UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

+ + + + +

DEPARTMENT OF HEALTH AND HUMAN SERVICE'S FOOD AND DRUG ADMINISTRATION/CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

PUBLIC MEETING ON THE INTERAGENCY RETAIL

LISTERIA MONOCYTOGENES RISK ASSESSMENT

+ + + + +

June 23, 2009
8:30 a.m.

L'Enfant Plaza Hotel
480 L'Enfant Plaza, S.W.
Washington, D.C.

MODERATORS: JANELL R. KAUSE
Food Safety and Inspection Service

SHERRI DENNIS
Food and Drug Administration

ROBERT TYNAN
Food Safety and Inspection Service

PANEL MEMBERS:

JOHN BUTTS, American Meat Institute
JILL HOLLINGSWORTH, Food Marketing Institute
AMIRHOSSEIN MOKHTARI, RTI International
CAROLINE SMITH DeWAAL, Center for Science in the Public Interest

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

SPEAKERS:

AL ALMANZA, Food Safety and Inspection Service
STEPHEN SUNDLOF, Center for Food Safety and Applied Nutrition, Food and Drug Administration
FREDERICK ANGULO, Centers for Disease Control
ANN DRAUGHON, University of Tennessee
JOE CORBY, Association of Food & Drug Officials
MARTIN WIEDMANN, Cornell University
JANELL KAUSE, FOOD SAFETY AND INSPECTION SERVICE
DAN GALLAGHER, Virginia Tech/FSIS
REGIS POUILLOT, Food and Drug Administration

I-N-D-E-X

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

(8:30 a.m.)

MS. KAUSE: Okay. I think we're ready to get started. It is 8:30. I want to welcome all of you and say good morning. I'm Janell Kause, the Director for the Risk Assessment Division in the Office of Public Health Science in the Food Safety and Inspection Service. It's certainly a pleasure that all of you are here today, as well as those of you participating by phone for this joint public meeting on the Interagency Retail *Listeria monocytogenes* Risk Assessment.

The goal of today's meeting is twofold. One is to provide background information on the current stated knowledge with regards to *Listeria monocytogenes* at retail. The second goal is to welcome public and stakeholder input, data, and information for the U.S. Department of Agriculture Food Safety Inspection Service as well as the Department of Health and Human Services Food and Drug Administration for this new risk assessment.

I will be moderating this morning's session

and then pass the baton to Dr. Sherri Dennis of the Food and Drug Administration for the afternoon session. Mr. Robert Tynan will be helping us as well and will moderate our stakeholder panel discussion, as listed on our agenda.

Also, for your information, the Food Safety Inspection Service and the Food and Drug Administration have substantially extended the comment period to September 29th. This is a three-month period to ensure that the public, stakeholders, and academia have adequate time to provide input, comment, data, and information to us for this new risk assessment.

You will notice on your agenda that there is several opportunities for questions and comments throughout the day. There is a half-hour this morning as well as a half hour in the afternoon. There is also an opportunity for public comment at the end of today's meeting. Anyone wishing to make a public comment that did not sign up at the registration table may do so during the meeting at any time. We want to allow everyone that wishes to

make a comment or ask a question the opportunity to do so and therefore would ask that you take no more than three minutes. We have left time at the end for more Q and A and will be happy to take more questions if time permits.

As you can see, we have a full agenda. So let me start with just a few housekeeping items. The restrooms are both to the right and left of the room as you step out. The L'Enfant Plaza Hotel has a restaurant, and there are several restaurants and sandwich shops in the mall below. There is a set of stairs located in the lobby area that leads you directly to the mall. Just check with the hotel reception desk if you don't see them.

The PowerPoint presentations from this meeting are available on the website, and the transcripts will be available in a few weeks. Any presentations that are not available at the registration desk will be posted on the website after today. After each presentation this morning, we will be able to take maybe one or two questions from the audience, time permitting, and then move on

to the next speaker. Time has been allotted for more Q and A before we break for lunch.

Because this meeting is transcribed, we ask that you please state your name and your organization when you come to the microphones. There will be students walking around the room with microphones to hand to you. I will also ask that the operator to also let me know if we have questions from our conference participants online.

Before I ask Mr. Almanza and Dr. Steven Sundlof to take the podium, let me take a moment to introduce them.

Mr. Al Almanza became the Administrator of the Food Safety Inspection Service in June 2007. In this position, he leads FSIS and its almost 10,000 employees in their mission of protecting public health through food safety and food defense.

Dr. Sundlof was appointed as the Director of the Center for Food Safety and Applied Nutrition at FDA in January of 2008. He provides leadership to the center's development and implementation of programs and policies relative to the composition,

quality, safety, and labeling of foods, food and color additives, dietary supplements, and cosmetics.

Please help me welcome Mr. Al Almanza followed by Dr. Steven Sundlof.

(Applause.)

MR. ALMANZA: Thank you, Janell, and I want to thank everybody in this room and the people on the phone. Don't want to forget about them.

But before I get started, I want to acknowledge a few people. Certainly, Dr. Stephen Sundlof from FDA for taking time, and I know that this is just as important to them as well as to FSIS; also to today's presenters, and at the state level as well, with Cho down there, and the FSIS and FDA employees that will be doing presentations; the staff from both agencies and their joint effort in this public meeting, as well as work on *Listeria* in general; and to our public health partners and stakeholders in the room and on the phone for participating in this process.

This is not the first time that FSIS and FDA have come together for work on *Listeria*. We

issued a joint study in 2003 that looked at the risk that *Listeria* posed to public health in certain ready-to-eat foods. And among those foods, deli meats posed the highest risk.

In response, FSIS outlined ways establishments could address *Listeria* in their HACCP plans. So as everyone knows, all products are not created, or are not equal in risk, and we know all processes do not carry the same hazards. So we place establishments producing ready-to-eat products into one of three categories based on the product and the process that they use to help control *Listeria*. We also sample based on risk. The higher the risk, the more sampling we do.

Since we launched these efforts, establishments have generally strengthened their programs, and we're using our personnel to more effectively assess whether establishments maintain control over *Listeria.* Last year, FSIS followed up with our comparative risk assessment looking at the risk of illness from *Listeria* on deli meat sliced and packaged at plants under federal inspection

versus deli meat sliced at retail establishments.

The results from that assessment were staggering. It predicts that 83 percent of cases from deli meats would be from those prepared at the retail level. There is clearly a need for more research in this area and regulatory action and guidance based on research.

That brings us here today. Through this joint risk assessment, we want to look at retail practices across products and across jurisdictions that affect contamination. We also want to evaluate how effective the processes and interventions that we use to reduce it. We will use the information from this study to make public health decisions. We never forget that our policies and guidance can help reduce food-borne illnesses and save lives.

Today, we would like your input. We look forward to a productive meeting, and I want to thank everyone for participating both telephonically and by being present today once again and know that we value your comments. Thank you.

(Applause.)

DR. SUNDLOF: Well, good morning, everyone, here and on the phone. It is a pleasure to be here. This is obviously a very important issue. One of the major food-borne diseases is *Listeria monocytogenes*. We're finding it in places we have never found it before. And it just goes to the point that we need a lot more science. We need a lot more data, and that's what this meeting is all about, to try and collect as much information as we can to make informed science-based decisions.

FDA and USDA have had a long history of collaborating on microbiological risk assessments, beginning with the *Salmonella* in egg risk assessment in 1998 and then, as Al already mentioned, the 2003 *Listeria monocytogenes* risk assessment, which was the first quantitative risk assessment of relative risk of listeriosis from consumption of a variety of ready-to-eat foods. And here we are today pursuing that even further.

There is also an ongoing risk assessment that FDA and USDA are participating on, which involves avian -- high path avian influenza in

poultry and eggs and whether or not, first of all, there is a risk to the public health, and then, secondly, if there is, are there ways to mitigate that risk. And so that is currently ongoing.

The current risk assessment on *Listeria monocytogenes* in retail food represents another thoughtful and productive USDA/FDA collaboration. This public meeting is an example of our commitment to transparency in government and the proactive involvement of our stakeholders in the risk assessment process.

And I just, not in my notes, but having been involved with codex since 1986, I've seen how the U.S. risk assessment process has influenced how the codex operates and with the addition of a new joint expert committee, the joint meeting on risk assessment, which is -- really shows that the United States has been in the forefront of this area of risk assessment.

Obviously, this is a relatively new area of science, and it was going to require a lot more work to really perfect some of these risk assessment

processes. But I think being able to work together and share information, you know, we can make much better informed decisions.

So this is, again, a very transparent process, and we want to make sure that we get as much public input as possible. As you may have heard, greater transparency is one of President Obama's and our Secretary of HHS, Secretary Sebelius' top priorities. And to that end, FDA recently formed a transparency task force, and this task force is chaired by the FDA's lead deputy commissioner, who is Dr. Josh Sharfstein. And it's charged with developing recommendations for making useful, understandable information about FDA activities and decision-making more readily available to the public in a timely manner and in a multiuser -- in a user-friendly format.

FDA's transparency task force is having an open public meeting tomorrow at the National Transportation Safety Board Conference Center in L'Enfant Plaza, so right around the corner. And beyond tomorrow's public meeting, the task force is

exploring additional ways to seek input through the internet and is planning to hold a second public meeting in the fall of 2009, and that meeting announcement will be published in the federal registry.

Then lastly, I want to emphasize the importance of working with industry and academia to obtain specific, specialized data that are needed to best inform our risk assessments. And with respect to this risk assessment, I want to personally thank the Food Marketing Institute and the FDA University of Maryland Joint Institute for Food Safety and Applied Nutrition for their assistance in developing an observational study for food handlers and delicatessens. The data that are obtained for this study will be useful in the *Listeria* risk assessment that we are working on now.

So, again, I look forward to a very productive meeting, and everybody on your way out, leave data. Thank you.

(Applause.)

MS. KAUSE: Thank you, Dr. Sundlof and

Mr. Almanza. With that said, we're going to begin the program with a background session for this morning with Dr. Fredrick Angulo. Dr. Angulo is the Deputy Branch Chief of the Enteric Diseases Epidemiology Branch in the Division of Food-borne Bacteria and Mycotic Diseases at the Centers for Disease Control and Prevention. His research interest areas are food-borne disease burden of illness studies, attribution efforts, and antimicrobial resistance among enteric bacteria. Please help me welcome Dr. Fred Angulo.

(Applause.)

DR. ANGULO: Thank you very much for the introduction and the invitation to participate. My talk will cover five general areas. I'll first describe the clinical characteristics of a *Listeria* infection, then talk about the human health burden, trends and incidence of laboratory-confirmed infections, sources of *Listeria* infections, and end with conclusions.

So, first, the clinical characteristics of *Listeria* infections. *Listeria* infections can be

categorized broadly into those that are pregnancy-associated infections and non-pregnancy-associated infections. In the non-pregnancy-associated infections, those occur amongst people who are immune-compromised, and there are also infections among previously healthy individuals.

In the pregnancy-associated infections, the pregnant woman may have fever or may have no defined illness. The infection may spread to the fetus, resulting in sepsis, miscarriage, and stillbirth, or the infection can result in infection of the newborn resulting in meningitis of the newborn child.

In non-pregnancy-associated infections amongst immune-compromised persons, which may be people with malignancy, organ transplants, immune suppressive medications or HIV infection, infections result in invasive disease manifested as sepsis, meningitis, and encephalitis. In previously healthy individuals, most infections are asymptomatic. A diarrheal illness may occur. Rarely, invasive disease will result in a previously healthy individual. We conduct surveillance largely of

invasive infections.

To show the scope of the clinical characteristics, we can look at four years of FoodNet data, so clinical outcomes of 169 laboratory-confirmed cases in FoodNet from years 2000 to 2003. In that case series of 169 cases, 28, or 17 percent, were pregnancy-associated cases. All of these pregnancy-associated cases were invasive. Eighteen, or 65 percent, resulted in hospitalizations. Seven resulted in a stillborn.

141 of the 169, or 83 percent, of the non-pregnancy -- were non-pregnancy-associated cases. All of them were invasive infections. 108, or 76 percent, of the non-pregnancy-associated cases were among previously immune-compromised individuals. And 33, or 24 percent, were among previously healthy individuals. 131, or 92 percent, of non-pregnancy-associated cases were hospitalized. And 22, or 15 percent, died.

Overall, the hospitalization in this case series was 82 percent, with an overall mortality of 17 percent.

Secondly, I'd like to talk about the human health burden of *Listeria* infections. In 1999 we at CDC, Paul Mead was the first author, published an estimate of the annual human health burden of food-borne diseases in the United States. *Listeria* is estimated to result in over 2,000 infections per year, about half of which are laboratory-confirmed, and result in 500 deaths, with an overall case fatality rate of about 20 percent. In fact, *Listeria* is the second most common cause of deaths due to bacterial food-borne diseases.

We published a paper in 2007 that describes different select populations. Although the incidence has changed since this case series 1996 to 2003, in this case series, the overall incidence was four cases, for laboratory-confirmed cases, per one million persons in the general population. And you see that there was a lower incidence in Whites and African Americans. Remarkably, there was a high incidence in Hispanics.

Continued analysis of this case series demonstrates that amongst infants, the incidence

rate is 12 times higher amongst Hispanics than non-Hispanics, infants being pregnancy-associated infections of the newborn and infections therefore of the newborn. Among women of child-bearing age, the incidence is 11 times higher in Hispanics compared to non-Hispanics. This case series demonstrates the Hispanic population is apparently at highest risk of *Listeria* infection.

The third part of my talk is I would like to talk about the trends and the incidence of laboratory-confirmed infections. But I'd like to start with an early timeline of *Listeria* surveillance activities in the United States. In 1985 there was a large California outbreak of *Listeria monocytogenes* resulting in 142 laboratory-confirmed cases and 40 deaths. The outbreak was due to Mexican-style soft cheese, a queso fresco product.

This led to a 1986 CDC establishing act of surveillance in sentinel locations under the sponsorship of FDA. In 1989 there was an incidence associated with *Listeria* isolated from turkey hot

dogs, and the industry resulted in efforts to control *Listeria* in food processing environments. In 1996 active surveillance within the FoodNet program incorporated *Listeria* with the support of USDA-FSIS and FDA-CFSAN.

This is the long timeline from 1986 through 2008, showing the incidence of laboratory-confirmed *Listeria* infections in the sentinel sites in the United States. The first half of the graph is the sentinel sites that were established as a consequence of the outbreak in the mid-'80s. And in 1996, FoodNet began, and these active surveillance activities were incorporated in the FoodNet activities.

As most of you know, FoodNet is an active surveillance program in ten states' health departments in the United States, shown here in yellow. The population under surveillance is 46 million persons in 2009, or 15 percent of the U.S. population.

As is with many bacterial infections within FoodNet, there have been national health objectives

for the incidence of laboratory-confirmed *Listeria* infections established. In the Healthy People 2010 National Health Objective was a 50 percent reduction in the incidence of laboratory-confirmed *Listeria* infections by the year 2010. The baseline for establishing this goal was the incidence in 1996 through 1998, and to achieve this goal, the hope was to attain an incidence of 2.4 laboratory-confirmed cases of *Listeria* in 100,000 population in the United States.

In response to a large, multistate outbreak due to turkey deli meat, there was a presidential initiative that accelerated the National Health Objective to 2005 in hopes that we would achieve this National Health Objective by the year 2005, a 50 percent reduction in the number of *Listeria* infections.

These are the most recent FoodNet data published in April of 2009 in CDC's morbidity and mortality weekly report. In this trend, the baseline is 1996 through 1998, and you see that the incidence has declined since the baseline years at

the far left of the graph. And so in 2008, the incidence of laboratory-confirmed cases in 2008 is 36 percent lower than the baseline years, a statistically significant decline in the incidence in this past decade.

