I hermetically seal every sale as it's going through the

process, okay, that risk drops, okay. It's now do to 1.1. So the difference between those two is the cross contamination effect. It's about a 25 percent increase for this one. Okay. So informally a clean store, where it's just the products coming in, this is the impact that cross contamination comes into play.

Next slide.

Let's add some *Lm* into the store. This is our multiple niche baseline, and again the absolute number here could go left or right depending upon whether it's 10 a week, 100 a week, 1,000 a week, okay. That's a continuum we'll see in a minute. But because there are more *Lm* in this store, it's a riskier situation than the no niche baseline. That's why that 1.4 is lower than the 1.7 we're seeing here. Okay. More *Lm* in the store, it's going to be riskier. But this is contaminating a site, a food contact surface, not a food directly.

Let's turn off cross contamination. Same absolute risk that we saw before when we turned off cross contamination.

So the magic, right, not real world, but a

magic virtual deli, if I contaminate a slicer but don't let it move off there, we don't see an added risk from it. That's about a 50 percent increase in the risk because there's more *Lm* in there. If more *Lm* gets in, the impact of the cross contamination gets higher and higher for these non-growth scenarios.

A completely different kind of scenario to increase the *Lm* coming into the store. This is the non-growth chub, okay, where the average concentration on the chub is 10^{-9} to 10^{-5}. So about a factor of 10,000 increase on the average concentration.

Okay. We can't really compare the multiples in the incoming because they're really different loadings, but let's go down to the no cross contamination one. Again, that exact same number we were seeing before. So if it can't grow out, right, by definition this is a non-growth, and it can't move off because we've turned off the cross contamination, there's really not much added risk of that product in and of itself. It's the cross contamination that really leads to the additional kinds of risk.

Now one of the things we can do here, and

this will be important more on the next slide, we can have a food security agent sitting at the door saying, oh, you had an incoming, that chub today, that's a little off. Let me have that bag back, all right. So we can calculate what the risk would have been if that chub sales had not proceeded onto the consumer. So they were collected at the door as you left the store.

And what we see is that most of this risk is arising -- next slide, yeah, that's good – because the cross contamination from this non-growth chub to a growth supporting. There's only a little bit that's due to the product in and of itself being more contaminated as we would expect for a non-growth kind of chub.

So this increase in risk which is again more coming in, it's a higher percentage, it's about 100 percent, it's slightly more than double, okay, because of the cross contamination or growth supporting product.

If we turn off that cross contamination in these non-growth scenarios, we've got that same baseline risk.

Now I don't know how to tell you turn off cross contamination, but I want you to understand the mechanisms that are driving this increased risk.

So the necessary conditions are if you've got a non-growth scenario on a contact surface or an incoming chub, but it's non-growth, you've got to move it off of these to get an increase in the risk. All right. It's got to move over to something that supports the growth. So cross contamination, then a growth product after that.

Same final graph that we had before, the non-growth one. I want to look at what happens if it comes in as a growth supporting product. So it's the same thing as I had before but I've changed the scale to go up higher. So we're on a consistent scale between these two graphs.

Okay. So what you see with the growth chub is these are roughly comparable, the concentration one from 10 to the -9 to the 10^{-5} on average, all right. So the difference between those two is because of the added growth that can occur in the growth supporting chub, much, much higher, much worse. There's an

inherent risk from the growth product.

Next slide.

But if we turn off cross contamination here, it's not that big drop to 1.1. The product in and of itself is risky if it's contaminated. It does not need to cross contaminate to cause an illness. It just needs to grow out. If we have the food security policeman at the door collecting these chubs, that's where you get the major reduction in risk, all right. So the cross contamination, next slide, so that's the sales of contaminated product.

One more and then I'll talk for a minute.

That's the cross contamination. All right. So two things to note, okay. In this case because it's growth supporting, it doesn't need a cross contamination step. If it's contaminated, it's risky in and of itself. The other situations require cross contamination or a growth supporting product.

Thus, the contaminated sales are what we need to prevent. The cross contamination, depending on how you look at it, it's only an 11 percent increase. So it looks like a low increase, but on

terms of an absolute difference it's a 2 which is as big as the higher ones we were seeing on some of the others.

All right. So next slide.

So necessary conditions, growth plus additional cross contamination because we've got that product that can cross contaminate other ones, all right, it does increase the risk compared to in and of itself, but it has an inherent in and of itself risk.

Next slide.

All right. I promised you we'd look at some of those baseline kind of sensitivity analyses. So what we've go here is means of susceptible risk, just like we've been doing all along. This black one is our no niche store. All right. That's the 1.4 we've been seeing all along a couple of different times. Okay.

The blue bars here are different levels of exposure from the environment from a niche, okay. The first 3 are the niches only associated with the slicer, and in those 3, there's 100 per week getting transferred, a 1,000 per week getting transferred, 100

per day getting transferred.

Okay. As we increase the number of *Lm* moving off the niche and onto the slicer, the food contact surface, the risk is getting bigger, okay.

The next three are if we have multiple niches including a slicer in the store. But again 100 per week, 1,000 per week, 100 per day. Again we see the same scenario.

Now it's multiple sites. So the risk goes up. As we increase the loading from a niche, the risk goes up.

All right. Let's look at the red bars. These are for the contaminated products coming into the store. The first ones are for an incoming growth supporting product. Now these numbers are the ones where we did have the food security agent removing the product before it left the store, all right. So $10^{-9.2}$ is what we observed from the FSIS monitoring in-plant data. As we go 10^{-7}, 10^{-5}, that was our concentration that we looked at before, 10^{-3}, a strong, strong impact increasing the risk as that incoming *Lm* gets higher and higher. And this is after we've already removed

the contaminated product. This is all due to additional cross contamination.

Okay. Let's look at the non-growth. So same kind of situation on these next red bars starting off at the FSIS observed data level going up -7, -5, -9. We see the same trend, okay. It's not quite as strong, because we can't get growth of the product inside the store, but the more *Lm* we let into the store, even though it's a non-growth product, it can cross contaminate and leads to more and more risk.

Okay. This is the baseline for the zero tolerance rule, right. The more *Lm* you let in, the more it can move around inside a retail deli, the higher the risk that's going to arise from it.

Next slide.

All right. So what are the key findings coming out in here. Okay.

If you want to reduce the risk of listeriosis, the predicted risk of listeriosis, keep *Lm* out of the store to the best extent possible. Okay. Critically important for a growth supporting product because that includes an inherent risk of the

product itself, but it's also true for non-growth product and for environmental contamination in niches. The more *Lm* gets in the store, the higher the risk that's going to arise. Growth supporting is clearly worse here.

Okay. To the highest extent possible, we want to encourage growth inhibitor use. Growth inhibitor use is really one way to prevent customer abuse and really can reduce the risk that we see because that works at both the retail environment and the home environment.

We need to improve temperature control. That reduces growth inside the store. It's a low hanging fruit. We want to work with stores to make sure they follow the FDA Food Code on that one.

Okay. Finally, the sanitation and the glove use that we see turns out to be critical factors for keeping the risk low. We want to make sure that they don't get any worse. There might not be much benefit from making them stronger, but they should not get worse because the risk will go up if we do that.

Okay. So the main takeaway is, there's no a

magic bullet here. There's no single one intervention that's going to completely eliminate listeriosis risk from retail environments. You've got a lot of processing going on, a lot of handling. There's nothing that wipes it out completely, but there are a series of steps that can provide multiple barriers to the risk that we ought to be encouraging.