However, as this graph demonstrates, in the last several years, there has been little change or no change in the incidence of laboratory-confirmed *Listeria* infections, in fact, there's been no change in *Listeria* infections in the last three years. And as I mentioned, the National Health Objective was accelerated to 2005 in the hopes of having 2.4 cases per million populations, which is also written on the screen here as 0.24 cases per 100,000 persons. I hope that math is okay this early in the morning.

So our national goal is 2.4 cases per million population. And you see that in 2004 we approached that goal, with 2.7 cases per million population. But we achieved no decline in incidence of laboratory-confirmed cases in the last four years. And in 2008, the incidence is 2.9 cases per million population, still short of the 2.4 cases per

100,000 population National Health Objective.

This is demonstrated here with this graph, which shows the confidence intervals around the percent change in the incidence in the previous three years -- that's 2005 through 2007 -- to 2008. And you see the boxed area, *Listeria's* incidence, showing no significant decline in the last three years. This is also a graphic from the CDC's MMWR of April of 2009.

So, in general, we can say that the trend in incidence of laboratory-confirmed listeriosis has declined since 1989. And there's been two periods of greatest decline, a decline in 1989 through 1993 and a decline in 1997 through 2001. However, in 2009, although the incidence was 36 percent below the incidence in 1996 through 1998, we did not meet the National Health Objective of a 50 percent reduction by the year 2005.

The fourth part of my presentation is to discuss sources of human *Listeria* infections. We can discuss sources of laboratory-confirmed *Listeria* infections, introducing a process we would call

source attribution in which we partition the human burden of *Listeria* infections to specific sources. It's important to recognize that such attribution efforts may be conducted at different places along the farm to table continuum.

The data that I'll be showing will be point to consumption attribution because illness will be illnesses resulting from the -- or it's looking at causes of infections at the point of consumption. You could do point -- you could do attribution exercises at the processing plant or in other parts along the food chain. We used two approaches for point to consumption attribution: case control studies of sporadic infections and outbreak investigations.

Before I talk about this attribution efforts, it's recognized that it's often very difficult to determine the sources of human *Listeria* infections. That's because infections are commonly geographically dispersed. It has a low incidence. And the incubation period is up to 30 days from the time of eating a contaminated food item, making it

very difficult to remember foods eaten. Furthermore, in these two attribution approaches in case control studies, selection of controls is particularly difficult because we use controls that have a similar illness, similar type of illness, immune-compromised controls are commonly used. Furthermore, in outbreaks, delays are common in outbreaks because of the long incubation period and the broad geographic distribution.

CDC has conducted three sporadic case control studies. In 1986 through '87, we did a case control study that found that eating -- that *Listeria* infections were associated with eating uncooked or non-reheated hot dogs. In 1988 through '90, we did a case control study that found that human *Listeria* infections were associated with eating soft cheeses and other food purchased at retail at deli counters. And then, most recently, within the FoodNet program, we published a case control study of sporadic *Listeria* infections in which infections were associated with eating hummus and sliced melons purchased at retail and grocery

stores.

In addition to sporadic case control studies, of course we can use outbreaks to try to determine sources of *Listeria* infections. And returning to the timeline, it's important to recognize that in 1998, PulseNet began routine PFGE-ing of *Listeria* isolates. This shows, again, the incidence in human *Listeria* infections since 1986. And shown on the graph is when FoodNet began active surveillance in 1996 and PulseNet began subtyping *Listeria* isolates in 1998.

Of course, with the PulseNet program -- most of you are familiar with the PulseNet program -- all 50 states and many other reference laboratories participate in which they forward the PFGE patterns to the PulseNet list server and the national database, allowing comparison of molecular fingerprints.

The PulseNet program has directly led to the recognition of two large multistate outbreaks, the first outbreak in 1998 immediately after PulseNet began the initiative and associated with

hot dogs and an outbreak in 2002 associated with turkey deli meat. I'll mention these two outbreaks in particular.

In the hot dog-associated outbreak of 1998 through 1999, there were 108 laboratory-confirmed cases in 24 states. Thirteen of these infections were pregnancy-associated infections. It resulted in 14 deaths of adults and 4 deaths of fetuses, or miscarriages. Epidemiological investigation implicated eating hot dogs from one specific plant. These findings were published in *Epidemiology and Infection.*

The second outbreak I'd like to highlight was an outbreak of turkey deli meat -- that was associated with turkey deli meat in 2002. This outbreak resulted in 54 patients, laboratory-confirmed patients, in nine states; 42 of the infections were pregnancy-associated infections. The infections resulted in eight deaths and also three miscarriages, or stillbirths. The outbreak was caused by turkey deli meats, as I mentioned, in which post-processing contamination of the turkey

product was likely. In result of this outbreak, USDA-FSIS issued a new microbial sampling policy, which resulted in increased environmental testing and also permitted the recall, based upon testing, of food contact surfaces. These findings were also published in peer-reviewed literature.

Extending on the recent timeline, in addition to PulseNet becoming involved with PFGE-ing of *Listeria* isolates, in 2001 *Listeria* infections in humans became nationally notifiable by all 50 state health departments. Furthermore, in 2004 CDC, in partnership with state health departments, began a *Listeria* initiative that I'd like to highlight.

The *Listeria* initiative calls for all isolates of *Listeria* nationwide to be PFGE'd and patterns submitted to PulseNet. Furthermore, all cases of laboratory-confirmed *Listeria* infections are urged to be interviewed using a standard case report form, and then at CDC PulseNet, we monitor the PFGE patterns for clusters and immediately do analysis of clusters using a case control study design comparing cases that have a PFGE similar

pattern to the controls, which are persons infected with *Listeria* of different patterns and allows us to rapidly do analysis to try to determine food sources quickly.

This time I just extended the same timeline that showed where these two important surveillance activities occurred in 2001, making it nationally notifiable and the *Listeria* initiative beginning in 2004.

This is an important slide showing the consequence of the PulseNet efforts. You see on the far left of the slide that this begins in 1978, and this shows the number of outbreaks that occur each year through 2007. And in the first 15 years of surveillance, there were five outbreaks of *Listeria*, all of which were single-state outbreaks, and the average size of those outbreaks was almost 54 laboratory-confirmed cases. So they were large outbreaks but geographically local and rarely identified.

When PulseNet began routine subtyping of all *Listeria* isolates, we immediately began to

detect more *Listeria* outbreaks. And during the next seven years, from 1998 to 2004, with the assistance of PulseNet, we identified 13 outbreaks of *Listeria*, four of which were multistate outbreaks. The average size of the outbreaks were smaller, about 21 laboratory-confirmed cases in each of the outbreaks. Finally, after 2004, when we started the *Listeria* initiative, in first four years of the *Listeria* initiative, from 2004 through 2007, we've had nine outbreaks of *Listeria*, one of which was multistate. The average size of outbreaks now is 5.5 laboratory-confirmed cases. So because of this enhanced surveillance activities both in the laboratory with PulseNet and amongst the epidemiology group, in terms of rapid patient interviews, the average size of outbreaks have declined and more outbreaks have been recognized.

This is a comprehensive list of all *Listeria* outbreaks reported to CDC from 1998 through 2007, which is the last year of closed-out data. During this interval, 20-year interval, there have been 21 outbreaks of *Listeria* infections amongst

humans. Highlighted in yellow are the two outbreaks I previously mentioned, the large multistate outbreak in 1998 associated with hot dogs and the large multistate outbreak in 2002 associated with sliced turkey deli meats.

But of the 21 total outbreaks, seven of the outbreaks have been associated with deli meats. Four have been associated with Mexican-style soft cheeses. Two have been associated with hot dogs. And then other food vehicles implicated have been pate, salad -- the salad was a taco or nacho salad -- and chicken. The actual food -- was not implicated in four of these 21 outbreaks.

Importantly, of these 21 outbreaks, only one of which was a restaurant-associated -- that was the taco and nacho salad outbreak, with two laboratory-confirmed cases in Minnesota in 2007. The other 20 outbreaks all resulted from foods purchased at retail, in grocery stores, including deli counters.

So this is a comprehensive list of outbreaks in the last 20 years. All these outbreaks

are available on CDC's website. The line list of all these outbreaks are available on our website. But I'd like to highlight four outbreaks that have occurred in the last two years that show particular features.

The first selected outbreak, recent outbreak, occurred in February of 2008 in which routine testing of chicken salad in New York state yielded *Listeria* and the product was withdrawn. Later, a patient's PFGE pattern matched the recalled, the product -- matched the isolate from the recalled chicken products, although the chicken product that the patient ate was not part of the recalled products. This led to expansion of the recall to include those products. The key thing was that -- part of this identification from this was the rapid, prompt interview of the patient's family. Furthermore, because of these efforts, the product was traced back to the plant, and the outbreak strand of *Listeria* was isolated at the plant. I highlight this because it shows the high value of routine testing of some high-risk foods and sharing

of the patterns from those foods with patients, with a database of patient isolates.

A second outbreak to highlight is the first described outbreak of *Listeria* that we would call nosocomial. This is an outbreak in a New York City hospital in the summer of 2008, resulting in five laboratory-confirmed infections. Three of the patients died. The five patients were all hospitalized for other reasons, had immune-suppressive treatments while they were in the hospital, and then became infected with *Listeria* at the same PFGE pattern. The outbreak was caused by tuna salad contaminated in the hospital's kitchen. *Listeria* of the same PFGE pattern was isolated from the kitchen environment.

A survey conducted of New York City hospitals found that this hospital with the outbreak had no special diet for patients who were immune-suppressed. They all received the routine hospital diet. And a survey of New York City hospitals, conducted as a consequence of this outbreak, found that no other New York City hospitals had special

dietary requirements or diets provided to their immune-suppressed patients.

A third outbreak I'd like to highlight shows the value of rapid patient interviews. In this instance, an outbreak occurred during the winter of 2008 to 2009. Rapid patient interviews of the first three people with PFGE-matched isolates identified Mexican-style soft cheese in common with these patients. Ultimately, the outbreak, although it lasted six months, resulted in eight laboratory-confirmed patients, all Hispanic, and it was traced to commercially produced, pasteurized Mexican-style soft cheese, and the *Listeria* with the same PFGE pattern was isolated from the patients, from leftover cheese and from patients' homes, and from the plant that produced the cheese. The plant has been closed.

Finally, most recently, to highlight an outbreak, a remarkable outbreak that actually has occurred over the last 12 months, this prolonged outbreak was frustrating from the standpoint that although we embarked upon the *Listeria* initiative,

using the long *Listeria* interview form, which takes 30 minutes to interview a family and has over seven pages of questions, we could find no common exposures identified in these rapid interviews. Ultimately, the outbreak resulted in 20 laboratory-confirmed cases in seven states.

Finally, a breakthrough occurred, based upon the very energetic state health department in which they found out that some of their recent -- one of their recent cases had eaten alfalfa sprouts, leading to a hypothesis that alfalfa spouts might have caused this outbreak. We embarked upon a case control study and implicated alfalfa sprouts as the source of the outbreak. The outbreak -- the alfalfa sprouts were produced by a single sprouter, single grower. *Listeria* of the same PFGE pattern was isolated from the patients, from sprouts, and from the sprouting facility. The facility is closed. This is the first outbreak we're aware involved -- first outbreak of *Listeria* infections in humans that we're aware of that involves fresh produce.

In summary, to summarize information

gathered from these sources, for the last two decades, outbreaks have most often been caused by processed, ready-to-eat meats, especially turkey, sliced turkey deli meat, and hot dogs. Typically, contamination occurred after initial processing. The focus of contamination appears to be in the processing plant. Fresh soft cheeses made with raw milk is another important source of *Listeria* infections, but we had a recent outbreak associated with alfalfa sprouts. Sporadic case control studies have identified other foods, giving us an impression of the general sources of *Listeria* infections.

Finally, the fifth part of my talk is the concluding slide. In conclusion, general conclusions from these epidemiological data, first, on the burden, the mortality of *Listeria* infections in humans is high. About 20 percent of people with laboratory-confirmed infections die. The highest incidence of laboratory-confirmed *Listeria* infections is amongst Hispanics.

The trend, the overall incidence has declined from eight per million to 2.9 per million

in the last two decades, but there has been little change in the incidence of laboratory-confirmed infections since 2002. We did not achieve our National Health Objective of 2005. It's not clear that we'll meet it in 2010.

Sources of infections, we've been able to identify more sources of infections recently because of enhanced surveillance, which is leading to the detection of more outbreaks. But novel foods continue to be identified, as a highlight at the produce, the fresh produce outbreak -- identification of fresh produce as a source of infection for the first time.

Finally, the important point is that targeted efforts to reduce contamination have been followed by declines in the incidence of human infections, but we're at a stalemate period in which there has been no decline in human illness for the last seven years. Thank you.

(Applause.)

MS. KAUSE: Thank you, Fred, for that very thorough background on listeriosis in the United

States. I believe we have time for one or two questions, maybe one here in the audience and maybe one online. Martin? Dr. Wiedmann?

DR. WIEDMANN: Fred, the first question is there's an increase in listeriosis in Europe, which is predominantly attributed to a population older than 60. And if you break up the number in the U.S., you see it's a flat line, but the distribution among the different groups, let's say, immune-compromised, under 60, over 60, pregnant woman, has that changed over those five years because that might be important to sort of look at sources, and do we see a similar trend here and is it hidden in that flat line? And I guess the second question is why is New York state such a hot bed of *Listeria* outbreaks?

DR. ANGULO: The second question, I'll defer to our presenter from New York state, but I think it demonstrates the unique partnership between their state Department of Agriculture, their state Department of Health, and their local health departments, that they have a focus on *Listeria*.

The first question is, yes, we're aware of the increase in *Listeria* in Europe. We are partnering with partners at the European Centers for Disease Control to do a multinational study to try to look at the, ecologically, at the trends in *Listeria* infections between the United States and Europe. The decline that we see in human infections in the United States, although stalemated in the last seven years, that decline is largely in the pregnancy-associated infections. If you take out the pregnancy-associated infections, you see a non -- but there is still not a significant increase in human infections in the non-pregnancy-associated infections. So we don't appear to have the same -- or we aren't seeing what they're seeing in Europe, in general, although it is remarkable that we -- the only place we have a decline in the United States is in the pregnancy-associated infections.

MS. KAUSE: Thank you. We'll take one more question. Dr. Hollingsworth?

DR. HOLLINGSWORTH: Thanks, Fred. Really great information. And one of the things that you

mentioned -- or actually, I have two questions based on some information that might really help with this risk assessment, and that is when you were looking at these geographic clusters or outbreaks that you can now identify because of the initiative, you mentioned that the majority of them had an origin from retail deli-purchased products. Was there any additional follow-up to determine if those implicated products were contaminated at retail or if they came into the retail department already contaminated? And secondly, in these geographic clusters, has there been any trace back to identify if they're coming from a single retail store location or are they dispersed more geographically that, in fact, they implicate more than one retail environment?

DR. ANGULO: Thank you for the questions. In preparing for this talk, our group recognized that we do have an opportunity to summarize the outbreaks that we have in our database. These are outbreaks reported to us of various sizes from state health departments that describe there have been 21

outbreaks since 1998 through 2007, the last closed-out year. The last two years, we've had a number of outbreaks. And it would be useful to review those outbreaks reported to us from states to see what information they have in their investigations, in terms of the location of -- where they think the location of contamination might have occurred. So many of the outbreaks are smaller outbreaks, which may not have much information that allows trace back through the food chain. But that summary needs to be done. We have not done that yet.

MS. KAUSE: Thank you, Dr. Angulo. Without further delay, we're going to move on to our next speaker, Dr. Ann Draughon. Dr. Ann Draughon is a Rodney distinguished professor and co-director of the Food Safety Center of Excellence at the University of Tennessee in Knoxville and served as the first female president of the International Association for Food Protection in 1996. In 2006 she headed up a team of scientists that conducted a study for the National Alliance for Food Safety and Security on the occurrence and enumeration of

Listeria monocytogenes in over 8,000 samples of ready-to-eat meat and poultry products. With that, please welcome Dr. Ann Draughon.