And this point, I think, Janell, you're next.

(Applause.)

MS. KAUSE: All right. Thank you, everybody.

I'm here to just kind of talk about next steps. You've heard quite a bit this morning about the data and the studies from the various universities that have been conducted and presented. Many of them have been published. You also have heard about the risk assessment and the report is out on our website. It's been there for a few weeks now. The model is also available to anybody who wants it. You'll see both on the FSIS and FDA website that you can simply send us an e-mail and we will send you the model code.

What we'd like you to think about here today is we are focused on the science. We would like you to provide input on this risk assessment. The comment period does close on July 12th, and we are looking for comments on both the underlying studies conducted by the universities as well as the risk assessment modeling approach, some of the assumptions and the findings. Thank you.

(Applause.)

MR. DiNAPOLI: Thank you, Janell.

I believe we'll take some questions at this moment. Please identify yourself.

MR. FORD: I beat Bob I think to the microphone. This is Tom Ford with Ecolab.

Dan, I had a question for you on the temperature component of your study there. Did you note the trend in that, of the reduction of temperatures along the longitudinal part of that study? I noticed you used 2007 as the reference model, right. So the temperatures are dropping in the history of that study. We started it in 1999. I'm with Ecolab.

DR. GALLAGHER: Okay.

MR. FORD: We -- that EcoSure study. Almost all the stores markedly got down below 45, almost to 41 by 2007. I expect with NSF7 requirements, you're going to meet that Food Code requirement. Did you factor into account though that the at home refrigerators were widely irregular and remained widely irregular at that time, and if you factor that into the model, what would be the implications of that? It looks to me that that's where the focus should be.

DR. GALLAGHER: I understand the question, and let me see if I can get it. So we did use the 2007. We did not look at historical trend to see if it is decreasing. The 2007 EcoSure data was consistent with what FDA is seeing in their time series in terms of number of people exceeding that temperature.

We did use observed data for consumer refrigerator storage which sometimes is quite abusive, right. Some of those home refrigerators get to be quite warm and the storage time gets to be quite long.

So that clearly is a component leading to that grow out in the consumer home, and we ought to think about educational approaches or how could we talk to the consumers really to maintain a better temperature. I agree with you there.

But there is a range of temperatures from observed data in the consumer home in our model.

MR. DiNAPOLI: Bob.

MR. BUCHANAN: Yeah. Hi. This wasn't designed for short people.

MR. DiNAPOLI: Can you identify yourself and who you're with.

MR. BUCHANAN: Bob Buchanan, University of Maryland.

MR. DiNAPOLI: Thank you.

MR. BUCHANAN: I tried to do some back of the envelope calculations based on the data you put forward, and so stick with me while I make a couple of assumptions.

I'm going to assume that 20 percent of the population is in your susceptible group. That's probably an overstatement.

And I'm going to make an assumption that somebody in the meat industry can get back to me on, is there's about 10 billion servings, deli servings of these products on a yearly basis.

So I do a little adding and subtracting, et cetera. I come out with somewhere between 200 and 2,000 cases of *Listeria* per year based on the calculations that you've provided here.

Can you give me a ballpark? Because that was the one number that I didn't hear presented in any of your data which is the one that really has the impact. So any idea of what this is going to predict in terms of total number of listeriosis cases in the United States per year?

DR. GALLAGHER: I think you're using the risk assessment in a manner that we weren't really trying to. We were trying to look at what mitigations might be successful. So we compared the risk per serving based upon things like temperature control, growth inhibitor use. All right. We weren't trying to calibrate it back to the total number of illnesses.

Now your low end of 200 though is within the

predicted, right? And just minor points, I think it's 17.5 is what we used for susceptible.

MR. BUCHANAN: First off, lesson one, and again, I just did this very rapidly on a piece of paper. Lesson one, people don't use risk assessment only the way you want to.

DR. GALLAGHER: Agreed.

MR. BUCHANAN: Okay. And then, number two, if you provide these estimates on a product basis, is it possible to then extrapolate what should be the predicted number of cases associated with this group of products?

DR. GALLAGHER: We have not formally calibrated the model to the total number of illnesses. That wasn't one of our goals. That wasn't one of the things we were trying to do.

The relative change, remember what we focused on, what you saw most of those were a percent change relative to the baseline. So if the baseline is off a little bit, those percent changes are still valid.

So I think the key takeaways are perfectly

valid to look at even though we have not taken the next step in terms of trying to say that means 200, that means 2,000 people actually die.

MR. DiNAPOLI: Any other questions in the room?

MR. KOHL: Hey, Dan. Larry Kohl with Delhaize America.

My question is around maybe carrying out the consumer side of this, and if I think way back when to the risk assessment that, I don't know, years ago that came out and said, hey, consumer education and the home refrigeration was 99 percent of the fix, if you will.

With your model, have you been able to look at the abuse or more details from a standpoint of what if and is there a predictive number of days that would be helpful to the industry and to the consumer or we might be able to rally around, that says, hey, if you buy in-store sliced lunch meats or cold cuts, that this is kind of the best practice from a guidance standpoint before you get into more risk or less risk? Hopefully that makes sense.

DR. GALLAGHER: I can answer the first one. we have not done an analysis in terms of activities that the consumer might want to do to reduce the risk. Clearly there are some. The model's capable of it. It just wasn't one of the risk management questions we've got, but if somebody comes to me and says, run the consumer storage time or temperature, different than what we observe it to be, so that it's reduced, we can go ahead and do that with our model.

I'm a little confused on the second one in terms of, is that for the retail storage time or is that for the consumer storage time?

MR. KOHL: Consumer.

DR. GALLAGHER: Same kind of thing. So really it's a product of temperature and time that permits growth. We can run those analyses with this model if somebody asks us to do so, but that wasn't one of the risk management questions we were asked.

And, keep in mind, that a what if scenario from the 2003 FDA-FSIS risk ranking model, it was one of the "what if" ones, that looked at consumer temperatures, that was before the Gombas and the NAFSS

data sets came out, that did highlight the additional prevalence that was occurring at retail.

MR. DiNAPOLI: I'm going to stop you before you start because I've forgotten the folks on the phone. Is there anyone on the phone, on the line, that would like to ask a question?

Okay. We will check back with you.

Please identify who you are and who you're with.

MR. DUNN: Thank you. I'm Mike Dunn with Sodexo, Product QA.

Just a quick question. Was HPP, the high pressure pasteurized products, deli meats, a consideration for a risk control factor?

MS. KAUSE: Hi, this is Janell Kause with FSIS. I appreciate that question. So we do look at that kind of scenario when I presented the 2003 FSIS *Listeria* risk assessment, and that's one we call the post-lethality intervention. And we do spell some of that out in our compliance documents as well. So, yes. You know, this risk assessment here, and as I said, we do a number of them, this one specifically is

looking at the interventions at retail, but absolutely.

DR. GALLAGHER: This is post-process lethality is what this is?

MS. KAUSE: Yes.

DR. GALLAGHER: Okay. I can answer that in terms of we used observed FSIS in-plant monitoring across all the different plants they're doing. So the plants that do incorporate post-processing lethality impact on that average concentration coming in. We didn't change anything from what was observed there, but that part's included in the model.

MR. DUNN: Okay. Thank you.

MR. POCIUS: Joe Pocius with Boar's Head.