(Applause.)

DR. DRAUGHON: Thank you for that introduction. It's a delight to be here today. And I would like to point out that this was a collaborative study done under the guise of the National Alliance for Food Safety and Security. This is an alliance of universities throughout the country. And my collaborators on this project, Rodine Cliver and Maha Hajmeer, at UC Davis, Dr. Ryser, who is in the audience today from Michigan State University, and Omar Oyarzabal, at Auburn University.

The objectives of the study were to determine the occurrence of *Listeria monocytogenes* in 8,015 selected ready-to-eat meat and poultry samples sliced at the deli counter and product that was pre-packaged under USDA inspection. The second objective was to enumerate, or determine, the levels of *Listeria monocytogenes* in those ready-to-eat meat

and poultry samples that were positive for *Listeria monocytogenes*.

The study was exhaustively designed in order to meet some of the statistical requirements, in order to try to establish data for a national risk assessment. And the number of samples that was arrived at was a combination of two things. One was the number of samples needed to have a statistical validity and a good representative sample of the national ready-to-eat meat and poultry. The other was based upon practicality, how much money could we spend to do this. The study was done for about $400,000, which is actually pretty much operating on a shoestring for this type of sample. The other thing that USDA wanted was to look at 125-gram samples rather than 25-gram samples, which we'll often work with, in order to have a very representative sample and, if it was there, to have a better chance of detecting *Listeria monocytogenes.*

In designing this study, in discussions with FSIS, we wanted to look at both poultry, cured and uncured, beef and pork, and the beef was both

cured and uncured. And of course, the pork that we found at the deli is cured. We also looked at 1,000 previously unopened chub samples or whole breast samples or whatever type of sample that was at the delicatessen in large packages. What we found was that none of those samples were positive for *Listeria monocytogenes.* So I won't be presenting additional data on those large, unopened packages.

What we did find was one of those packages did have *Listeria monocytogenes* on the exterior. We sampled the exterior of each one of those before it was opened for sampling. Once we opened up a large package or chub or a large breast intact, we would take ten samples once we had opened that package. The team sat down and developed all types of sampling protocols, and for these chubs, each group that was sampling sampled exactly the same area, geometrically, on those chubs.

In order to collect samples, there were a number of constraints and a number of things that we thought about in where would -- to sample. First of all, we wanted to collect data in locations where

there was food-borne illness data that was routinely documented by FoodNet and PulseNet since this data would be needed for a risk assessment. We also wanted to choose locations that were somewhat representative of the United States as much as possible, looking at geography, the availability of different types of products, so we had a good cross-section. We wanted to look at age of the population, at demographics. And so a variety of factors went into the selection of the locations of where the samples would be taken.

The third thing that we wanted to look at was areas where we had National Alliance scientists who were willing to work collaboratively and to follow some very highly specific and identical detailed protocols. We wanted to have those for sample collection, for how we handled samples, for the actual analysis of those samples, and for how we put together the data for reporting and when we provided that data to FSIS.

This is a map of the United States showing the FoodNet sites at the time of the study. And in

an original study that was performed by Gombas, et al., and there are several of you in the audience who were involved in that study, this study was funded by FDA and was also done by NFPA at the time. Of course, NFPA became FPA and then joined with GMA to become GMA at this point in time. But that study was conducted to do an overall sampling of deli items of which ready-to-eat meats were a part of that sampling.

In their study, they sampled California and Maryland. Because of that, we wanted to also look at, at least, one state which they had looked at, and so California was chosen as one of our sampling states and also because we had scientists at UC Davis willing to do this study.

The universities who agreed to do this ended up contributing about $100,000 of their own money just in time and effort, and so it was a very generous move on their part for those scientists that were willing to do it. They also had to contribute a very specific block of time for the study so that we would all be done in lockstep

together.

The other states that were chosen were Minnesota, and Michigan State had a NAF scientist. Minnesota did not. So Dr. Elliot Ryser at Michigan State was willing to work on those samples, and they used an FDA inspector in Minnesota to collect those samples, and they collected all of those samples using the protocol that we developed. Tennessee was chosen as one of the states since that's where I'm from and my lab was willing to do that, and the other state was Georgia. At the time, we did not have any NAF scientists from Georgia, and so Omar Oyarzabal, who's at Auburn state, was willing to do those samples, and they were close enough, geographically, to drive there and collect samples. So in three states, California, Tennessee, Georgia, those samples were collected by the team themselves every week for about a year. And 50 samples, approximately, were collected per week.

Now, as far as the sampling protocol that we used, it was a very detailed sampling protocol, and in that original slide that I was showing the

collaborators, you may have noticed that a number of the commodity organizations or consumer organizations or industry organizations were mentioned. And this was because we passed all of our protocols, including our sampling, our methodology for the microbiological analysis through some very prominent individuals in those associations. Randy Huffman who was with AMI at the time -- he's now with Maple Leaf Foods, as you know -- was the person that we passed our protocols through. Jill, who is in the audience, she looked at our protocols as well. We had someone from the Turkey Federation look at the protocols, Oulis (ph.). And then Jenny Scott was the person, who, at the time, again, it was FPA and now, of course, GMA.

A lot of changes were made in those protocols based upon their recommendations. We collected about a one-pound sample at each deli, or in each -- the packages. And the reason we did that was because we needed 125-gram sample for the FSIS protocol, USDA, but we also needed another 125 if it was positive because we had to run that through an

MPN assay. In addition, we saved about a hundred grams of each sample for analysis for organic acid, of acetic and lactic acid, hopefully, to get financing in the future from some group in order to do an analysis of some of the antimicrobials that were in the meat products and the levels of just acetates and lactates, although that doesn't really always represent the diacetate in the products that were there being used as antimicrobials. But it did give us an idea of the organic acid content. That study has been done, by the way, and that data should be released in the near future.

The way that the samples were collected, everything was weighted, everything was generated by random numbers. For example, in Tennessee at the time, we had a population of about 5.6 million according to the census. We have 98 counties. So every county, the population was determined for that county. For example, Shelby County has a population of 897,000 people. So if we took the population of Shelby County, which was 15.7 percent of the state, and multiplied it times the number of samples to be

collected in Tennessee, which was 2,000, that meant we had to collect 315 samples from Shelby County.

So all 98 counties in the state were randomized by just the numbers. Those numbers were selected. And then, for example, Shelby County was put into the random pool seven times because we can never collect more than 50 samples in a week. So Shelby County was not sampled sequentially, for example, week after week. It was sampled when those random numbers came up. Some counties, only ten samples came from those counties, so that meant we had to go to five counties on that week, perhaps, or, you know, four counties, whatever we needed to make up the 50 samples.

Stores were selected in each of the sampling areas using the yellow pages and then the internet. And again, the stores themselves were all assigned numbers from one to whatever happened to be according to that county, and those stores were selected by random numbers. Information at each of the delis was collected on the samples that was developed by the team and by our people who

consulted with the team so that we could collect as much information at the time of sampling as possible. We tried to think of everything. Of course, you can never think of everything that you would like to collect.

From the store to the lab required less than 24 hours. The samples were all kept at less than or equal to 4 degrees Celsius. Temperature data loggers were placed in the coolers, not in the product. We didn't want to damage the integrity of the samples. But in each cooler, there was a temperature data logger as we would collect samples.

These are some examples of the types of information that were collected at the time of sampling. We would collect any code numbers that we found, the name and the type of the product, the store random number was recorded, the purchase date, whatever county, any inspection code information. We collected manufacturing and sell-by dates, manufacturing dates, and the date -- if a product was in seven -- a pull-by or sell-by was within seven days of collection, we would not collect that

sample because we wanted to make sure that nothing exceeded the storage time on those samples. The amount of samples I had said was about a pound.

And we also recorded the amount of product remaining in the deli before we would initiate slicing. Now, this was very rough. It was, like, half, a quarter, three-quarters, or a brand-new package was opened at the time of sampling. We did not get that on all of the samples. We got that on about half of them. Any manufacturing codes were recorded, the product collection temperature, the ambient temperature of the store itself since some were not even air-conditioned, the formulation, if it was available, for our future study, whether the place was state or federally inspected, and then we also encouraged brand varieties so that we would get a good cross-section of the market. Brand-matching, as far as retail case versus the deli case was not possible. As you know, most of the time, those type of products do not match, so we did not try to do any brand-matching between deli case and the deli slicing area.

We also developed something that we called a consumer-based deli practices score. This score was our system. It's based somewhat upon a public health inspection of the store. Of course, we're consumers at that point. We can't go back and check the temperature of their coolers, so it had to be modified. So we don't call it a sanitary inspection, but it was based upon trying to see if the stores were clean, sanitary, from a consumer perspective.

The information that was provided to FSIS under our agreement was that we would blind all of the data so that they would never know which stores were positive, which products were positive, that we needed to protect the confidentiality of the manufacturers and of the stores themselves so that there would not be any problems with that. We also gave them collection temperatures. If we had it, we gave them -- if there was antimicrobials added, and of course, they got which samples were positive, the MPNs on those samples, but they did not know the manufacturer or any personal information about those

samples.

Again, we tried to do as much as we could in order to do some parallel sampling with the Gombas study that was published in 2003 in the *Journal of Food Protection*. And this was a procedure that they used, which we thought was very good. Based on data they had, they found that most consumers shop at what we call Type A stores. So 75 percent of consumers shop at the larger supermarket brands, and these are some examples of the names of those brands. They're in the top 100 retailers in the country. About 25 percent of consumers shop at what we call Type B stores. These were regional chains, private or family owned, some of the smaller national chains.

So this is how we broke down our samples. Seventy-five percent were collected at the A stores that we called and then 25 percent at B. So in a week, say we had 50 samples, then three-fourths of those would be collected at A stores. We would always go to two A stores and two B stores in a week. So half of those A stores we'd collect in one

store and half in the other.

This is the analysis protocol for *Listeria monocytogenes.* It is the USDA protocol with a couple of modifications. We wanted to collect some additional data, so we compared these three media, MOX is what we normally use, but we also compared rapid LM and CHROMagar in this study, and that is published right now. It's in *Rapid Methods* -- to determine which one of those we thought did the best job of picking up on *Listeria monocytogenes.* According to the USDA protocol, we went to horse blood overlay.

We also used the gene track *Listeria* assay at this point in addition to conventional just to see how that would work in comparison. And then, also, to give us a much more quick presumptive -- because at this point, if we got a presumptive positive here, here, and here, then we would go -- or any one of those -- we would go to our MPN assay with a second 125-gram sample because we didn't want that sample to be sitting around, you know, for several days before we would know whether it was

positive or not. We wanted to know within 24 hours or less whether we needed to go to an MPN assay so that it wouldn't be sitting in the refrigerator with *Listeria* potentially increasing in numbers.

In addition, once we had positive, of course, those were isolated, then we went to API. We also did a GeneQuence genetic confirmation. GeneQuence is a Neogen product, and originally, we were hoping to use that for our study so that we could just quickly pull out *Listeria monocytogenes.* But at the time of that study, they were still trying to perfect the assay, and we were not able to use that. So we did a lot of preliminary studies in our laboratories before we started this study, and we could not at that time validate that particular assay. Now it works very well. In addition, these samples were then taken into storage for PFGE and for PCR.

Before we look at the overall positives that we found in this study, we took these and we broke them down into our deli products, deli poultry, the deli beef, the deli pork, and what we

call mixed. The mixed cured might be a bologna-type product that would have beef/pork, beef/turkey, turkey/pork, whatever, or all three of those mixed together. We didn't have very many of those samples. We only had 36, but in those mixed cured products, we only had one positive, which was 2.8 percent.

Now, the deli poultry, we had 1,015 samples of the uncured and 1,000 of the cured. 1,000 of cured is, like, turkey/ham. And so the overall positive on those was about 0.7 on the cured and about 1.5 percent on the uncured product. If you looked at deli beef, the cured was 0.8 percent, uncured was 1.8. The uncured is, like, beef roast. The cured is, like, pastramis and things of that sort that have nitrites. On the deli pork, all of them were cured, and we had an overall rate of 1.3 percent of the pork products.

If we go down to the pre-pack, I use the PP for a pre-pack. This is a retail case product that was packaged under USDA inspection at the plant. It was never opened until it was received at those

laboratories and opened for analysis.

In those, if we looked at the pre-packed poultry, the cured, we had 0.1 percent positives, the uncured, about 0.2 percent. With the beef, we had no cured beef products that were positive for LM, and with the uncured, about 0.2 percent. That's beef roast, primarily. And then with the cured pork products, about 0.2 percent.

So we begin to see a trend very quickly in that with our deli-sliced product, the percent positives were quite a bit higher than our pre-packed product. The other thing that was notable, I thought, in this was that there does seem to be something of a trend between cured and uncured products since with the poultry, we had about twice as many positives with our uncured. And again, with our beef products, we see the same thing. So it appears that the nitrites and the salt that occurs with the cured products and probably the pH change as well, those are less likely, at least by half, to be contaminated with LM. This is a fairly representative sample with this large number of

samples.

Now, if we look at the overall study, California had 2,015 samples. They took a few extras for some reason. And each of the other states had 2,000, for a total of 8,015 samples. California had no positives in their pre-packed. Georgia had no positives in pre-packed. Minnesota had four. And Tennessee, two were found. That gave us a total of six positives.

We had a total of 55 positive LM isolates from the ready-to-eat meat and poultry products in the study. There were 49 of the deli-sliced that were positives. And you can see they're pretty well-distributed throughout the states. This gave us an overall positive for the entire study of 0.69 percent. But again, we see in the pre-packed, we had an overall positive of 0.15 percent, and then our deli-sliced, 1.23 percent, which is about eight times higher at the delicatessen than it was at the pre-packed product.

If we compare this to the NFPA/FDA study that was published in 2003 by Gombas, et al., they

found 0.4 percent positive in the pre-packed product, so this is a fairly sizable reduction in that time period between 2003 and in 2005 and 2006, when our study was done. Also, the deli-sliced, the reduction there, they had 2.7 percent overall, and our deli-sliced is about 1.23. Overall percent is about the same, and this is because about 78 percent of their products actually came from the case where it was already pre-packaged. So only about a quarter of their samples were actually taken at the deli, so the majority of samples were taken at the pre-packed product. So this brought their overall percentage down.

If we look at this just on a percentage basis, with the pre-packed product, we see about a 63 percent reduction between this period of time when they collected their samples and in 2005/2006. With the deli pack, again, there was a 55 percent decrease. Still, the ratio of the LM in the deli versus the pre-pack, there's was about 7:1 and ours, about 8:1. So the ratio of positives really hasn't changed that much although the occurrence of these,

or the prevalence, has changed.

One thing that I think is interesting, we all know that what a lot of us call the *Listeria* rule was put into practice in the fall of 2003. That was when each of the meat and processing plants had the opportunity for ready-to-eat meats to choose one of three alternatives for their product as a part of their HACCP program. So with the study that was done before the implementation of the *Listeria* rule and the various alternatives and what was done afterwards, this does appear to have contributed to a significant reduction in the *Listeria* that was in the product since we're getting less than half. Also, I think it's attributed to the fact that the retail industry has implemented more and more emphasis on sanitation, HACCP programs at retail, and this has also certainly contributed to the reduction at the retail level as well.

Now, if we go to looking at how many cells of *Listeria* were actually present in the products that were positive, if we look at the MPN of these samples, you see that the majority of the positive

samples were in the 0.08 to the 0.3 -- this is MPN per gram of sample. Remember, we were checking 125 grams. So one sample in 125 grams would be 0.08.

And so with an MPN, you don't always know exactly the number since they're based upon a statistical table. A lot of times, it'll be, like, less than 0.3 or less than whatever is the lowest amount that is recorded under an MPN. But still, we're looking at number of positive samples, and the total samples, as I said, are here. And so very few samples were in the 0.3 to 0.1, and we've got three samples here at the 1 to 10 range, two samples at the 10 to 100, and three here that were greater than 100. And those that were greater than 100 were in the 200 to 300 range. So they were not at the upper level but at the lower level of that range. One thing you see is that the pre-packed, we had none in any of these ranges here. All of our pre-packed samples were at the 0.08 to the 0.3 range, which tells us that the levels in those pre-packed are also lower than what we're seeing at the retail deli.

Again, looking at a comparison of the study done in 2002 by Gombas, et al., that was used for the national risk assessment in 2003 and the 2005 samples that we did -- they're used under the current study that we're talking about today -- the majority of samples in their study also was in this 0.04-0.08 to 0.1 to 0.3 range. So that has not changed. The majority of these samples are very low, as far as levels of *Listeria monocytogenes.* Now, this is at the time of sampling before they've had a chance to sit in the refrigerator and incubate.

However, the one thing that we see is that they did have more samples in this 0.1 to 0.3 range. These are looking at percent positives. They had 78 positives in their study, and we had 55. So I wanted to put them on a equal basis, and that's why you're looking at percentages here. In the 1 to 10 range, again, they had probably about twice percentage-wise as many samples. In the 10 to 100, I think we had slightly more. In the 100 to 1,000, they were higher on the levels of MPN, as far as the

Listeria. And then they had just, I think, one in that 1,000 to 10,000 range. And in this study that was done in 2005, there were none in that range. So we are seeing a reduction in the overall level of contamination of *Listeria monocytogenes* in ready-to-eat meat and poultry whether it is in, you know, the deli or in the pre-packed product.

The deli checklist that we did was based upon a score of total of ten. Part of that was so we didn't go to a 100 and people would think that it was a public health inspection. So we wanted to have as little confusion about this as possible. Under this little scale that we did of zero to ten, what we did was assign two points to each of five categories. Personnel, the most you could get was two, the least you could get was zero; product, you could get zero to two; display case, zero to two.

For example, if your personnel were unclean, if their aprons had blood on them, if they were wearing no hairnet, if they didn't wear gloves, they would probably get a zero. And again, we trained our samplers. We had the same people

sampling all the time so that they would always try to score these places as consistently as possible.

With product, if it was not properly refrigerated, if they would leave it out at room temperature after slicing or if they'd pick up a product that had been left at room temperature from the previous customer, they'd probably lose a point. If there was raw meat in the case with the deli meat, they usually went immediately to zero because that was just a deadly critical mistake, of course, putting raw meat and ready-to-eat meat together.

The display case, if it was unclean, they would lose points. Some people at the smaller places do not have a display case. They have a refrigerator, and they would very carefully reach into the refrigerator and get your product out. Often, it would be wrapped in butcher paper. Sometimes the product was not even wrapped at some of the smaller locations.

We'd look at the visible deli facilities. Remember, we're not going inside the work area. We're a customer, so we can only see what a customer

would see. And as far as the premises, if we smelled off odors, if we saw rats, if we saw mice -- yes, we saw a few of those -- did we see dead mice, yes. Not in your major chains. I never saw anything like that in the large chains. But in some of the smaller places, we would see things. We would see cockroaches. We would see ants. We would see flies in different places. And, of course, you see those flies in some of the larger places, but by and large, these unusual types of things that were rather disgusting were in these smaller chains. We would also get ambient temperatures. If we saw standing water and things like that, we would make notes of it.

This is what the checklist looked like. I know you can't see it, but each of the delis would be scored. Since we were having them slice eight to ten products at a deli, it gave the person plenty of time to sit there and do the checklist, and they would do it as surreptitiously as possible. We had talked with Jill in case people gave us a lot of trouble. And so if anyone had a real issue with us

making this little checklist or taking temperatures, she had given us a letter to say, you know, they're going to do this, they're going to protect your confidentiality, so try not to worry about it too much. So we didn't get thrown out anywhere.

If we look at these deli checklist scores, this is for all the stores that we looked at. The A stores are the green. The B stores are the red. You can see that your major brands, your major chains, are all pretty much in this, you know, five and above; predominantly, in the eight to nine to ten range.

Now, our B stores went all the way to zero. All the way to zero was the guy who came out with blood on his apron. He was just finished cutting up some meat. He had raw and ready-to-eat meat in the same deli case, and he didn't bother to wear gloves, but he was nice enough to wipe his hands on his apron before, you know -- so that was a zero. And we had a few of those, as you can see. And of course, ones were about as bad, and two. It had to be pretty awful to get down into this range. But

you see none of your major chains were there.

Now, we did have a few of the major chains that were the three to four range, and then, but as I said, predominantly, we were pretty much up in this area, which was good news. This area down here is troubling and particularly since those B stores often don't have the educational programs in place that some of the larger chains have the resources to do.

Now, if we look at the positives in these stores based upon their checklist, this data was pretty interesting. The majority of our positives, as you see, are in the eight, nine, and ten range. Of course, that's where most of the stores were rated, and so there was also this frequency of you've got more stores, you've got more possibilities for positives.

Down in this area, these were your B stores, you know, that were positive. We only had maybe ten of those stores, so about 10 percent, then, were positive. So if they're getting these low scores -- this one, we only had maybe ten or

twelve of these stores. So the scores that are getting these lower scores, even though it's not a sanitation, it's just a visual, you know, look at the area, if they don't have a clean facility, they were much more likely to have positives. That's what this is saying.

On the other hand, the stores that do look clean are not necessarily going to be free of *Listeria*. Clean and sanitary, as we know, are two different things. You can be very, very clean, but if you're not sanitized, then we'll still have *Listeria* present. And I'd like to note none of the A stores, though, that were in this ten range, none of your big chains that got a ten were positive, had positive samples. So our larger stores -- and we had a lot of those in that ten range. So the stores that were doing a really good job as far as looking clean and having clean facilities and taking care of business, none of those were positive, and I thought that was a pretty interesting sign.

If we look at the product temperature at the time of collection, we would not actually

penetrate that product. We would use an infrared thermometer. As they would hand it to us, we would use the infrared thermometer to get a product temperature. You can see that with just -- these are just our positives because, of course, we had 8,000 samples. But looking at the number of samples by temperature on the x-axis, you can see that the temperature range of these positives ran the gambit. But we did have product in the 15, 20, you know, well above five degrees where it should have been. The way this product got so warm was that it had been sitting out. And in one instance, the store -- the refrigerator was broken, or the display case was broken. And so they had product in that. And they were trying to get it fixed.

This is just a quick reminder for us that how long do consumers keep deli meats in the refrigerator, and this was a study -- it's AMI, FDA CFSAN. And you can see that around 80 percent are keeping sliced deli meats for up to seven days. And we know that *Listeria* grows quite rapidly under refrigeration. So even if we're starting out 1 to

10 cells, we could very quickly get into ranges that would be quite hazardous within the times that the average consumer might hang on to some of that product.

Also, I was kind of curious. Fifty-six grams is a little bit less than two ounces, which is considered kind of an average serving for a sandwich unless you have children like my sons, who consider half a pound an average serving. But if you -- 83 percent of our samples were less than one MPN per gram. And if 56 grams was the typical size, then they would be consuming maybe 56 grams, which, you know, it's problematic, but maybe not so of great concern as we get into these higher ranges. Eighty percent of our samples were in the 1 to 10 MPN per gram, which means that you would be consuming in this range. Four percent were 10 to 100, which means that now we're getting into an area that we begin to get a little more concerned about. And then 5 percent were in this range here, where I would be quite concerned about those levels. And again, this is at the time of sampling, not after

they've sat under refrigeration and been allowed to increase. And we know that the generation time on *Listeria* is somewhere to up to about one log in every 24 hours at five degrees. So it can go up as much as a log per day in the refrigerator.

Some concluding thoughts for all of us is that our prevalence has decreased quite significantly based on the previous study done by Gombas, et al., and FDA, NFPA at the time, so we were down to about 0.15 percent in pre-packed and about 1.2 percent in the deli-sliced products. LM levels were reduced, also, compared to 2002 samples, and you saw the MPN tables on those.

We believe that intervention is really needed to assist some of the smaller grocery deli operators to improve deli practices. They do not have in-house resources for that. They often do not have people trained. And so I'm not quite sure what the solutions are. The people in this room certainly are better qualified to come up with some ideas than I am.

And finally, the delis that look clean and

are very attractive and have beautiful displays, as we are beginning to learn, may still have some issues with LM. But certainly, cleanliness and sanitation, based upon the fact that none of our large chains had any of the positives in the ten rated stores, shows us that, you know, that's a good start. If the place is clean, if it looks clean, if everything is picked up, if they have hand-wash stations, if they're being very careful not to let the product touch the balances when they're weighing, those all make a great difference and contribute to a healthier product. Thank you.

(Applause.)

MS. KAUSE: Thank you, Ann Draughon. I think we're going to adjust the agenda just a little bit. We're going to go ahead and take one or two questions right now. Then, at 10:00, we'll take a 15-minute break, and then we'll resume with Mr. Joe Corby and Dr. Martin Wiedmann. With that, are there questions online or here in the audience? Dr. Martin Wiedmann?

DR. WIEDMANN: So you found that the cured

meats sliced at deli have a lower prevalence than the uncured ones. I presume that there would be no reason why at deli they would be less likely to get contaminated. So if they both get contaminated with the same frequency at deli, why do you recover less from the cured ones, because it's indicated that curing, or cured products, interferes with detection. I can't quite explain those findings.

DR. DRAUGHON: Well, I have the same problem. And the only thing I could think of is that there appears to be some continuing lethality or problem with detection of LM in these cured products, some residual lethality. And of course, everything comes back to detection. You saw that the majority of our samples were less than, you know, 0.3 MPN. So at that very, very low level, anything at that point could contribute to the inability to detect. I think that's probably part detection and partly, we may have some residual lethality of the nitrites.

MS. KAUSE: Thank you, Ann. Do we happen to have anybody on the phone line who has a

question?

OPERATOR: If you would like to ask a question via the phone, please press star, then one. One moment, please. Press star, then one to ask your question. I show no questions at this time.

MS. KAUSE: Thank you very much. Are there other questions here in the audience? Dr. Dan Gallagher?

DR. GALLAGHER: Ann, an interesting talk. I just wanted to ask one question about the percent reduction from the earlier study to this current one. Could that possibly even be more than the 50 percent that we were talking about here because of the difference in the sample sizes between the two studies? In other words, I know you used 125-gram samples. I believe the Gombas study used 25, but I'm not certain. But since you had a lower detection limit, would that perhaps even drive -- show that we've improved the situation even more considerably than the 50 percent?

MS. DRAUGHON: That's a good question. And we had thought about that. And that's a very good

point because our level of detection on these samples was five times higher. So yes, I think that that's a very pertinent point. It's even actually lower. If we'd taken the 25-gram instead of the 125, I would imagine that we would have had a lot less positives just because of sampling sensitivity. So the circumstance is actually much better today than it was five years earlier.

MS. KAUSE: Thank you.

(Off the record.)

(On the record.)

MS. KAUSE: All of you have had a chance this morning to hear a little bit of background on listeriosis and also a study on retail. We're going to follow-up the morning session on two more talks on *Listeria monocytogenes* at retail. Our next speaker is Mr. Joe Corby. Joe Corby worked for the New York State Department of Agriculture and Markets, Division of Food Safety and Inspection for 37 and a half years, where, in 1994, he was appointed Director of the Division of Food Safety and Inspection until he retired in May 2008. He

currently serves as the Executive Director for the Association of Food and Drug Officials and continues to work on a part-time basis for the U.S. Food and Drug Administration State Training Branch. With that, would you please welcome Mr. Joe Corby.

(Applause.)

MR. CORBY: Well, thank you. Thank you for the invitation and the opportunity to defend the great state of New York.

(Laughter.)

MR. CORBY: A number of years ago, after I did a project with FSIS, and we did a survey of the states to see which states were active in conducting surveillance with *Listeria monocytogenes.* And I think there were 12 states that had active surveillance programs. And it was clear that New York was doing the bulk of the work in the states.

And a lot of people would ask me, well, why are you doing that? Why are you doing so much work with *Listeria?* And one of the reasons is we have a history in New York. My agency that I directed did both the manufactured foods and the retail

supermarkets. We did everything in New York except the restaurants. And there was a history that goes back to the smoked fish industry. I, in fact, worked in Brooklyn for a few years working in the smoked fish plants because we had an issue with clostridium botulinum. And we spent a number of years trying to work with them to put action plans together and to write regulations relative that were focused on clostridium botulinum.

And no sooner did we complete that, that *Listeria* really hit that industry and hit that industry very hard. And although I don't think there's really been a listeriosis outbreak associated with cold smoked fish, it clearly has been very damaging to that industry because in routine surveillance samples, there's a lot of samples that wind up being *Listeria*-positive. And we did some things with that industry that I'll explain a little bit later. Government is always ragged on for being reactive and not being proactive. So rather than just turn our backs on this and because we were exposed to it with the

smoked fish industry, we wanted to be proactive.

And we did not choose to throw up the white flag when it comes to retail food stores. And from our perspective, and I think this is a very important point, there is a huge cultural difference between large supermarkets and small supermarkets that exists. And it's not only in the level of training and education that exists with large supermarkets and does not exist with the smaller ones, but it's practices that routinely occur in these small businesses.

The use of deli ends of meats when they're not selling in the deli, well, they throw them in the ham salad; the practice of making fermented sausage without starter cultures; and there's a whole host of other practices that routinely occur at these smaller establishments, not to mention cash and carry firms, where small businesses, restaurants, and stores will go to a cash and carry, buy all their provisions and drive them back to their restaurant or their grocery store in an unrefrigerated vehicle. Those things routinely

happen.

And of course, when we see things like that, and that's our expertise, the price of poker really goes up because it really becomes a risky adventure then, and because it's a public health issue. The Post Standard is a Syracuse paper. I think the one below it was out of one of the New York City papers. And when these things occur, they do not call -- the media does not call the federal government. They call us, and they want to know what we are doing about these issues. And so because that's another reason that we have to be proactive on these issues.

So what do we do? Our surveillance is we began with scheduled samples, had about a hundred inspectors across New York State, and we would make assignments throughout the year that they would go and take samples at grocery stores, manufacturing plants, food warehouses, and it would be tested for *Listeria*. And where we found positives, we would take enforcement action. That could be going back and closing the deli. It could be a recall, a press

release, depending on where we believed the product may be in the domestic channel, whether we believe the consumer could still have that product.

Some of the worst case situations is where we would get into establishments that would have multiple recalls and multiple cases of *Listeria*-positive. We would wind up getting injunctions against those firms, and we'd put them on a hold and test. The two biggest cases was a sandwich manufacturing plant and a huge salad manufacturing plant. We just couldn't get the *Listeria* out of those plants.

And the best story, and Martin sometimes talks about it, is where we found it in one deli case in a small store. They couldn't get it out of the case. It got down into those hard-to-clean areas. They had to get rid of the deli case. It's the only way to get rid of *Listeria* was to get rid of the equipment. And it was just that persistent of an organism.

And because of this huge cultural difference in retail, we believe that the education

and training we could provide to the small business associations that represented the Korean grocers, the Chinese-American grocers, the Dominicans, and all of these groups was very important to inform them of the critical importance they have when they work in these deli areas. And the things that they're exposed to every day, like a mop and a bucket, that they think is nothing, the fact that people walk into their little deli areas and they think it is nothing, and yet it's very important. And that's where we wound up targeting a lot of our resources was in these small establishments who were unaware of those circumstances.