The question really revolves around consumer behavior, and I don't know if you're really taken these things into consideration. We talked about consumer behavior in the home.

You said that a way reduce listeriosis and illness is to reduce cross contamination or reduce the growth. And the third way is if no one eats it.

So with all the emphasis that was put on,

and I don't know who, one of the authors in the risk assessment did make an observation and a conclusion about growth inhibitors, because of the impact on the flavor and in our current society, we want natural products, we want clean labels, we want gluten free, we want low sodium, we want green packaging, et cetera, et cetera.

If you put these things on the label, you're going to reduce a lot of the consuming public's desire to purchase those products. The numbers will go down, but not necessarily for the reason that you want them to be.

DR. GALLAGHER: Does that mean though we've done a pretty poor job of educating the consumer in terms of the risks that are involved? That just because something has an organic label means it doesn't have a growth inhibitor and that's really where the risk might be. So maybe our education to the consumer needs to incorporate some of that.

The other thing I would point out is, based on your first comment, one of the reasons we look at retail is that those first set of slides, the

potential for abuse by a consumer who doesn't know whether they've got *Lm* in there, is increased when the prevalence leaving the store is increased. So if we can cut that down, even if the customer abuses something that's got no *Lm* in it, they're not going to get sick.

MR. POCIUS: Okay. The other observation to keep in mind is, if you've been with us for the past 15, 20 years, back when -- can I say mega reg any more? Is that an accepted term now? When that was first promulgated, there was a lot of discussion about sanitizing fecal material. Whether it's sanitized or sterilized, it still is what is and nobody wants to eat it. And, the argument was you're just covering up mistakes. Rather than cleaning up your processing and cleaning up your product, you're just removing the bugs that may be there.

Caution on presenting this. It may present the occasion that you're just covering up poor practices or condoning poor practices by putting these in the product.

MS. KAUSE: Thank you, Joe. This is Janell.

So I heard that, and I know you're using the analogy to *E. coli* O157. Just for everyone in the room to be clear, *Listeria* isn't fecal related. It's an environmental contaminant.

I wouldn't say growth inhibitors covers it up. It simply inhibits the growth of anything that could be there. We still promote a zero tolerance policy. We're looking for you to control it back in the processing plants so that it's not there. You can use a number of interventions to do that, and at retail, what we're working on is if it is there, to try to prevent cross contamination.

So I mean I think we're never in a situation we're saying it's okay for *Lm* to be there. We're always saying it's not okay to be there.

One of the things that I think a lot of people have begun to look at, too, when they look at the public health data, is they see that we've had some success with reducing *Lm* in our products. You've also seen listeriosis levels go down over time and plateau out, but again I harken back to some of the CDC's statistics and we say about 16 percent to 20

percent of those who are infected die. So that's still a very severe outcome.

So at no point are we trying to point out that we're trying to cover up. We're actually trying to prevent it at all times.

MR. DiNAPOLI: Okay. Thank you. Thank you, Dan. Thank you, Régis.

I believe we'll take a quick break, if that's okay with everyone. Let's take a 15 minute break, and I have 7 after. I'm not good at math.

(Off the record at 2:08 p.m.)

(On the record at 2:25 p.m.)

MR. DiNAPOLI: Welcome back, everyone.

We'll welcome our panelists to the stage. It's nice to look up once in a while since I don't get to do that very often at 6'4.

Our first panelist is Dr. Hillary Thesmar, Vice President, Food Safety Programs for Food Marketing Institute. Dr. Thesmar provides leadership for all food safety programs for FMI's retail and wholesale members and provides leadership support for members on food safety training programs, recall plans

and crisis management, research and overall food safety and sanitation programs. Did I miss anything? I'm sure I did.

Caroline Smith DeWaal is the Director of the Food Safety Program for Center for Science in the Public Interest. As a leading consumer analyst on reform of laws and regulations governing food safety, Ms. DeWaal represents CSPI in Congress, in the regulatory arena in a broad range of food safety issues including meat and poultry safety, seafood safety, food additives, pesticides, sustainable agriculture and animal drugs. She's also President of the International Association of Consumer Food Organizations, where she represents consumer organizations in international food standard setting at the Codex.

Dr. Betsy Booren joined the American Meat Institute in 2009 and serves as a Chief Scientist of the AMI Foundation. Her responsibilities include coordinating research activities for the Foundation, responding to the technical and scientific needs of AMI members. Dr. Booren is also Staff Liaison to the

AMI Scientific Affairs Advisory Committee.

Welcome our panelists.

(Applause.)

MR. DiNAPOLI: So we're going to pose just a few questions to start. How do you see your organization using the risk assessment and related retail studies? Caroline, would you like to start or anyone want to jump on it?

MS. SMITH DeWAAL: Well, I'll start if you don't mind. Do you mind?

UNIDENTIFIED SPEAKER: Not at all.

MS. SMITH DeWAAL: If you don't mind, I'm going to start just with a couple of observations. I think this is, having sat here all day, this has been quite a treat. I think this is a really very informative new risk assessment. So I would like to congratulate all the leaders who were involved from FSIS and FDA.

With all risk assessments though, you need to ask, is the risk assessment the servant or is it the master? And by that, we really need to think about how does it serve the needs of risk managers and

risk communicators.

The risk assessment, this risk assessment, I was involved in the original meeting and part of the question that gave rise to this risk assessment was a proposal by FDA to modify its zero tolerance for *Listeria monocytogenes*, and a number of stakeholders raised the question of would that mean that more *Listeria* would find its way into the retail sector where cross contamination could actually lead to an increased risk for the public.

I think that this risk assessment is very valuable because it does show, in fact, that incoming *Listeria* levels on products is a major driver for the outcomes. Once in the retail environment, it becomes very hard to eliminate *Listeria*. There can be niches. It can appear and reappear over many years.

And also in the retail sector, high turnover within the workplace, the employees, means that training to make it right, to really have a critical control point for this means that training must be almost continuous because of the high rates of turnover.

So how will we use this risk assessment? Well, certainly we'll use this risk assessment to inform our efforts both at the Conference for Food Protection and also in general to inform consumers.

But, I think more than anything, it reinforces our concerns that the USDA and FDA not modify their current policies on *Listeria monocytogenes*. They use a zero tolerance for this hazard, and this is an appropriate risk management tool. In fact, it's one of the few risk management tools available to the Federal regulators. So they use a zero tolerance which is used for pathogens which are simply too dangerous to be controlled in a consumer's kitchen.

I think we'll also look at the risk assessment to see whether the federal agencies should require more among the people who produce meat and cheeses that can carry *Listeria monocytogenes*, whether they should be using growth inhibitors or other methods that would reduce the risk in products coming into retail.

So those would be my first observations.

MR. DiNAPOLI: Thank you, Caroline.

Hillary, do we want to --

DR. THESMAR: Sure. Well, first of all, thank you so much for inviting us here today. I'm thrilled to be here this afternoon.

MR. DiNAPOLI: You're welcome.

DR. THESMAR: We are already using the information from the academic studies and look forward to using this risk assessment, the draft risk assessment and then the final risk assessment when it comes out.

The academic studies and the process for developing the academic studies has been very helpful. We've known that deli meats have been a high risk food, and the research surrounding retail delis has been informative, and we've learned a lot about the retail deli environment. We've been using that within FMI in our food protection committee for several years now, and have developed some guidance documents and best practices in order to help retailers hopefully get ahead of this issue and address the problems as we see them to ensure the safety of our consumers that

shop in our stores every day.