And then we decided to do some research with our friends from Cornell University on *Listeria*. Regulatory agencies typically do not do research. We decided to do it because we wanted to know if what we were doing was the right approach, whether we were looking at the right areas, whether we should even be going out and taking all of these surveillance samples.

We began sampling in 1997. It took us

three years to be smart enough to decide that we ought to start collecting this data and recording it. So we really don't have the data coordinated in a proper fashion since 2000. And since 2000, we've taken about 6,000 samples. Now, I left last year, but I think New York has discontinued a large surveillance of products because of what I'm about to show you. And again, it was a multilevel approach, trying to identify through sampling whether it was an issue at retail or perhaps an issue at the manufacturing plant. I told you about the enforcement actions, collecting the data, and providing education.

Here's our data results here. And typically, it was from a high, when we first collected, coordinated the data, of four and a half percent, to a low, back in '06, which was about the end of when we did all of this surveillance, of 2.8.

And here is the establishments that we regulate, where we found the products. A, where it says store, it is not the large supermarkets. Those are the smaller places, and you see the majority of

what we found was in those small stores who may be doing some of the manufacturing. They may be establishments who are making -- is an ethnic butcher shop that's making their own fermented sausage. Dairy manufacturing plant, we have one dairy plant in Brooklyn that makes the Mexican-style cheeses, and we spent a lot of time doing samples in that particular plant. And we have had some problems in that plant. The food manufacturers are the larger manufacturers, the salad manufacturers, the sandwich manufacturers. We even go in warehouses because we do collect some pre-packaged products, including some of the packaged lettuce or salad mixes. The multiple operations are typically the large supermarkets.

And here are the implicated products. The smoked fish was one of our large ones. And again, we have some skills and training about smoked fish. We know which ones to target. We know there is hot-smoked and cold-smoked, and typically, we will focus on those cold-smoked products. An interesting thing about the smoked fish, however, is that industry was

so devastated that the large ones in Brooklyn got together with, I believe, it was the National Fisheries Institute and I believe the Food Processors' Association and Cornell University and FDA and put together a *Listeria* action plan. And they employed this. And this is not a plan that should be used in retail. It is a specific plan for smoked-fish operators. And you know what? It seemed to work because, originally, we would get all these positive samples of our smoked fish plants, and then later on, we did not.

There were other processed fish where there was a lot of handling. And again, this is the thing we began to learn as we did this research. You would get establishments that would trim the bellies off these cold smoked salmons and they would throw them in a bucket, and they'd keep refrigerating that bucket day after day after day until they could fill up the bucket and ship it to somebody for further processing. Great target for *Listeria*. Great target because the more you handle a product, the more you refrigerate it, the higher the risk for

Listeria.

Fermented sausage, you go in a wholesale plant, the USDA does, I would imagine in all of those plants, they will use starter culture, which reduces the pH in that mixture that is to be fermented, immediately. It'll get it right down to 5, 3, or even lower so you can control Staph. In a small, ethnic food store, they don't use that stuff. They have recipes that their grandfather's grandfather's grandfather had passed down to them, and they ferment with salt, which means they mix it, put salt in it, and then they put it in a cooler for a month. And that is to prevent the growth of Staph. But what does that do to *Listeria*? Nothing. It does nothing because *Listeria* will grow at those refrigerated temperatures. So that became a big target for us.

Cold cuts, the deli-sliced, we had some problems, but our big one was with the sandwiches. And again, it's the multiple handling of these products that raises the risk with these deli-sliced products. The processed meats are prepackaged USDA

products that we would sample in the package, in the chub, and we had some of those. Salads was a big one, and again, it's the multiple handling. And the dairy is our friend in Brooklyn with the soft cheeses.

Our messages from our surveillance is the organism is very persistent. We recognize the importance of establishing a *Listeria* action plan specific to that type of establishment. The use of starter cultures and the multiple handling of products raises the risk, and the training of employees is very critical.

The next thing we did was a collaborative project with Cornell University. And it was done in three phases. The first phase -- and again, the purpose was to get a better understanding of what we were doing and the transmission and sources of *Listeria*. Phase 1 was a 12-month project. And we took select inspectors, and we trained them on specifically how they needed to do this project. And they would go into ten retail food stores each month. And they would collect samples of deli meats

and salads, including intact products: the whole container of unopened salad, the whole chub of a deli meat product. And they would also take up to ten environmental swabs. And where there were positives, we'd share those isolates with Cornell. They would be ribotyped.

Out of 185 foods that were tested, five of them were positive. The only deli meat we found positive was an intact product. It was not a deli-sliced product. However, we did find four other salad products, of which one was an intact product, that were positive for retail.

Of the environmental samples, we took 1,158 environmental samples. Seventy-three of the 121 establishments we went into, we would find *Listeria*. Again, these are the big supermarkets. Generally, we might find one, might find one floor drain here or there in these large supermarkets. So 60 percent of those establishments that we visited, we found *Listeria*. And there's the products. And of the 1,158 environmental samples, 151 were positive.

Here is where they were, and I think this

is -- okay. Here's the interesting thing, or what we believed was the interesting thing of the positives is that 12 of them were in the deli case right out in a consumer area, where a consumer purchases their milk. The other thing we saw was this deli sink interior, not typically viewed as a contact surface, but there's a lot of things that happen in these deli sinks. You can thaw products. You can open these packages. And there's a lot of things that go on in these deli sinks. And we thought, jeez, maybe that is a good place for cross-contamination. But you see the bulk of them in the large supermarkets were in the floor drains. And I think there was one contact area was the deli slicer. So from this, we looked at, you know, well, it's mostly floor drains, but why the dairy case and why the sinks?

So we believe that, based on this initial study, that the large supermarkets really did have good sanitation programs, that they seemed to be protecting their deli areas, this high-risk deli area where there was a lot of handling going on.

Yes, we found in the environment we would find *Listeria*. But it appeared as though through good sanitation, they were protecting their deli areas. And so we did not believe that what we found was all that surprising. *Listeria* is commonly found. But we believe that it can be controlled.

And we began to think that our surveillance might be best applied in establishments where sanitation was very poor, which took us, then, to Phase 2. Let's go into the smaller establishments, the small butcher shops, the small stores that simply make sandwiches or dispense salads. This was a six-month project. And again, these inspectors would go into ten retail food stores a month.

Again, these are establishments that do not typically have a sanitation program or have consultants coming in or have somebody within a company that has food safety expertise. Again, the deli meats and salads were collected. And where we could get intact samples, we would do that as well. And we would do the environmental swabs and ribotype those isolates.

A little bit lower here. Of the 60 establishments, 32 of them, we found *Listeria* either in the product or in the environment. So 53 percent of the establishments that we went into, we would find *Listeria*. No cold cuts. All the establishments that we did cold cuts either intact or sliced, we did not find any *Listeria*. We did find one positive salad sample out of the 51 that were collected. So our focus is let's look at the environmental samples.

In this case, we find a few more contact areas, five, six places, contact areas, where we're finding *Listeria*. This is not good. This is not good, we said. And there is our friend, the sink interior again, which was still high. There is our dairy case again, which was still high. And, aha, the milk crates, the milk crates. In the smaller stores, they typically use these milk crates. And again, I go back to what I said about the culture difference between the large and the small. It is not uncommon to drive through New York City or Buffalo through these small stores and see these

products stored out on the street. Yeah, it might be raining, and the milk is there and the milk crates, and they bring the milk in off the street or off the dirty truck, and they put it in their cooler. And all they're doing is transferring *Listeria*. So we believed, wow, what a great study. We've just incriminated these dairy crates. And they're used a lot in these grocery stores. But there it is: the milk crates to the dairy case, and the *Listeria* lays in those coolers.

The other thing we found as we ribotyped these is certain establishments were really laced with *Listeria*. And here is one establishment right here. And I believe this is Martin's data. And there's seven or eight, and you see all but one are the same ribotype. And it's in the floor drain. It's in that doggone sink interior, and it was transmitted right to the utensils that is used on product. So there was a great case of the transfer or transmission of *Listeria* from a floor drain to the sink interior right to the utensil.

Messages there? Well, yeah, there were

fewer stores implicated than large supermarkets, and we were beginning to see, well, maybe there's just 50 percent of these places we're going to go in where we're going to be able to find *Listeria* in the environment. But again, some of these places it was really laced in these small stores. And there appeared to be a more widespread distribution of the organism.

And we began to think again that surveillance might be best applied in establishments where sanitation was poor, which brought us to our final phase, Phase 3, which was to go into the bad stores. And we do have some bad stores in New York. We decided that we would target retail stores who failed their last three consecutive inspections for unclean equipment or cross-contamination issues in the deli or salad prep area. We identified all those through our data systems, and we sent our inspectors back out to do the same thing.

And the only positive product we found was an antipasto salad, which was using some of the end cuts of the deli meats that I talked to you about

earlier that, you know, rather than throw that away, let's get it in a salad. Let's get mayonnaise in it. Let's get a salad dressing or an acid into it. And that's where we found an antipasto salad positive. And again, not only did we do the food products, we did environmental samples.

Thirty-nine of the 60 establishments we found *Listeria* in. We're back up to the 60 percent. So whether it was the big supermarkets, the small supermarkets, the dirty supermarkets, or the dirty grocery stores, it appears that we were able in all three examples to find *Listeria* in about 60 percent of those places.

So let me conclude by going to the environmental samples to see what we can find there. Well, pretty much the same thing except we had more contact equipment again. There you have the deli slicers. Our friend, the deli sink, is still quite high. There is the dairy case. You know, the floors and the mats at the front, the shopping carts, we did all those, and I mean, that was easy to find *Listeria* there. People are always bringing

in *Listeria* into the establishment. There's our milk crates again. That is fairly high. There's the floor mat that you see at the front of the store when you walk into some of these little stores.

It was a very great experience for us to do this. It really helped us target our education on who really needed us. I think it helped us target our inspection approach, what products to look at, what type of practices to be concerned with, you know, like the sandwiches or the trimmings or extending a product. And I think it made us better inspectors. And though I'm not in New York anymore, I do believe they have stopped doing their routine surveillance of all of those products, and they have started collecting samples at establishments where we believe there truly is a risk. When we believe there is cross-contamination, unclean equipment, that's the time we need to be proactive and take our surveillance samples. I thank you very much.

(Applause.)

MS. KAUSE: We have time for one or two questions, and just as a reminder, if you have a

question, please state your name and your organization. Thank you. Anybody here in the audience? Yes?

AUDREY: My name is Audrey. I'm from FDA CDM. I have a question because I'm late. I don't know if someone already asked it. So compared to the *Listeria* contamination versus *E. coli* and *Salmonella,* which one is the most popular in the overall retail from your --

MR. CORBY: Well, that's an interesting question. It seems to evolve. It really seems to evolve. You know, for a certain, it was *E. coli* at one time. And then it became *Listeria*. That's a hard question for me to answer, which one is more popular. None of them are popular. It's just that it just seems like, you know, I guess *Listeria* kind of slowed us down from what we were doing with the *E. coli*, and I guess we're waiting for the next bomb to go off to see what that will be. But I guess I can't give you a good answer. They're all unpopular to us.

MS. KAUSE: Yes?

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. Joe, if you were put in charge of another city/state health department and wanted to implement *Listeria* control plans and monitoring and surveillance, what would you recommend as the best approach? Is it product sampling, environment, contact, big store, small stores? How would you sort of go about, based on your experience here, focusing your attention?

MR. CORBY: I think I would start with identifying the sanitation practices that I think all states are aware of. If I was to find out that an establishment has failed nine of its last inspections because of unclean equipment or cross-contamination, I think that probably would be a good place to target surveillance. I would also try to find out the types of practices that exist in these stores, the ethnic food stores, what they're making, what they're handling, and things like that. And again, I go back to the multiple handling of products, the practices that exist that extend a product. I would look very closely at that, and

that's -- and I would always have an education program for all businesses.

One thing we did is if a particular chain or an ethnic trade association wanted a specific program for them and them alone, we would do it, and we thought that was very important. If D'Agostino's in New York City, and we did it for D'Agostino, we would go into their stores. We would just take some very simple pictures with them, and we would bring all of their deli people together, and we would talk about *Listeria*. And we would show them in their own environment. And again, these are people that walk by these mops and buckets and they walk by these issues day in and day out thinking there is nothing wrong with it when it is. So I think that is another thing that I would do, okay?

MS. KAUSE: Thank you, Joe. We're going to hold questions. We have Dr. Martin Wiedmann next. And right after that, we'll have a period of time for questions and answers, and I'll start with folks online on the phone.

Dr. Martin Wiedmann is the associate

professor at Cornell. He serves as the Director of Graduate Studies for the field of Food Science and Technology. His research interests focus on molecular biology, genomics, and the transmission of food-borne pathogens, with a particular focus on *Listeria monocytogenes* and *Salmonella*. With that, would you please welcome Dr. Martin Wiedmann?

(Applause.)

DR. WIEDMANN: Thank you, Janell, and good morning, everyone. So what I'm going to do is I'm going to report to you some data we collected over quite a few years, collaboratively, with both New York State and -- you know, Joe's group and the group now as well as working with New York State Department of Health and the New York City Department of Health, looking sort of at, I think, a pretty global view of *Listeria* transmission, *Listeria* epidemiology, using sort of New York as our study site, I'm going to say.

One of the key tools we used is really to do molecular subtyping of *Listeria monocytogenes.* And Joe already alluded to that, that we would get

isolates from him, from his group, from the lab group there, but we also get human isolates from New York State Department of Health and for a while from the New York City Department of Health and characterized those comparatively.

So what I'm going to do today is sort of give you an overview of subtyping method just to make sure we are all on the same page, talk a little bit about diversity, different types of *Listeria monocytogenes,* and then take you into the delis to see what we really found out with using these subtyping methods on transmission and ecology of *Listeria monocytogenes* in these deli environments and how that might relate to intervention and control strategies.

So Fred already alluded to sort of molecular subtyping tools. Obviously, they allow you to take a bacterial isolate -- say you have two *Listeria monocytogenes* and, therefore, they're the same at the level of *species*. To further differentiate them to see whether they're different subtypes, and then if you have two *Listeria* from

different locations, a food and an environment, to see whether those *Listeria* are similar or identical and, therefore -- recent common answers to a recent period and, therefore, might be indicative of some sort of cross-contamination or relationship.

The methods currently used sort of predominantly is really banding pattern methods you could see here. You take different *Listeria monocytogenes,* all the same species. You apply one banding pattern-based method for subtyping, and you can see that they really represent different subtypes, DNA fingerprints, however you want to really name those. The widely used method, and PulseNet is obvious -- Pulse Field Gel Electrophoresis. And again, here, you can see a number of isolates which display the same pattern and then other isolates which are clearly distinct from each other.

These methods not only allow you to sort of detect disease outbreaks, use it for surveillance through PulseNet and other systems, or to sort of do source tracking, so if you have a food isolates, you

have isolates from different environments, in a plant or in a retail operation, to understand the relationship between together. But they also allowed us to take sort of a bigger picture at the diversity of *Listeria monocytogenes.*

Now, these are some other methods, fingerprinting methods where you take all *Listeria monocytogenes,* and when you group them based on sequence data, you really see that they fall into two major groups. One of them is sort of in green, one of them is sort of in red, and sort of a less common group, which is in blue. And it sort of doesn't really matter which subtyping method you use. You will always come up with the same three groupings of *Listeria monocytogenes.* And you could think of that as, like, sub-species, major breeds in an animal population, however you want to think of those. But these are clearly very distinct subtypes within *Listeria monocytogenes.* And then within each major group, you have further different subtypes. And that's just another example, a completely different technique, but again, you find same

groupings, Group 1, Group 2, et cetera.

And what we did initially is to look at just the distribution of these different types of *Listeria monocytogenes,* so what we call Lineages I, II, III, among human isolates, food isolates -- and these were actually isolates from the Gombas, et al., NFPA study, which was mentioned before -- as well as animal isolates from our collection.

And what you find there is that Lineage I is really overrepresented among human isolates. It's about 54 percent of all human isolates represent that lineage. But it's not that common in foods, but it is still regularly found in foods, while this, Lineage II, is more common in food isolates and less common in human isolate, sort of suggesting that if you're exposed to this type of *Listeria monocytogenes,* you're more likely to get disease. If you're exposed to this, you're less likely to get disease, at a very, very rough, superficial level. We've actually done, again, collaboratively with NFPA at that time some studies on putting this into a risk assessment framework,

and it showed that there is a significant difference between Lineages 1 and 2 with regard to the infectious dose.

But what's more interesting is if you then look at subtypes within these groups, drill it down at one level -- saying it's Lineages I, II, III, and these are subtypes based on a banding pattern-based method, you get more subtypes, and again looked at food and human isolates, and what you find there is -- and it's about the same number. So the denominator in both is about 500, 502, 507 isolates.

More interestingly, what we found is there's one group here, which represents 150, so a little bit less than a third, of all food isolates, so exposure could be common -- and again, these were the NFPA study isolates. We had quantitative data. These were also found at high levels. It's not that they were present but at low levels. They were found. They were found at high levels. So exposure is common, but human disease is very rare. So again, the same denominator. So if these ones will be equally likely to everything else, you would

expect about 150 human cases. So significantly reduced, and that's basically the statistics, significantly reduced association with human disease. Well, we have other subtypes, which are rare in food and are more common among human cases, suggesting that these are more likely to cause human disease if exposure occurs.

So now through a lot of hard work and a variety of other factors, we sort were able to figure out, initially, why does one specific subtype, which we call 1062A, is so severely underrepresented among human cases.

Basically, what *Listeria* does is the first step in its pathogenesis or in its causation of disease is that *Listeria monocytogenes* has to attach to human intestinal epithelial cells. There's a very specific molecule which facilitates that interaction. That molecule is called internalin A. Your typical *Listeria monocytogenes* have about a 800 amino acid protein which have a membrane anchor. So that membrane anchor puts that protein on the surface of *Listeria monocytogenes*, and then the

other part of this protein or parts of this other part of the protein interact with the specific receptor on human intestinal epithelial cells to facilitate attachment and subsequent invasion into these human cells.

That is, subtype 1062A has a shorter internalin A which is lacking this membrane anchor, basically meaning this protein does not get attached to the cell surface of *Listeria monocytogenes*, hence, cannot dock *Listeria* to the human intestinal epithelial cells, hence should and will reduce invasion of *Listeria monocytogenes* in these human cells. And so that's a very, very specific group of *Listeria monocytogenes* which does not cause disease. And we'll get back to how that sort of fits into a risk assessment and retail.

We actually found that this is not just one specific type which has this sort of shortened internalin A, but you can find that in a variety of different isolates all around the world. So this will be the typical full-length internalin A, 800 amino acids along, and there are various *Listeria*

monocytogenes which carry shorter internalin A molecules which shall reduce the ability to attach to human intestinal epithelial cells, as we've shown in sort of an assay here, where we actually grow human intestinal epithelial cells.

We add *Listeria monocytogenes,* which have the full-length internalin A and sort of corresponding strains -- and it's been published, so I'm not going to go into details -- which have a shortened internalin A. And you can see the invasion of the ones with the shortened internalin A is always significantly lower than the corresponding strain, which has a full-length internalin A. And you can actually do these experiments, where all you do is change that one little piece of internalin A and you take a strain to go from invading very well to not invading human intestinal epithelial cells very well at all.

This was not just studies. This was actually some initial work in France, found these isolates in France. We found them in the U.S. And if you look overall current data, 35 percent is

actually probably a low estimate -- finding about 35 to 50 percent of food isolates are actually *Listeria monocytogenes* which have these mutations and are less likely to cause human disease. And that's been confirmed with doing studies in guinea pigs, which is an animal model where we've used those to infect guinea pigs to actually show reduced ability to cause human disease.

And so these data have been floating around for a while, you know, generally by my group as well as by a number of other groups. But the bottom line is that not all *Listeria monocytogenes* are equally likely to cause human disease. And for those of you interested in the sort of details of details of it, there's sort of a series of paper which takes it from initial identification and characterization of these *Listeria* to doing animal experiments to show that these *Listeria* show reduced ability to cause disease to actually developing assays to rapidly detect these *Listeria monocytogenes.*

So bottom line is there are some *Listeria* which are less likely to cause disease. There are

other ones which have a higher association with human disease. So one of the things we did was to retail isolates, and these are the isolates from what Joe referred to as Phase 1, and I'm going to stick with the Phase 1, Phase 2, Phase 3 nomenclature Joe introduced. So there were 156 isolates. They represented Lineage I, which is overrepresented among human disease, and Lineage II. There were actually more Lineage I isolates than Lineage II isolates. So those are the ones which are more -- typically more highly associated with human disease.

So bottom line number one, the *Listeria monocytogenes*, at least some of them, a considerable portion of them, are the ones which are typically associated with human disease.

We also did some work to look at serotypes. Traditionally, *Listeria monocytogenes* has been classified in serotypes, and those of you who are sort of *Listeria* junkies like me looked at Fred's slide and saw a lot of these outbreaks were caused by serotype 4b and serotype 1/2b strains. These are

the ones which are more commonly associated with outbreaks. And again, 44 of these isolates were serotyped 1/2b, most likely, 43 were serotyped 4b. So these strains which are associated with outbreaks are found among these retail isolates.

Also, by ribotyping, we identified -- we know which certain ribotypes are associated with previous human outbreaks, multiple human outbreaks. It's these three ribotypes. Again, these are represented among the isolates from deli. Environments, including this one, which represents about 13.5 percent of these 156 isolates is this one subtype which has been associated with multiple human listeriosis outbreak.

But on the flip side of that coin, a number of ribotypes identified at retail include these, where we have isolates with these mutations, which caused reduced virulence. But there's clearly a considerable portion of these isolates out there at retail have the ability to cause disease. So it identifies that that shows that it is an issue which we need to deal with.

All right. Now, how did we -- now I'm going to move on to sort of *Listeria* distribution ecology. Before we go into a retail environment, I'll sort of talk about *Listeria* in the general environment, because unlike food processing plants, which we can do a good job with isolating them from the surrounding general environment to restrictions of entry, foot bath, door foamers, you name it, that is an option we don't have easily in retail environments. So they're intimately connected with the outside environment. So we cannot look at *Listeria* in a retail environment without understanding *Listeria* surrounding the retail environment.

And these are some studies we did in New York State. Again, where we went out, we sampled what we called pristine environments. At the time, it was probably a bad term. It should be natural environments. So these were state parks with minimal animal influence, no cows, no farming influence, at least no recent farming influence. And out of about 900 samples, 1.3 percent were

positive for *Listeria monocytogenes*. Twenty-three percent were positive for *Listeria species*. So these are these other *Listeria* which do not cause diseases, which are not associated with human illness.

In urban environments, literally, we went out into four cities in New York, collected sponge samples from sidewalks, soil samples from parks, water samples from rivers flowing through, but 7.3 percent of these samples were positive for *Listeria monocytogenes*, again, about 22 percent positive for *Listeria species*.

If we looked at -- we did not do extensive sampling of rural environments. But what we did instead, particularly because it's relevant for New York, is we did sampling of farms there. And we looked at cattle farms or dairy cows -- farms, with a history of listeriosis cases. *Listeria monocytogenes* causes an animal disease, so these were farms where some animals had listeriosis and other farms where animals did not have a history of listeriosis and then small ruminant sheep and goat

farms.

Overall samples, in general, sort of 20 to 30 percent of samples were positive for *Listeria monocytogenes* except for sheep and goat farms, which did not have a history of listeriosis. They were lower. They were about at the range of urban environments. And for those of you interested in the veterinary side, we can go over those.

So to give you a more specific example, this is Albany, New York, where we took 214 samples. Twenty-seven samples were positive for *Listeria monocytogenes*. That's more than 10 percent. Think about people, carts, other things moving into a retail establishment. It basically suggests that about 10 percent of the time, something moves and which has touched the ground, *Listeria monocytogenes* will be introduced into that environment.

And interestingly, ten of the isolates we obtained from that city were ribotype 1038B. That is one of the ribotypes which has been responsible and associated with multiple human listeriosis outbreak. So again, some of these might be subtypes

which rarely cause human disease, but they clearly are also the ones out there which cause -- which have been linked to human disease cases. We cannot make a direct correlation between that subtype causing a human disease, but it suggests that the types of *Listeria* found there have a possibility and likelihood of causing human disease.

This is just a sort of cattle environment. I just want to point out sort of the soil samples. So these are percent positives of soil samples on cattle farms from 20 to 30 percent, 30 percent if the farm had a history of listeriosis, 20 if it didn't. But again, any time people move from a farm onto a retail establishment, that probably sort of establishes the likelihood of them introducing *Listeria monocytogenes* on shoes, et cetera.

So I'm going to move on now -- so now that we sort of established what *Listeria monocytogenes* diversity looks like in the surrounding environment, let's start to take a look at these retail environments. But I'm also going to start with some data on processing plants because, really, we have

more dense data there. And it will establish some of the general ideas on the ecology of *Listeria monocytogenes*.

So this was an early study we did, actually, in New York in a smoked fish plant about five to eight years ago, I'm going to say, where we went into this one smoked fish plant over 24 months. We took samples every month. And we sampled virtually the same sites every time we went in. Drain, an apron of a person working in the raw environment, cutting fish, a filet knife, drains in the environment where finished products were assembled and packaged, coolers, floor mats, cart wheels, et cetera, and then food contact surfaces.

And what you see is not unusual for some of the more highly contaminated environments for some of the plants or maybe even retail establishments which don't have good control strategies. You see a number of different *Listeria monocytogenes*. So every time you have a colored box here, that means that sample was positive for *Listeria monocytogenes*, different boxes, different subtypes.

Now, there are issues we can discuss. We only tested one isolate from each sample. If there are multiple *Listeria monocytogenes* subtypes in a given sample, we would only identify one of them. But overall, we can establish and see a few things here. Yellow is found almost every time we come in here. That's one specific subtype. And that seems to be in this plant basically over the whole 24 months. Now, we also sampled in an earlier study three other plants in the same city within five to ten miles of this one. That subtype was basically not found in these other plants. So this appears to be a plant-specific subtype.

This one survives -- we don't really know where it is because it's found distributed through the whole plant. On the other hand, what we have here is we have one specific subtype found four times every month in a piece of equipment which is used to pull bones out of the seafood filets and to also then prepare them for making seafood salad, which is used in a mixer. So this subtype showed up four times in a row in the same piece of equipment.

It also showed up in the mixer, which basically you took material coming from here to make salads.

The conclusion from this was that *Listeria monocytogenes* found a niche in this specific piece of equipment, survived over time, and when they actually took the piece of equipment apart, steamed it, heated it to a high temperature, they were able to eliminate that *Listeria monocytogenes*.

We can spend all day talking about war stories where we find *Listeria monocytogenes*, finding it in a specific place surviving over time. Joe talked about deli cases at retail. We found it in almost every processing plant we went to. Sometimes it's a foot mat. Sometimes it's a slicer. Take Maple Leaf, where we know it led to an outbreak. Sometimes they are other pieces of equipment. But *Listeria*, if you take a big environment, it's very, very good, appears to be very, very good at finding an environment where it's protected from cleaning and sanitation and can survive over time. If that location is a food contact surface or close to food, then there is a

high risk of it continuously contaminating product. Not every product, not necessarily every day, but regularly. And that's what we found here.

And we as well as a number of other groups have published that. The most extreme example of that is a *Listeria* case in 1988 linked to one specific plant. That was the hot dog case, and Fred mentioned it in his talk. Now, that same plant 12 years later, 12 years later, different owner, was responsible for listeriosis outbreak with 29 listeriosis cases linked to sliced turkey. So a different product produced in the same plant. The only thing that stayed the same was the *Listeria monocytogenes*.

This is a subtype of the *Listeria monocytogenes* from '88. These are *Listeria monocytogenes* from 2000. We went as far working with CDC, with -- to actually fully sequence the genome of these strains to show that these are basically identical from '88 to 2000. That has been published.

So *Listeria* can survive for extremely long

periods in these environments. This is not just work from my group. This is industry experience and a number of published papers from all over the world, basically.

So when we initially started working with New York State, we looked at some of the isolates retrospectively. So some of the isolates we collected from 1997 to 2000, from 50 supermarkets and retail environments throughout -- food and environmental samples from retailers throughout New York State. This was published, but basically, we concluded that 16 of these retailers showed evidence for persistence of one or more *L. monocytogenes* over time because we found the same subtype either in product twice or in product and the environment twice, often a few weeks apart, often multiple months apart.

And again, if you want to see this, this is published. You know, it's just one example. This will be sort of very typical. New York State would go in, would find foods positive with one subtype 1062A. They would come back later, sample

environments to find the same subtype, they'd come back later to find the same subtype. This, I think, is actually the deli case example Joe mentioned. The only way they were able to get rid of that one is to get rid of the deli case. So this *Listeria* seems to have persisted in the deli case. Every time we identify a specific site, we have other retail establishments where we have absolutely no clue where *Listeria* is surviving over time. It is not easy. It is not trivial to find these niches and places of persistence.

So now if you look at the subtype data from Phase 1 Joe had mentioned, so we have 27 of these 121 establishments had two or more *Listeria monocytogenes* with the same ribotype. That was cross-sectional. So that was at a single time point.

In 19 establishments, we had two samples that had *Listeria monocytogenes* with the same subtype. Up to two establishments where we had five samples which had LM with the same subtype. Those of you who are going to do math are going to add

this up, saying, well, you said 27 here, but these add up to 28. Well, one establishment had two strains which both were found in multiple samples. That's why the numbers don't add up.

And in 11 of these establishments, isolates with the same subtype were found in multiple environmental samples and at least one of these isolates was from a food contact surface. So that says food contact surface and a drain, food contact surface and a floor.

We cannot easily establish directionality. Did it go from the floor drain to the food contact surface or the other way around? But it does indicate some level of cross-contamination and dispersal. Identifying the direction is obviously very, very difficult.

In seven establishments, isolates with the same subtype were found in multiple drains or floor samples. So it seemed to have dispersed throughout the plant.

Let's get into some specifics. So what I did here is I took sample delis, which we worked on

in this Phase 1. These were the ones -- there was a subset which New York State went in and sampled twice. So this first, here, is a set of samples from one deli, which was sampled in February '06 and again in March '07, so 13 months apart.

Here are the positives from the first sampling. Here are the positives from the second sampling. Blue marked as this was deli area floor drain had this subtype. This subtype was still found in the processing in this retail establishment 13 months later in different environments, the raw meat area floor drain and the seafood area floor drain. But the same subtype was there, both by ribotyping and by PFGE. So we used multiple subtyping methods now to confirm this.

So this is the one where we had two subtypes persist. We had another one which was found in the deli sink on number one, raw meat area floor drain, in the dry aisles, so that's the aisle where canned goods or dry goods are sold, grocery cart wheels, produce area floor drain, and found again in the deli sink, of all things, 13 months

later. Now, does that mean it survives in the deli sink? No, not necessarily. But that subtype sure seems to be somewhere there, where at least it can recontaminate it. And it is possible it's actually the deli sink where it survives.

And another one. Four samples positive the first time, deli case positive with this subtype, produce area floor drain, same subtype later confirmed by PFGE.