One of the things that we've recently done within the past 6 months or so is develop a *Listeria* action plan. It is a document that's available on the FMI website, on the food safety pages. I'm going to hold it up so you can see the visual. It's green. It's called FMI *Listeria* Action Plan for Retail Delis.

And what we did is we gathered our retail experts, retail food safety experts, and asked them what are the simple and impactful things that you would do to knock down *Listeria* in the delis, to reduce and control *Listeria* in your delis.

There were two things that floated to the top really easily that everyone agreed upon, and those are training and execution of proper sanitation and employee practices. Everyone agreed upon this. So it all comes down to people.

The second thing was temperature control to limit *Lm* growth, and some of that data was out. Janell had shared some of that with us, what you were seeing in the observational studies and the EcoSure data. So we knew that was really important.

Obviously we had some other literature that was out there about temperature control and *Lm*. So those two were really easy.

We also identified five other what we call our opportunities for evaluation, areas for improvement. And we wanted to keep it really simple. So this isn't a typical guidance document. Scientists might look at it and say there's nothing to it, but for a retailer without a food safety professional on staff, this is implementable and that's what we wanted.

So the other five areas for improvements are floors and drains. Number 2 is cleaning. Number 3 is slicers. Number 4 is controlling cross contamination which involves control of products and control of people, and then number 5 is consumer use by dates.

And every step has an explanation and then action. So it's very action oriented, and we've had this out there since early January, and the response has been very positive even from independent operators, and some of the anecdotal comments, some of the direct comments I should say are, thank you for

doing this. This is something I can take back and actually implement. They can understand it and they can implement.

So we're running with this. We are broadly promoting this to our members. We're sharing it as widely as we can, and we're saying, let's make a difference with this.

So it is simple. It's based on what we knew about the academic studies at the time. Haley Oliver talked earlier. We based it on a lot of the studies that she's done for us, but what we plan on doing is matching this up with the risk assessment and seeing what are the gaps, what might we have missed, where might we dig a little bit deeper.

So that's the next step, digging into the draft risk assessment a little bit more, and then we'll look at the recommendations and see what we get. And it looks like it lines up pretty closely. There might be some areas where we need to fine tune some things, some things where retailers might say, well, I'm not going to go there. I'm going to go here. But I think we're on a really good path, and this just

gives us more information, and the more information, the better. So we're excited to move forward.

MR. DiNAPOLI: Thank you, Hillary.

Betsy, please.

DR. BOOREN: Thank you, and I want to reiterate my appreciation for being here. It's really been a pleasure and many of our members are in the audience.

I would say the meat and poultry industry really finds a tremendous amount of value in this type of risk assessment because it allows us to evaluate how our food safety systems are working within our own facilities, and how they go on to our customer, and in this case, our customer is not only our consumers, but our retailers, and that's an important relationship for us.

The battle that we've had with *Lm* is one that has caused more change to producers of ready-to-eat products than any other single factor for the last 40 years. Our industry has a tremendous amount of scars that are numerous and deep, and I would say when you look back, and this risk assessment makes me look

back and our members look back, at where we were 20 years ago, where we were in 2000, where we were 5 years ago.

And, I think what it has shown and what we're hopeful on the market basket survey that was brought up in 2003, that update, we are hopeful and supportive that that is finished because I think it's going to show the tremendous amount of dedication the meat and poultry industry has done to change the profile, the risk profile of their products. We're able to produce products with and without growth inhibitors in a very safe manner. And that's gone onto our customers and our consumers, and they're eating them every day.

We think that this risk assessment really has enforced what we know. Having the ability, what we call our "seek and destroy" philosophy, has been an effective preventative tool for our industry, and that's something key. It's a preventative tool for control and elimination of *Lm* in our facilities.

It's become a scientific method for us to seek harbor sites and growth niches, and it allows us

to use that as a measurement when we haven't been able to redesign out of equipment and our facilities, and I think we're able to share those experiences, we're willing to share those experiences, with the retail industry because we had those same challenges in the early '90s and early 2000s as well.

And so I'm almost all the way through this model. I've got about 10 pages left, and I've got about 200 Post-It notes of questions and our members are going to sit down in the next couple of weeks and look at it very critically from a scientific standpoint and see what we think, what can be improved, what can't be done.

But I'd also like to point out something else that has been alluded today but hasn't been really mentioned. There's been a lot of research that's been done. Unfortunate, I help manager our research program at the AMI Foundation. It's been a great program, and I can give you numbers a little later on, but what it has done, and what is needed is working with the researchers and academic to do real world research that's immediately applicable to our

industries, and that's hard to do.

And also, maybe even more importantly, we're training the next generation of students that understand the real world, that are going to end up working in those meat companies, food companies, retailers or become researchers, and that's a long-term legacy of food safety, that for us has been a really effective model. Thank you.

MR. DiNAPOLI: Thank you, Betsy.

We've conducted the risk assessment with great stakeholder engagement. What do you think of this process and what suggestions would you give for future risk assessments?

DR. BOOREN: I'll start --

MR. DiNAPOLI: Go ahead.

DR. BOOREN: -- since I just finished. We've been supportive of this process. I would say the one thing our foundation is incredibly proud of is transparency.

We have funded in the last 13 years 42 research projects on *Lm* alone, totally just under $2.9 million. Every single 1 of those 42 projects are

sitting on our website right now. You can download it and read the final report. We don't hide our data. Some of it is stuff that has caused our industry some trouble, but it was what we needed to know to move forward.

So we're in support of this project and this process because it allowed us to have the dialogue in the beginning, work with our researchers, work with FSIS, work with FDA in a collaborative fashion, that I think ultimately became a non-competitive issue and for us, food safety at the Foundation is a non-competitive issue, and it allowed us to solve the problems early on and help contribute to the data and future data that will make this other and risk assessments a success.

One thing to add that I think will also help is we held a lot of educational briefings, and FSIS and FDA have briefed our industry, and we do the same to them. We've held over 25 different workshops looking at *Listeria* control within our facilities, with upwards of 1600 individuals that have participated in those. And we're going to continue to

do that because it's helped us train our employees and be successful.

One of the things that came to me as we were listening to researches, niches and designings, our industry has spent a tremendous amount of time working with our suppliers, both equipment and design, and we've created a sanitary design list and equipment list. We're in the process of updating that, and we're hopeful that those lists and update guidelines will be available not only for the meat and poultry industry, but the RTE industries of interest, particularly the retailers as well as dairy and produce as well.

So we think this process has helped us in all of the activities we've done, and we look forward to working with FMI and Caroline's group as well as the agencies to move this forward.

MS. SMITH DeWAAL: I will get into a little bit more on data needs, I think with our last question, but I think the stakeholder involvement has been very beneficial. I think your early consultation helped to set the stage for answering the right

questions. So I think from a consumer standpoint, we've been quite happy with it, and I am looking forward to hearing more stakeholder comment later this afternoon.

But I also would be amiss if I didn't mention how important it is to get state regulatory officials who are actually in charge, state and local and county officials, who actually do the retail food safety inspections. I don't see them in the room today. Maybe we'll hear from them later. I did see that they were included in one of your expert elicitations and I think that's very important. I calmed down immediately when I saw that, but these people are critical in really figuring out what are good solutions at retail.

MR. DiNAPOLI: Thank you, Caroline.

DR. THESMAR: FMI has welcomed the opportunity to work closely with the Agency. Is my mic on? Can you hear me?

MR. DiNAPOLI: In the back, are we --

DR. THESMAR: Okay. It is. It is. Okay. There it is.

FMI has welcomed the opportunity to work closely with USDA, and we think that you should adopt this model for all future risk assessments and any project that you involve stakeholders in, in the future. We think it's been a really great collaborative effort, and we value the interaction with FDA and USDA and, in particular, being part of retail in this risk assessment, being so involved with retail, it was particularly important that we were involved, and we welcomed that involvement.

We also think that the retail industry, we believe heavily the retail industry has a lot of value and expertise to bring, and we were very privileged to be able to partner with you in that way, and thank you for allowing us to do that, and we hope that just more collaboration.

And, we think that the increased collaboration and sharing of ideas and expertise will also result in a better product in the long run because you've had that input and guidance throughout the risk assessment and instead of having a product at the end, and then having, you know, comments to shift

it, we think that the end product is going to be a higher quality product in the end, and that the whole process might go a little bit smoother with greater stakeholder involvement.

So we welcome it and hope that you adopt it for future projects.

MR. DiNAPOLI: Okay. Thank you, Hillary.

I'm going to go back and I'd like to ask Betsy, how would you respond to Caroline's stance that more needs to be done in manufacturing.

DR. BOOREN: I think we're always seeking to improve our process. I can't think of a single member that I know that is not trying to improve their process in some form or fashion. And they do that as technology changes.

I think as we've looked, we have a lot of research that's been done on interventions and processes that we haven't been able to get approved, and so we've looked at different interventions and have the ability and know that they could be effective in a whole wide variety of products, including a lot of the emerging natural and organic products, but it's

hard sometimes to get those through the regulatory approval.

And so we are going to continue to search for those processes and ingredients and hopefully work with our regulators to get those tools for our members to use.

So for us, this is a continuum. This isn't we're done. This is a continual process. Our scientific group meets quarterly. We talk not only about this issue but a wide variety of issues, and that group includes not only the packer processors, but our suppliers, whether that's ingredients like Purac or it's testing companies and laboratory kits. So we're not looking at this just from a processing standpoint. How do your suppliers contribute to the safety of our products. How does the equipment contribute and all of that is a continuous ongoing discussion?

So we're always at the table. We want to be at the table. We're producing products that everyone eats, and I think everyone of us in this room knows someone that's been susceptible or has been

susceptible in their own lifetime. These are serious issues that take serious solutions, and we're here.

MR. DiNAPOLI: Great. Thank you, Betsy.

And another quick question, this one is for Hillary. There's a focus on floors and drains. Are we trying to model after the meat industry or is that -- I mean it was touched on earlier. Is that something that --

DR. THESMAR: So for two reasons. In Dr. Oliver's study, that was one of the areas where *Listeria* was found in the environment. So I think we'd be remiss if we didn't focus on floors and drains. The delis that were medium to high prevalence in *Lm*, that's where we found it, and the non-food contact surfaces, floors and drains and other places, but it was there.

Also in lessons learned from the meat industry, we know that we need to pay attention to floors and drains.

So we are thinking ahead and also we're working with our chemical supplier partners. Ecolab has been phenomenal with support, technical and

product support. Johnson, or actually Diversey now, they were JohnsonDiversey, Diversey and also Chemstar have been amazing in their support of the industry, and they have a lot of R&D that they've put into their products and have a lot of information around cleaning and sanitation of floors and drains. They've helped our members and they've done a lot of R&D that's published and non-published.

So those two pieces together made us really focus on floors and drains. If you've walked in retail delis, it's not unusual to see product on the floor. It's not unusual to see wet areas on the floor. And also I come out of the manufacturing environment. I worked for the meat and poultry industry before I came to retail. So if you put all of that together, we're not going to ignore those clues and we're going to address it before it becomes a problem and pay attention to it.

So that's why it's a focus.

MR. DiNAPOLI: Thank you, Hillary. So is there other data that we should consider that's current? Who would like to start with that, that

would help us finalize, you know, the risk assessment

DR. THESMAR: I can start with that one. There is a lot of research that's ongoing and I think you can do an open call for information. We can certainly share some information. I feel very strongly as a scientist that peer reviewed data, published papers, should be more heavily weighted than data that's not peer reviewed yet. So I think there should be a mechanism to weight peer reviewed published data heavier in the risk assessment model before information that's not peer reviewed.

But there are a lot of studies. At FMI, we have a Foundation, FMI Foundation, and we're funding additional research because we don't have all the answers yet.

So we're continuing to work with Dr. Oliver. We're still looking at interventions. We've done three additional projects. So USDA started with Phase 1 and 2. We've picked up with 3 and 4, and we've done three projects since then. Two of them have been jointly with the AMI Foundation.

So I think as scientists we always come up

with additional research questions once we finish a project. We're good at asking more questions.

So there are a lot of projects out there, and just in the last year, I've seen a lot of papers published, and I know there are a lot of projects in the works. So I would encourage you to get the word out there. I know that people in this room probably know about a lot of them, and we can do an open call and find out more, but I encourage you to weight peer reviewed data more heavily than non-peer reviewed.

MR. DiNAPOLI: Thank you.

MS. SMITH DeWAAL: At CSPI, we would very much like you to consider survey data on the effectiveness of both retail control programs, both informal and government, more regulatory based programs.

The information from state inspections, state and local and sometime county inspections at retail are very important. However, the Federal Government's role in that is pretty strictly advisory. They advise on the Food Code but it's up to each individual state and sometimes county or local

government to actually adopt that Food Code.

And we have done a number of surveys, the last one in 2008 on restaurant inspections done at the state, county or local level. What we found with restaurants I think is informative. We found that at least 66 percent of the restaurants had at least one high risk violation when they were inspected including a large number of those being contaminated food contact surfaces. So while this study is not directly on delis, and I think if you could find information from A F T O or others that has survey data on thee kinds of retail inspections, it will help inform your practice.

The other issue is we really have to look at where the critical control point is, and the critical control point appears to be the meat that's coming in, and the condition of that meat, and then sanitation practices in the retail establishment.

But there are also a lot of limitations. Worker training is a huge limitation. Even worker practices after they've been trained. I mean you can train people but it doesn't necessarily mean they're

going to follow that practice each time.

And then this issue of employee or government oversight and the role that it plays.

So I think additional data in that area would help to further inform the risk assessment but as I mentioned earlier, you know, one of my big takeaway messages is that the federal controls, the controls that can be exercised by the federal agencies here including their zero tolerance policies, are very important in controlling conditions in the meat before it comes to retail or having a regulatory approach to having those controls exercised by the industry are critically important.

MR. DiNAPOLI: Thank you, Caroline. Betsy.

DR. BOOREN: Thank you. I can tell you that the Foundation, the AMI Foundation is waiting really right now on two white papers. We have a wide variety of *Listeria* work being done mainly in lethality but we have two white papers that we anticipate being available. They're final reports. They're in the process of being put into peer review.

One of them is a review of the epidemiology

of all foodborne listeriosis both domestically and internationally, and this is not only meat and poultry, but all RTE foods, and part of the reason we did this was to get to the scope of how is the meat and poultry industry's risk changed and what's the current data. And the challenge with any risk assessment or any report is in the context of what the data is.

So we've commissioned these two white papers really to give us an update, and if they are not done to the comment period, we will still submit them to the agencies for their consideration.