Another one. Here's the interesting example. Here was a second one July 2006, March 2007, and deli sink, deli area floor drain, deli area floor drain. So that was found in the deli area floor drain both times. Again, does it mean it survived in the deli area floor drain? Not necessarily. But it sure looks like it survived somewhere in that area.

So we find evidence for persistence in these establishments where we go in and take multiple samples up to more than a year apart. So it seems to be some of these patterns we observed in processing plants also hold true for these retail

establishments.

And here is the last example, where we find, interestingly, here December 2005, March 2007, so 15 months apart, deli sink, deli sink, same subtype both times.

Again, we're starting to move -- I'm not going to say these are strong data -- they are. It's still two retailers, it's still some type of an anecdote, but at the very least, it suggests we should not ignore these deli sinks if we start looking at *Listeria* in this environment. We need to consider that. Whether it means more studies, whether it means including them in the model, in the general term, I don't know. But there is some data to suggest we cannot ignore these, okay?

I can fly through those because Fred set me up very nicely. So what we did -- published, actually, in 2003, working with New York State Department of Health. We also found there are these small clusters of human listeriosis cases because the question now arises, okay, what's the public health impact of *Listeria* in retail. We found these

small clusters of cases, three cases in three consecutive months, three cases in two consecutive months, two cases with the same subtype in one month. So all these small clusters, which the *Listeria* initiative was started, I think, about when we published this paper -- also started to discover when they started looking at this nationally.

And when we look at a geographical distribution, it becomes even more interesting. Some of these clusters, which are multiple cases with the same subtype, are actually located in close counties or in the same county. So there are these clusters. And again, that fits with what CDC later on found on a larger scale and the state health departments found on a larger scale. If you have these clusters, which are in a single county and a few adjacent counties, which obviously referred -- suggests what I'm going to call a local source. That could be a retail establishment. That could be anything which serves and distributes food locally in this area could be, for all we care, raw milk processor -- we don't know. But it suggests that

some of these local events are there and, together with the data we saw from CDC, suggests that some of these small clusters and outbreaks may be linked to retail operations.

So what does all this mean? So this is sort of, you know, my personal opinion in terms of what did these data show. So I hope I've given you the data so you all can draw your own conclusions from it. And I hope some of you will disagree with me.

But what we show is that *Listeria monocytogenes* contamination in retail environment, at the very least, is not uncommon. It's not surprising because *Listeria* is also not uncommon in the surrounding environment. Our data suggests, if you look at some of Phase 2 and 3, where we've done some initial analysis, that, actually, inspection scores seem to not have that much predictive value when we look at just *L. mono* presence because what we found is, I think, 13 percent of environmental samples were positive regardless of whether it was Phase 1, 2, or 3, and about a similar proportion of

retail establishments.

There is a trend, which we're going to have to test statistically, which is to see whether there are more samples positive in the smaller and the bad -- and the environments with bad scores. That means if an establishment is positive, it's more likely to have a lot of positives. That we can test. That we will test. We have not done that yet.

But we have done some initial analysis where we looked at establishment size from the Phase 1 samples, number of employees from the Phase 1, so the 122 establishments, and *L. mono* prevalence. In the initial analysis, losing some linear regression, did not show any significant trend that, you know, the larger ones would have either less or more *L. mono* prevalence than the small ones. So we will expand this analysis now to do that with the Phase 2 and 3 data.

And *L. mono* can persist in retail environments, not surprising to me. At least some of the *L. mono* found in retail environments have the

potential to cause human listeriosis. These are not all the virulence attenuated subtypes. They are the subtypes there which are linked to outbreaks, et cetera. And then the patterns of cases and small outbreaks suggest these local events and combined with the CDC data, obviously, there is some idea that retail contributes to that.

We have actually in my lab done in collaboration with the people in the vet school done a similar risk assessment to what USDA has done with some differences, but we come up with basically the same idea about 70 to 80 percent of human listeriosis cases are attributed to deli meat, probably caused by deli meat contaminated at retail -- completely independent. We didn't even talk to USDA and FDA what we did there. Took a somewhat different approach, but -- the same data, obviously. But to me, that indicates, you know, risk assessment, epi, everything seems to fit together here.

Conclusions from this is obviously control of *L. mono* at retail is challenging simply based on

the prevalence surrounding it and that you cannot, you know, put door foamers in the entrance to each of these stores. *Listeria* is going to come in, no question about it.

Contamination of ready-to-eat products from environmental sources at retail is a major concern. We found it in environments. We found it in food contact surfaces. We find it in surrounding areas. So that needs to be considered as we look at this issue. I still believe that identification of the high-risk retail operations may need some environmental testing and monitoring. Ann mentioned that, you know, their scores, as rough as they may be, suggested that clean doesn't equal *Listeria*-free. I think some of our data when we do all the analysis is going to point us in the same direction, that we cannot just go based on inspection scores. So we need to do some environmental monitoring to look for *L. mono.*

Listeria species are too common. We found about 20 to 30 percent of, you know, urban environments, 20 to 30 percent of natural

environments, *Listeria species* are found everywhere. We start testing for *Listeria species* in a retail environment, you're going to be swamped with positives, and you cannot focus on the real public health issue, which is *Listeria monocytogenes*.

Persistence of *L. mono* in environmental niches is an important issue. The identification and the elimination of these niches is important. But the niches can and may be outside the retail environment. If you find the same *Listeria monocytogenes* three or four times in the retail environment, it doesn't mean it survives there. It could be out in the parking lot. It could be reintroduced. That is more likely to happen in retail than in a processing plant where you have good practices in place to prevent and reduce reintroduction. It could be reintroduced with the dairy crates Joe mentioned. There are many, many routes to allow reintroduction.

We need innovative strategies. Again, this is not easy. This is a challenge. And I think we also need comprehensively quantified contributions,

and this is sort of expanding broader, of *L. mono* contamination at processing. We're now at retail. We also do need to look at restaurant, home, and institutional kitchens. We got a great example from CDC: nosocomial outbreak. That's where we serve high-risk population. We can't and should not ignore that as we do these risk assessment. I think homes for the elderly, institutional kitchens, anywhere where you serve high-risk populations, we need to look at them because what is the risk of temperature used there. I don't know. It might be higher. We need to generate data. We need to look at that, too.

This was partially supported by CSREES, an integrated food safety initiative grant, together with John Sofos (ph.), and these are the people who actually did the work and other support for the overall *Listeria* work in my lab. I'm happy to answer any questions. Thank you.

(Applause.)

MS. KAUSE: Thank you, Dr. Wiedmann. We'll take questions, starting with folks on the phone.

OPERATOR: Once again, if you do have a question, please press star, then one. Please record your first and last name when prompted. Please press star, then one if you do have a question. I show no questions at this time.

MS. KAUSE: Thank you. We'll turn the floor over to the folks in the room here. Are there any questions for Dr. Wiedmann, and then we'll turn it over to the Panel as a whole. Yes? Dr. Bob Buchanan?

DR. BUCHANAN: Bob Buchanan, University of Maryland. Martin, I'm assuming that most of your analyses required enrichment techniques before you went into it. How much do you think you're underestimating the frequency of *Listeria*, due to the fact that *innocua* outgrows it substantially in an enrichment broth. I noticed that you had at least a tenfold *innocua* to *monocytogenes* ratio, which suggests that you may be using some.

DR. WIEDMANN: So to give some more background on the question, so it's been well-established that if you take a sample which contains

Listeria innocua Listeria species, and *Listeria monocytogenes*, put it in an enrichment broth, which is the general method used to do this, and grow it there for 24 to 48 hours, the *Listeria species* will actually grow faster. They can outcompete the *Listeria monocytogenes*. You might start with the 1:1 ratio -- and don't quote me on these numbers -- and you end up one *innocua* per one *monocytogenes*. You may end up with ten *innocua*, twenty *innocua* per one *monocytogenes.* Sometimes, the *monocytogenes* might die completely.

There are options to deal with that, multiple enrichments, et cetera, which are very time and labor-intensive. We did not do that. And we did use a plating media, which Ann mentioned that, too, which differentiates between *L. mono* and *L. innocua*. So it facilitates the needle in the haystack sort of searching. So we can look at the media. If there is a blue colony, that's going to be *L. mono.* And sometimes we pick up one blue colony in a background of a hundred white ones, which are *Listeria innocua* or the *Listeria species.*

So we've done something to deal with it, but it is an issue. And I'm absolutely convinced that you're right, Bob, that we're underestimating the number of *L. mono* positives because *Listeria species* are so common.

MS. KAUSE: Dr. Wiedmann, I have a question for you. In your past talks, I've heard you say -- I'm sorry. This is Janell Kause with FSIS. I've heard you say that at retail it was more important to focus on *Listeria monocytogenes* and not *Listeria species.* Can you speak to that?

MR. WIEDMANN: So the question is -- so currently, I think, it's USDA and a lot of processors will do testing for *Listeria species. Listeria species,* if you have an extremely well-run facility processing plant, you might find *Listeria species* in one out of a hundred samples, which means if you find *Listeria species*, you can suggest there's a problem, which you can follow up with and you have the resources to do that.

If you have a retail environment where 20 percent of your samples are going to become a

positive with *Listeria species,* no one has the resources to follow up on any of this as if it were *Listeria monocytogenes*. The trick with testing for *Listeria species* is when you find a positive for *Listeria species,* you have to treat it as if it were *Listeria monocytogenes*. With that frequency, you cannot do that. You do not have the -- no one has the resources to do that. If someone has, more power to them, but I do not think at the retail level anyone does.

So what we end up doing is we're going to not prioritize correctly because we have four samples with a positive for *Listeria species* or we have a chain, we have, like, ten stores which have *Listeria species,* we're going to treat them all equally, when one of them might only have *L. mono* and we should really focus all our efforts on that one.

It's a simple question of practicality. That's one of these issues where we cannot transfer what we learned from processing plants straight to retail. Even within processing plants, there are

differences. We have processing plants which have -- still working to get towards that goal, but they have a lot of *L. mono* positives, a lot of *Listeria species* positives. In my mind, and most people disagree with me, start out with focusing on *L. mono*. Get those under control first. Then you can move to *Listeria species.*

MS. KAUSE: Thank you, Martin. With that, we're going to turn it over to our panelists, Joe -- I'm sorry. Mr. Butts?

DR. BUTTS: John Butts representing AMI. I wanted to follow up a little, Martin, on your concept of testing for *monocytogenes* versus *species.* We represent the processing industry, and we do have all of our testing we do environmental is for *species*. And as I look at the sample sites that have been referenced here in our presentations today, we recognize almost all of those, maybe not all, but almost all of what we call transfer sites. And we define growth niches at that point where we can find *Listeria species* after the sanitation process. So when we're sampling transfer points,

yes, one would expect to find a lot more of these types of positives. But when you really look for the problem, we're looking for growth niches. I profess that we should be using *Listeria species* not looking at so many transfer sites, but really trying to get to the root of the problem, which is the growth niches. So I profess for more *species* testing and looking for where it really is residing as opposed to looking at transfer points, where it can commonly be found, particularly in the more contaminated areas.

DR. WIEDMANN: That's a good point, and maybe Joe can help us on this, but I think there's a practicality issue there, particularly where we did sampling, is that inspectors go and when will you find a retail establishment which has gone through sanitation to test after sanitation because the same site can be a transfer point and a niche, a slicer, for example. The only way to identify whether it is a niche is to take a sample after sanitation has occurred. That is usually at what time of the day? And then the question becomes, well, Joe's

inspectors go out at that time when they can sample the niches because the equipment has been sanitized. So in an ideal case, I absolutely agree with you. I think the practicality of it -- and that might be there more once we start moving towards testing by retail industry. But as long as it's from the inspectors, I think it's going to be much, much harder to sample those.

MS. KAUSE: Thank you, Martin. I'd like to open it up to the entire Panel. So questions that you have for either Mr. Joe Corby, Dr. Ann Draughon or Dr. Martin Wiedmann, and Dr. Fred Angulo. Not seeing any questions, we'll check one more online.

OPERATOR: If you have a question, please press star, then one.

MS. KAUSE: Well, with that said, if there are no questions, we'll take --

DR. WIEDMANN: I'll ask one. I'll start it.

MS. KAUSE: Okay. Please go ahead, Dr. Martin.

DR. WIEDMANN: I think someone needs to

start it. So I have a question for Fred. So when you look at these clusters and outbreaks, obviously describe these small clusters, how close are you to really identifying all the small clusters? What percentage of the listeriosis cases or current small clusters? Do you need -- looking in the future, as other subtyping methods, such as MLVA are applied, are you going to pick up more small clusters? And what's the chance of them then getting traced back to these local establishments, whatever they be? Are we there yet at detecting all these small clusters or how far are we away from that?

DR. ANGULO: Well, of course, the most success in getting to the point of contamination is when we have larger outbreaks, and we could do more, nationally, to improve surveillance at the state levels and also at the central level, at the national level. Not all patients that have laboratory-confirmed *Listeria* infections have the isolate from those patients make it to state public health labs. Not all state public health labs PFGE all isolates and contribute them to PulseNet. And

only about two-thirds of patients who have a laboratory-confirmed case are being interviewed now as part of the *Listeria* initiative.

All of this reflects priorities, in terms of resources at the front lines of surveillance at the state level. And so with enhancements in food-borne disease surveillance, which is likely to come because of initiatives on food safety, we would see more -- larger outbreaks or outbreaks -- we would see more clusters of *Listeria* being identified, and the clusters would likely to have more cases to be identified, which would increase the likelihood of trying to get to the source of contamination.

But I do think you do -- it's not reasonable to expect that in every -- we have a very, very sensitive cluster detection process with PulseNet. PulseNet detects the clusters quite well, but it's not reasonable to expect when you have a cluster of only three or four cases that you always will be successful to identify the source.

So I think the other arm of surveillance that's needed is we need stronger ties between --

with monitoring samples that are gathered for *Listeria* either at processing or at retail, as examples demonstrated in New York State, where isolates from the retail environments are put into PulseNet and compared with the human isolates and lead to a lot of opportunities to identify sources that would not be possible based upon only patient interview information.

So there are ways to also on the frontlines in which more states could be sampling food items like they have done in New York, and there could be opportunities for partnerships between the Departments of Agriculture and Departments of Health. But a lot of it is resources.

DR. WIEDMANN: But if those resources are there, we probably will see more clusters linked to -- as a retail, other operations, hospital kitchens, et cetera. And I think that's going to be a driver, which is going to happen regardless of what happens with, let's say, a risk assessment, et cetera, and that's going to drive some of the things we got to do because we'll have to generate more

knowledge on what is the source. Now that we have a cluster linked to a retail, what went wrong? And that's one of the big things in the processing industry is that these outbreaks were traced back to primary sources, to processing plants, and then the processing plants figure out what went wrong --

OPERATOR: Excuse me. I'm sorry. We're not able to hear you over the phone.

DR. WIEDMANN: So what I said is the long-term here is going to be that more clusters are probably going to be detected. They're going to be linked to retail investigations or other sort of, again, I call it local sources, for lack of a better word. Follow-up is going to happen. It's going to identify the underlying problems, and that's going to drive improvements from the -- you know, if you have that public health surveillance improvements there. And I think that's going to happen, and I think we all have to recognize that.

MS. KAUSE: Dr. John Butts?

DR. BUTTS: A point of clarification on our previous conversation. I think you may have been

talking about doing *mono* testing, or *Listeria monocytogenes* testing from the regulatory perspective. And I do agree with doing it that way.

(Laughter.)

DR. BUTTS: I was focusing on doing *species* testing and not looking at the effect sampling, which we believe should be done by the regulatory agencies, but finding the cause, which I truly believe needs to be done with *Listeria species* testing because of the point brought up by Dr. Buchanan. We do have outgrowth potential. So we're looking for any point where that organism can survive as a growth niche. Yes, from the regulatory, measuring the effects, please stay with *mono*. But encourage the investigative techniques to be with *species.* That way, we have a much better chance of finding that growth niche. Any comments?