The second white paper is a *Listeria* paper looking at the "seek and destroy" philosophy that the meat and poultry industry employs in their facilities. It's addressing the scientific support behind that philosophy. It's looking at the data of why we've chosen to do that and how effective it's been. It will outline it and provide the background and development and also put it into context to the other RTE products, the other, excuse me, non-meant RTE products.

So it will look at the regulatory program both from FSIS but also FDA. So we're looking at that. There are two or three manuscripts that will come out of that white paper, but we are working with both Cornell University and University of Wisconsin on this. So I'm hoping that they'll to the literature particularly in the research that's been done in the last couple of years.

But I will tell you this. As someone who runs and manages a foundation and a research program, what was very helpful today is I've got sort of a laundry list of RFP research items, that I think I can probably twist Hillary's arm and say how do we solve this problem?

One of the things that comes out of these risk assessments is now what we know but what we don't know, and I think this has shown today, in some of the questions asked, that we don't know a lot of things, and I think that will help drive some of this research in the future.

MR. DiNAPOLI: Thank you very much. I'm just briefly going to go back to what was said about

the meat and poultry industry and what AMI has said. Can we talk a little bit about the cheese industry? And that, of course, is per the CDC data on outbreaks. Is that something that any of you could mention?

DR. THESMAR: I can say that our advance *Listeria* workshop is a program that we've developed. I don't know how many of you are familiar with it, but it was developed in 2000, really by the leaders in the meat and poultry industry. They're the heads of food safety. They're the ones that wrote curriculum, continue to rewrite the curriculum, and teach the courses.

When you look at the participant list, while most of them are the meat and poultry industry, we see a lot people coming in from the dairy industry. We're seeing more people coming in from the retail industry as well as the produce side.

So we know what can kill and destroy *Lm* and in this unique situation with the cheeses, but we also know in facilities how to help perhaps teach them some of the lessons or share with them our lessons, and we're willing to do that. I can't speak for the

cheese industry themselves, but we are there with them when they ask for help. Many of our members will go in as consultants and work with them, as well as the produce industry.

MR. DiNAPOLI: All right. Caroline.

MS. SMITH DeWAAL: I think it's just really important to recognize that this is not a meat problem alone. Deli meats have been linked to these, but other foods have it as well.

I think clearly this risk assessment shows that the control in the deli case is very important, but I think over time, we may find that controls in the produce industry are also critically important.

But I think the work that's been done to date is quite excellent, and I would urge the Agency to move it out quickly, to finalize the risk assessment. Don't leave it dangling too long, and let's move on. There are lots of other things that need attention.

MR. DiNAPOLI: Okay. Thank you all.

Do we do closing remarks here or do we want to -- questions? We've got a little bit of time.

Great. Thank you all. Thank you, Hillary, Caroline and Betsy. We appreciate it.

(Applause.)

DRMS. KAUSE: This is Janell Kause with FSIS. I think Sherri would say this as well. We really do appreciate the time that Caroline, Betsy and Hillary took to be on our panel today and to talk about how they might use these results and the new process that we're using for stakeholder involvement as well as talk a little bit about data that they foresee coming.

We know science is ongoing. We do not plan to dilly dally with this risk assessment. We do plan to put it out because like many things, as we said earlier, you know, you ask one question, you get more answers, and those answers lead to different questions and then you continue on.

But with that, I just wanted to say, we thank you for coming today to talk a little bit about these issues.

MR. DiNAPOLI: Thanks, Janell.

So we're going to take another break. I'm

wondering if everyone's awake. No.

Okay. Public comment, we're going to go ahead and start with our first commenter. When you come to the podium, please identify yourself and who you're with. Unfortunately we're not going to take questions during the public comment period. We apologize for that, but that's why it's public comment. So we'll give you roughly about five minutes.

Right now I'd like to invite Tony Corbo from Food & Water Watch.

MR. CORBO: Yes, Tony Corbo from Food & Water Watch. First of all, I want to thank the folks who have been working on this risk assessment. It's quite a piece of work. I'm still going through it. It's taken a long time to develop it, but I really am pleased with the level of work that went into it.

But I do have questions, and they're rhetorical questions because to augment what Caroline said, how is this risk assessment going to be used? Are you going to develop new policies? Are there going to be new regulations? Are there going to be

national regulations?

The Food Code is voluntary. How is this going to be incorporated? To what level are the resources going to be available for state and local inspection agencies to implement the recommendations from this risk analysis?

I know I'm looking at several steps ahead, but I mean these are key questions because these folks have done an awful lot of work, have put in a lot of time, to develop this risk assessment, and it's going to be foolhardy just to leave it out there as a wonderful piece of work never to be implemented.

MR. DiNAPOLI: Thank you, Tony.

Tom Ford, Ecolab. Tom.

MR. FORD: Thank you. I just wanted to make a couple of comments, and no questions, but maybe we could comment on it later, but it seems like a lot is hinging on the data around the Gombas study, and maybe Janell could answer for me later, if you do have this knowledge base around it, but the meats that we're pointing towards, were they containing inhibitors or not? We did a study related off of Dave's study and I

don't remember exactly if they did or not. I don't think they were, and I think that becomes a real critical point here on the data. I don't know if you want to answer that now or not.

DR. GALLAGHER: I'll try and answer that real quickly. The Gombas data did not serve as an input to our model at any point. The data we used for the concentration was based on current FSIS in-plant monitoring data, all right. So it was part of the reason why we did the study but that data was not used inside it anywhere.

MR. FORD: Okay. My mistake then, but I think they're pointing at that kind of focus there, and as you've shown with the rest of the data today, that inhibitor contained versus non-inhibitor contained became a real focus today which leads to another couple of my points here.

I first want to applaud the associations and regulatory groups, the universities and even the retailers themselves that participated in the Cornell-Purdue Study. That was really courageous of that group. As a retailer in my past and somebody that

works in the cleaning and sanitation side now, I would have loved to have done research especially for *Lm* at the retail in vitro, and you run into regulatory issues because what happens if you find it? You run into legal issues. What happens if you find it? You run into ethical and moral issues. What happens if you find it. And as a sanitation provider, if a sanitation step fails in vitro, it can jeopardize a registration. All those hurdles were overcome to create that first in vitro study. So I applaud them for doing that, and I think that there's more that needs to be done. I love the risk assessment but based on real data in the field is where we need to go in the future. So I encourage that we do more of that.

My learnings with it when we did the further discussions of this study with Purdue was that this approach to *Lm* reduction and listeriosis reduction as our goal is multifaceted. It's not one piece. It's not one arrow that's going to kill this kind of an approach. It's really everything from the way the department's designed to incoming raw ingredients, how

we handle it, how we train people, the steps we take for a SOP standpoint, and lastly customer education. I think that's really a glowing part of this that we have not talked about enough today. I think the EcoSure study showed that a little bit, and what happens when it leaves the grocery store and how it's handled at the home is really critical.

And lastly I want to talk about some interagency cooperation I think that could be necessary here. We're regulated at retail by the FDA, the USDA, and the last one that's not really talked about is the EPA. As I mentioned, there's this registration process for all sanitizers, but if we're talking about growth inhibitors, and as a final intervention step, ideally getting as close as you can to the consumer is where we would have the most benefit but that's not really regulated in a lot of ways. In fact, if it's generated on site, nobody owns it right now, and there are technology available that you can treat, you know, the interventions that exist at the plant are available for retail, but if you look at it from the consumer's standpoint or even the

retailer's standpoint, if they're using some sort of inhibitor right there at the site, what does that look like to the person working the deli. I'm adding this additive right there. Is it an additive? Is it a chemical? Is it a treatment? And then the consumer sees that as well. What's their perception of that? So we need to be cautious about that and understanding what their positions are on that kind of intervention process. Thank you.

MR. DiNAPOLI: Thank you. Tom.

Greg O'Neill, American Cheese Society.

MR. O'NEILL: Good afternoon. My name is Greg O'Neill, and I'm a specialty food retailer, a small specialty food retailer. I'm representing the American Cheese Society which is the lead organization supporting and promoting cheese in North America.

In this role, ACS represents some 1500 producers, distributors, retailers and discerning consumers who appreciate the diversity and quality of American made artisan, farmstead and specialty cheeses. So we're pleased to be here today to comment on the draft interagency risk assessment in retail

delicatessens.

I am the current President of the Board of Directors of ACS. I'm also the co-owner of Pastoral Artisan Cheese, Bread and Wine in Chicago, small specialty retail shops and delicatessens and bar, Pastoral Cheese and Wine Bistro.

So specialty food associations latest state of the specialty food in industry reports cites that cheese makes up about 22 percent of the specialty food sector, the largest single category representing about 3.6 billion in sales in 2012.

Artisan and specialty cheeses displayed, presented and cut to order by knowledgeable professionals are an extremely important part of the retail mix for cheese and specialty shops, grocery stores and delicatessens.

As such, when considering food safety and procedures that may reduce the risk of listeriosis, we ask that FDA and FSIS will keep these products and the following three points in mind.

First, focus on solutions and procedures to reduce risk that have the potential to be implemented

regularly, consistently and cost effectively in real world settings including small specialty retail environments. ACS hopes that any new requirements for mitigating risk in retail settings will focus on strategies that can be implemented regularly, consistently and in a manner that will be cost prohibitive neither to large retailers nor small independent retailers. We also hope that any such strategies will take into account the unique needs of those retailers selling artisan products that are often made using traditional methods and require different care and handling than commodity products.

Secondly, emphasize the importance of education, training and upholding the highest professional standards among retail delicatessen workers. In 2012, ACS offered the first ever certified cheese professional exam. The exam open to cheese professional throughout industry and throughout the supply chain aims to elevate the understanding, visibility and expectation of best practices in a way that the marketplace has clearly embraced. Retailers large and small have sought out the certified cheese

professional designation as a way to distinguish their employees and enhance food safety in their facilities.

The first professional certification of its kind, the exam has garnered international support and interest as well, particularly with French and British organizations with which ACS strives to work closely.

In addition, ACS offers its members an ongoing education through educational sessions at our annual conference and webinars and 24/7 resources, some of which people in this room have participated in and we appreciate.

We believe that focusing on education, which has been central to our own work, can make a significant difference in ensuring the safety of ready-to-eat products sold at retail.

Finally, considering consumer demand for cut to order cheeses and the potential economic impact on both large and small retailers of any changes to the availability of such items, practices that may prevent risk of *Listeria* in retail settings as outlined in this report, include the use of growth inhibitors in suitable products, the strict control of temperature

during refrigerated storage and the pre-slicing of products.

ACS would like to remind FDA and FSIS that artisan and specialty products are often produced differently and should be handled differently than commodity products. Artisan and specialty cheeses may not maintain their integrity if recipes are modified, when storage temperatures are set too low or when products are precut and packaged before shoppers arrive.

In general, it is difficult to prepackage and sell fine cheeses that often retail in excess of $30 per pounds to discerning consumers who wish to order very specific portion sizes and who expect the fine cheeses will be sold in peak condition.

If new rules or guidelines don't take the unique needs of artisanal products into account, then retailers may lose a significant source of revenue.

We believe strongly that consumers deserve access to a wide range of cheese sold in optimal condition and we hope that FDA and FSIS will keep this in mind when developing any new rules or guidelines.

We hope you will develop sound, science-based safety protocols that are realistic for both producers and retailers within our thriving specialty cheese market.

As an industry resource, ACS recognizes the important educational role that we play. This year we continue our emphasis on food safety by defining best practices for our members, providing more tools to help them create and improve HACCP plans and through outreach, education, training, resources and professional certifications from associations like ACS, we can ensure that cheese retailers have the tools and information that they need to proactively adhere to best industry practices, and we recommend and hope to receive active FDA participation in industry education, expanding outreach exponentially through collaborative efforts.

We ask you to involve ACS and our specialty retail members as you consider any regulatory changes. Thanks so much.

MR. DiNAPOLI: Thank you. We're going to the phones. Is there anyone on the phone that would like to make a public comment?

Okay. We're going to finish early. This is great.

Our next speaker --

MS. KLEIN: Is there still time for a public comment?

MR. DiNAPOLI: Sure, absolutely. For everyone, please identify yourself and who you're with.

MS. KLEIN: Sure. I'm Sarah Klein. I'm a senior attorney with Center for Science in the Public Interest. I'm also a Board Member on the Executive Board of the Conference for Food Protection.

So I was particularly interested today to hear how many of the areas that are required in the Food Code are also so important to the control of *Lm* at retail.

As Caroline mentioned, we've looked very deeply into issues related to the Food Code and restaurant inspections, and I believe that there are enough similarities that make some of the things that we've looked at so carefully in restaurants, equally compelling for the retail setting.

One of the issues that we focused on a lot in the last several years is what incentivizes restaurants or retail establishments who are serving prepared food as if in a restaurant, what incentivizes them to maintain those optimal food safety practices that are recommended or required by the Food Code? It's our belief that transparency in inspections.

Obviously we've talked about, Caroline alluded to, the need for, and Tony did as well, for robust state, local, county inspections, and that without that kind of oversight, it is very difficult to ensure that the Food Code, that any of the recommendations of the Food Code are being followed.

But, we believe that another critical component there is the oversight but also the transparency. Our position is that that transparency can best be achieved through letter grades that are posted at the site of the restaurant or retail establishment so that consumers can see how well that establishment is doing in compliance, and we believe that that provides information to consumers and incentive for restaurants and retailers to maintain

that high level, so that it's not just that our employees are trained in these behaviors, but that they are expected to follow them because the result would be a very public inspection result.

And, so that's something that we'll be working on, particularly in light of the information that was seen here today. Thank you.

MR. DiNAPOLI: Thank you, Sarah.

Our next speaker is Dr. Chris Braden.

Dr. Braden serves as the Director of the CDC's Division of Foodborne, Waterborne and Environmental Diseases. Dr. Braden is a physician who completed his medical residency and fellowship in infectious diseases before joining the CDC in 1993. His major areas of interest include infectious diseases, surveillance and outbreak investigation and national programs in food and water safety.

Dr. Braden.

(Applause.)

DR. BRADEN: Thank you. It's been a pleasure to be here today, and it's been a pleasure to hear so much about some great work that's been going

on with this risk assessment. But, I thought I would talk a little bit about the bigger picture, especially from the CDC perspective about really why you're all here and what CDC can also bring to the table to address the issues having to do with *Listeria* infections.

As was just said, I am a physician, and actually I still see patients in addition to running a program at CDC. And it wasn't but a few months ago that I did see a patient who was admitted to the intensive care unit in very bad condition with sepsis in the night, and when I saw them in the morning, the patient had been treated appropriately from the beginning with antibiotics for both sepsis and meningitis, and it was just hours later, in that afternoon, that the laboratory called me and described a grand positive rod that they were seeing in the blood, and I knew exactly what that was at that time. So the patient went on to die the next day, a 50-year-old male with diabetes, active, family and so forth.

So that's why we're here today as a personal note but, you know, when CDC comes to the table, they

also bring the perspective of people, about how many people are becoming ill for different reasons and from different sources.

And most recently I think we've kind of reaffirmed in a historical perspective in an attribution paper that was published just recently that *Listeria* is the third leading cause of deaths among foodborne pathogens in the United States.

Now I'm going to say that that's a historical perspective. That was data from a 11 year period up until 2008, and I'll address that issue in a little bit.

But first talking about this particular risk assessment, you know, I'm impressed with risk assessments in a number of ways, and one of the ways in which I'm impressed with them is they're a lot of work, a lot of effort went into it, but then to be able to use that kind of model to adjust the input and to adjust the assumptions and then to say what happens if, is extremely useful and I think really drives that risk management discussion down the line.

And, I really did enjoy seeing some of the

outcomes of the risk assessment today and just, for instance, I was thinking that maybe gloves were going to be a big key factor there and actually they weren't, if we continue to use gloves in the way that we do. So that's I think a very positive outcome to a lot of good work, and I applaud the agencies for doing that.

But I do want to say that, you know, from the CDC's perspective, you know, what we're seeing in a risk assessment is what I call bottom up. We're starting with the food and the setting and so forth and seeing what happens when you multiply up what the effects are if you introduce contamination.

From a CDC perspective, we come from the top down and that is when we look at the population and then we see what's causing the illnesses in people. And I think that the two types of approaches to this can be complementary, one informing the other, and actually with the Interagency Risk Assessment Consortium and then the much more newly formed Interagency Food Analytics Collaboration, have met to discuss some of the ways that those two approaches can

inform one another.

And it's that latter approach that, when I'm talking about, for instance, the attribution that was most recently published, that looks at the deaths and so forth that are due to meats and some particular meats in particular, as kind of a historical perspective that needs to be updated because we know that there's been a lot that's happened and as Dr. Silk had portrayed, when you look at the incidence of *Listeria* over time, it really has dropped, and it's dropped coincidentally with the implementation of a lot of interventions on the part of government and industry.

So I think we have made a lot of progress. The question is, you know, where do we go from here? I would like to see as Bob Buchanan had pointed out to say, well, what are we seeing now with this kind of model as a prediction of what, you know, magnitude of the impact is on the outcome to patients? And then also look at the other direction when we talk about the attribution of illnesses to different foods in a more recent timeframe to see how those two match up

and see what is the impact that we can have by intervening, for instance, in the deli space. That's a bit of a question still in my mind at this point in time.

I was also impressed with what was done to kind of address some of the data gaps for the tool and the number of studies that were commissioned, paid for by different stakeholders to start to fill some of those data gaps.

Now I'm going to say we're at a disadvantage I think when we talk about what we can do, you know, coming from the top down approach and what we call attribution analysis because we're facing those same data gaps or not the same ones, but we are facing significant data gaps and we're having a hard time finding a way to fill those data gaps.

So I think we need to work together if we really want to update what we can do for attribution analysis to see what the gaps are so that we can come up with some more recent data to inform that type of analysis, and even harder is then to be able to say, what is the change in attribution over time? That's

going to be a very difficult type of analysis, not only in methodology but also to find the type of data that's going to be current enough to do that in a real way.

So I'm going to put out my own request as a comment here in this meeting that, you know, as we approach this kind of risk assessment, I think we need to approach other types of analyses that we do to inform our policies, and that should include looking at the top up (sic) and the bottom down (sic) type of approaches that I'm talking about. So that would be my major comments. Again, work well done.

I do want to put in a plug for some interventions that we are trying to put forward right now, and one is on the intervention efforts and one is with communication to the stakeholders. On June 4th, CDC is going to be coming out with a vital signs report, and vital signs, if people are not familiar with them, is a major rollout with kind of media centric messages to advance programs at CDC and food safety at CDC is what we call one of our winnable battles.

And so on June 4th, we will be doing a major rollout of vital signs focusing on *Listeria monocytogenes* and susceptible populations. So I want to put out a plug for that.

Same day and in coordination will be a multiagency webinar that looks at infections, foodborne infections in vulnerable populations. So please look forward to that coming up.

But then in the future, I really do look forward to this risk management discussion that we have based upon the findings of this and other data that we can pull together.

Again, thank you very much and congratulations on good work.

(Applause.)

MR. DiNAPOLI: Thank you, Dr. Braden.

Phil would like me to sit down.

MR. DERFLER: I'm Phil Derfler. I'm Deputy Administrator of FSIS, and I'm going to close this. Let me just say a few things.

First of all, Mike Landa started out today by saying this meeting really isn't about policy, but

as Dr. Braden alluded to and some of the other speakers, we wouldn't have invested in the studies that you heard about today if we weren't really interested in making sure that our policies are as well informed by science as they can possibly be.

As a wise man told me, listeriosis is an illness with low incidence but has very high consequences, and therefore it demands constant attention, and it's attention that we intend to continue to give to it.

So I would urge you all, if you have comments on the risk assessment or comments on any of the other studies that you heard about today, to be them into us by July 12th. That's the date that we need to hear from you by.

The studies I think were really valuable. The slides that were presented today were really valuable. I recognize that there might be problems in either looking at the slides that were in the handouts that you were given and also looking at the screen. All the slides will be on our website. They're on our website now.

In addition, we intend to have a transcript of this meeting, and we expect to have that out within a month.

So there's a lot of information that was conveyed today, a lot of really important information and we would encourage you to look there to get the information for yourself.

I think the second thing I want to say is that a meeting like this is not really possible without a lot of really hard work and I really want to recognize that work. All the people who spoke today and the presentations that they made, the research that underlie their presentation, obviously was really, really good work. You don't need me to say that, because you heard it over and over again from people who are a lot smarter than I am.

I'd particularly like to recognize Sherri Dennis and Janell Kause. They spearheaded this work for each of their agencies and they deserve a whole lot of credit for what you heard today and what you saw today and for what happened today.

In addition, there are a number of people

from FSIS who did a bunch of the sort of background work that allowed this meeting to go forward, and I'd really like to recognize them. I'd like to recognize Greg DiNapoli for doing the MC work, Stacy Kish, Kish, whatever, and Felicia Thompson who were the reception, when you were there, when you came this morning. I've got to look at this. Marla Moore and Patrice Palmer who operated the video during the course of the day, Megan Atwell and Delisa Robinson who provided sign language interpretation during the course of the day, Joan Lindenberger who did a lot of the work pulling the meeting together and Mary Katherine Jeffers and Peggy Riek who also contributed.

Finally, I'd like to thank all of you for coming, for your attention. Again, we really look forward to hearing your comments, and with that, we're done. Thanks a lot.

(Applause.)

(Whereupon, at 3:30 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

INTERAGENCY RETAIL *LISTERIA MONOCYTOGENES*

RISK ASSESSMENT PUBLIC MEETING

SCIENCE AND RISK ASSESSMENT:

LISTERIA MONOCYTOGENES

Washington, D.C.

May 22, 2013

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

_____/s/_____

TIMOTHY J. ATKINSON, JR., Reporter

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