DR. WIEDMANN: We can battle that for a while. I think, again, practically looking depends on how many positives you have. If you move down to a point where you can follow-up on every *L. mono* fully, rapidly, and deal with it, you're ready to

move to *Listeria species.* I do not believe, based on what we've seen at retail, we are ready.

And then there's the technology aspect to it, too. Yes, that competition issue was a problem. Now we move to PCR-based screens, it becomes much less of an issue. We used to plate. We have four colonies to all *Listeria species.* We said there's no *L. mono.* Now we do a PCR. One *L. mono* out of a hundred to 500 *Listeria species* will still give us that PCR positive. So the technology are there that we can actually reduce the issue -- we did not do PCR screens on those, but most companies will do that, will do PCR screens because it's fast. So there's technology which will drive that, which will make it more feasible at least in the -- I'm just worried people get overwhelmed, and I've seen it. I think you've probably have seen it, too. They get overwhelmed when they get too many positives and they just throw up their hands and do nothing. And if you test for *L. mono*, we are less likely to get it. It's a simple practicality issue, in terms of resources.

MS. KAUSE: I see several other hands in the

audience.

UNIDENTIFIED SPEAKER: Excuse me, Janell?

MS. KAUSE: Yes?

UNIDENTIFIED SPEAKER: Janell, this is Sheila. Can we take maybe one more question and let the group go for lunch so we can stay on schedule and make sure everybody comes back this afternoon?

MS. KAUSE: Okay. We'll take one more question.

MS. CHEN: Does anyone have any suggestions on how to do *Listeria* enumeration in regulatory agency, considering there are only 10 percent of sample becomes positive. And should we do *Listeria* enumeration and presence and absence at the same time or should we wait until sample becomes positive to start doing *Listeria* enumeration. And --

MS. KAUSE: Before the Panel responds, could you please state your name and organization?

MS. CHEN: Yi Chen, FDA.

MS. KAUSE: Thank you.

DR. WIEDMANN: So the question was I think if I understood it correctly should we do *Listeria* --

quantitative testing for *Listeria* to enumerate or should we simply test for presence/absence in retail. Do I understand that correctly?

MS. KAUSE: Hold on a sec.

DR. WIEDMANN: No, I did not? Okay. Let's try again.

MS. CHEN: No. The question is should we do *Listeria* enumeration simultaneously as you're testing presence and absence, or should we wait until you find out the *Listeria* is positive and then start doing enumeration?

DR. WIEDMANN: All right. So the question is should you test -- enumerate every sample with huge labor-intense, knowing that a number of them are going to be negative or do you wait and start enumerating until the sample is positive. So I think for a lot of the things we talked about, you know, testing environments, food testing, we don't need to enumerate right now. Where enumeration is critical is for it to get data which can be used in the risk assessments.

So I think there's a dichotomy there. For regulatory, I see very few applications where

quantitation is necessary right now. For generating data for risk assessments, where we are right now, it is very important that we do quantification. We need those data. That's how I see it, but I'm sure that someone else who has some --

MR. CORBY: I really can't answer that. Again, we just looked to see if *monocytogenes* was there, and we were not interested from a regulatory perspective whether it's enumerated or not. We would leave that up to Martin. So it was never an issue to us.

DR. DRAUGHON: I guess I can address that since we did a delayed reaction on ours. In a perfect world, it would be nice to have everything enumerated. It's just that it's so darned expensive, and most of us don't have --

OPERATOR: I'm sorry. We're not able to hear over the phone.

DR. DRAUGHON: Most of us don't have the unlimited resources, regulatory or anywhere else, that we can actually afford to do that based upon the value of the data that's being generated. While those of us

doing risk assessments, we would really like to have that data. At this point, it's just not practical for most people in those groups.

MS. KAUSE: This is Janell Kause, the Director of the Risk Assessment Division for FSIS. And look out at Dr. Sherri Dennis who also heads up a risk assessment staff at FDA. And we'll tell you, we cannot develop risk assessments to inform policy decisions without enumerations. So we all agree that quantitating it is important, but whether or not you can do it at the same time, it's a labor issue.

DR. DRAUGHON: This is Ann Draughon again real quick. Since *Listeria* does grow slowly, at 4 degrees C, although it may not be a perfect way to do this, if there is a 24-hour or less lag and we enumerate once we do have a positive, as long as we are documenting that and doing it consistently, then I think that would perhaps be a possible solution.

MS. KAUSE: Thank you, Ann. And with that, I would like you all to thank the Panel.

(Whereupon, a lunch recess was taken.)

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

DR. DENNIS: Want to welcome everybody back from lunch, and we're going to get started with the afternoon session. My name is Sherri Dennis, and I'll be the moderator for the afternoon. This is part 2 of our public meeting on the Interagency Retail *Listeria monocytogenes* Risk Assessment.

We have a full schedule for this afternoon. We're going to have a series of talks to give you a very good idea about the scope and the objectives of this risk assessment. We have talks on the conceptual model that's being developed and on the data. We'll have an opportunity for a few questions after each talk, and then we do have time set aside for question and answer.

After a break this afternoon, we'll have a Panel discussion, and then we have time for public comments. I would encourage you if you would like to speak during the public comment period to please sign up. There's a sign-up sheet out by the registration desk.

Following the question and answer period

before lunch, there was one question, and Ann, I think you wanted to respond to that. Do you want to do that now?

DR. DRAUGHON: There were several people that were asking about this, and it was the question regarding should you do simultaneous enumeration as well as detection of *Listeria monocytogenes* from samples. And I guess I wasn't clear on that last comment that I made, and I wanted to be clear about what we would recommend.

In preparation for that study that we did, we actually inoculated samples and did the 24-hour incubation while we were doing the normal protocol just for detection. And, of course, we did not enumerate unless the sample was positive. And when we did that, it made no significant difference in a 24-hour period.

So what we would recommend is rather than doing simultaneous enumeration and detection, which really is very time consuming and laborious, that you go ahead and run your normal detection methodology for *Listeria monocytogenes*. If you get a presumptive

positive, then start your MPN or your enumeration method.

And the reason for this is that the risk assessment people in this country need that enumeration data. So if we don't provide any enumeration at all, then that data becomes much less valuable, overall, for them. So from a regulatory perspective, I think, particularly, if you're doing that, we would like to see numbers in addition to the presence or absence.

DR. DENNIS: Thank you, Ann. We'll now go into the first talk for this afternoon. The first speaker is Janell Kause, and it's my pleasure to introduce her. She is the Director of the Risk Assessment Division at FSIS, and in that capacity, she provides oversight to the development of quantitative microbiological and chemical risk assessments that are required to guide Agency food policies, particularly those that are designed to further understand mitigation food-borne illnesses that are associated with meat, poultry and egg products consumed in the United States. Janell has led the development of a

number of risk assessments, including those related to *Listeria monocytogenes* and the 2003 FSIS deli meat risk assessment. Janell?

MS. KAUSE: Thank you, Sherri. I'm going to give each of you a brief overview and scope and purpose of today's risk assessment. As we've said, this is a kickoff meeting. We are initiating a brand new risk assessment. So rather than developing one and presenting it to you later for your input, what we are doing this time is we are seeking input early and often. So this is a beginning of a very long dialogue that we hope to have with each and every one of you.

Before I begin, I think it's important that everybody knows what is risk assessment. Risk assessment is the scientifically based process of estimating the likelihood or probability of exposure to a hazard and the resulting public health outcome as a result of that exposure. It is actually used to facilitate the application of science to policy or science to making decisions. A lot of times, people don't realize why we conduct risk assessments. It's not an activity in and of itself. It's actually a

really practical tool for informing decisions, wanting to have a better understanding of the extent of the problem and actually integrating data and information to do so.

Risk assessment is often confused with risk analysis. Risk assessment is one component of risk analysis. Risk analysis, by definition, is comprised of three primary components: the risk assessment, or science component, which is there to evaluate data and information and integrate it into an algorithm, and it's used to estimate exposure and subsequent risk of illness. Risk management takes that scientific information and weighs it with other policy considerations, legal, economic and other considerations that are practical in making the actual decision. Risk communication, of course, is the exchange of information not only among risk assessors and risk managers, but amongst stakeholders, risk assessors, risk managers, and the entirety of the process.

So today we're going to focus on risk assessment. So why do we use risk assessment? It's a

scientific basis for food safety decisions. As I said, it integrates data and information, systematically addresses food safety issues, focuses resources to improve food safety. Basically, it gives us a clearer picture of what is actually happening out there. It actually predicts public health benefits of changes in policies, behaviors, practices or interventions. So it is a tool that we use to actually link these things to public health outcomes rather than -- and it does so objectively and explicitly.

As Sherri has mentioned, we've conducted a number of *Listeria* risk assessments over the years. And up front, before I go into all the *Listeria* risk assessments, some people actually think it's a one size fits all. It's very important to know that each risk assessment is designed to inform a specific set of questions or options. And there's times to use risk assessments and there's times not to use risk assessments. And I wanted to make sure that this group heard this.

When you have complete information, you

don't need to estimate or predict the future. You don't need to use these tools. You just simply calculate. You do not need a risk assessment. You do not need a risk assessment when you have no data or information because if you try to do the estimation, you have so much uncertainty, you won't know what it's telling you. So when you do risk assessments, you do them when you have some information but not complete information, and you want to link it to the public health outcome.

With that said, the risk assessments that we've conducted over a number of years, we started building our first risk assessment in 1999, and that was the FDA/FSIS quantitative risk assessment for *Listeria monocytogenes* in ready-to-eat foods. And this risk assessment looked at 23 categories of ready-to-eat foods. And I'll go through each of these in a little bit more detail.

The next one we conducted was one for deli meats, and then we conducted one that looked at verification, how we can improve our inspection processes. And then, finally, we conducted one that

compared the risk of *Listeria* from deli meats sliced at retail versus those sliced in the plant.

So it's already mentioned that each risk assessment is designed to inform a specific question. So for the very first risk assessment we conducted -- and I'm going to walk you through a little chronology because it's a little bit helpful to understand how we took a tiered approach to where we are today.

The first question was which foods posed the greatest risk of listeriosis. Believe it or not, when we started, we know listeriosis was almost all food-borne, but we didn't know which foods caused the greatest challenge. We didn't know if it was hot dogs, deli meats, sliced cheeses. We just didn't know.

And so what we did is we conducted with FDA a quantitative risk assessment, looked at 23 types of ready-to-eat foods, and it is a retail to table probabilistic model. And after when we completed that, what we found out is this slide. This is giving you the predicted cases of listeriosis per serving among the total population, and I just marked a few of

the things at the bottom. You can see deli meats is far and away posed the highest risk per serving. And when you look at it again, you'll see on a per animal or population basis, it also posed the greatest risk.

If you're able to, with your handouts, look at the past slide, you'll see that some things that were a higher risk per serving like pate was not a high-risk on a population basis because not many people eat pate in the United States. That's the reason.

At this time, when we completed this risk assessment -- it was originally completed in 2001. At that time, it wasn't known that deli meats posed the greatest risk of listeriosis. In fact, the epidemiological data suggested it might be other products such as hot dogs. The following year, after we put out the very first risk assessment, 2001 and 2002, as Dr. Angulo pointed out, we had a nice big outbreak, and it was clear that deli meats were posing a problem.

The next set of questions we had: since deli meats posed the greatest risk of listeriosis in

the United States, we wanted to know what processing interventions effectively controlled *Listeria monocytogenes* for deli meats. So the 2003 FSIS *Listeria* risk assessment took the original risk assessment we built and used the deli meat pathway. And also, what we did is we added a module. So rather than it be a retail to table risk assessment, it was a plant to table risk assessment. We built this risk assessment in about three months, held a public meeting, and what we found from this risk assessment was very helpful for developing our policy.

This is the output of that particular risk assessment. Prior to doing this risk assessment, FSIS was focused primarily on testing and sanitizing food contact surfaces and testing product. That's all the bars that are in yellow there. As you can see, they weren't as effective in terms of an intervention as much as product formulation and post-lethality interventions. What this slide is simply showing you is that the most effective set of interventions is a combination of product formulation, for example, the antimicrobials, and post-lethality intervention. It

was far and away more effective than any amount of testing and sanitizing we can do.

The result was that we implemented in June 2003, the interim final rule, which was finalized in October 2003. We put forth Alternative 1, which was the use of post-lethality treatment and antimicrobial agent. Alternative 2, which many of you are familiar, was just the use of post-lethality treatment or use of an antimicrobial agent. And Alternative 3 was the use of sanitation only. And what we decided to do is that we would allocate our inspection resources based on the amount of control industry had in place for the process.

And what you're looking at here, there's a graph, and it's showing the adoption -- industry's voluntary adoption of these interventions. And over time, they will tell you that they did adopt many interventions, and they did put many controls in place. And we did see a decline.

This slide is showing a reduction of *Listeria monocytogenes* in deli meats from the manufacturer. And what you can see is there's been a

great amount of decline. But what we saw in the listeriosis cases out there was there was a decline, and then, as Fred Angulo pointed out, there was a plateau. So our question was we're seeing declines in contamination in the products that we're regulating. We're seeing forward movement at the manufacturing plant. What else could we look at?

Well, FDA and FSIS, back in 2004, quite some time ago, did a back-of-the-envelope analysis, and it was just a quick analysis using industry data. And what we found out is that it looked like listeriosis was predominantly attributed to deli meats sliced at retail. Instead of using that data, we went ahead and we decided that maybe we needed more representative data, which is the talk that Dr. Ann Draughon gave this morning. That was the National Alliance for Food Safety and Food Security data. She went out and they conducted an extensive survey on deli meats to garner that data for our risk assessment to revisit it.

And so we conducted a comparative risk assessment that looks at pre-packaged versus retail-sliced deli meat. And you can see I'm showing two sets of data,

the data we originally used, which was NFPA data, Gombas 2003, and AMI's data, consumer behavior data, versus NAFSS data and RTI consumer data. And I'll show you what the results were for that.

Basically, Ann has already shown you this, but what we saw with the new contamination data, NAFSS data, is we did see a higher prevalence in retail-sliced deli meat. We also said that the retail-sliced deli meat had higher concentration of *Listeria monocytogenes*.

On the next slide, what you'll see is when you compare them side by side, the NFPA data and the NAFSS data, you can see, overall, both of them had higher prevalence and higher levels of LM in retail-sliced.

We not only look at the contamination at retail, but when we do a risk assessment, we followed all the way up to the consumer. And originally, with the AMI data, we didn't have a lot of differentiation between how consumers handled pre-packaged deli meat versus deli meat sliced at retail. Some RTI data came out later, and Dr. Regis Pouillot, who is going to

speak later today, analyzed this data for us, and we took a look at it. And what we found is consumers tend to use retail-sliced product more quickly than the pre-packaged. This is probably not a surprise to many of you. So this limits the amount of growth of LM in retail-sliced product as it moves out towards consumption.

Using the newer consumer behavior data and the newer retail contamination data, what we found is basically about 83 percent of listeriosis cases and death attributed to deli meats are from those that are sliced at retail. And Dr. Dan Gallagher, who is here with us, conducted this risk assessment, and he broke it up by the use of growth inhibitors, with and without growth inhibitors. And what you're seeing, of course, is using growth inhibitors does help to some extent.

So why are we seeing it? I think we've had a number of comments that came in on that particular risk assessment. Our docket closed on June 8th. We had a number of comments that came in. And a lot of the comments that came in were centered around the

question of so what are we going to do next? Well, basically, each of these risk assessments have given you a piece of the puzzle. The first one told you which food. The second one told you which intervention during manufacturing. The third one told you that the challenge was probably more at retail, which is consistent with other studies that we heard today.

But what we don't know is so what does somebody do about that? So we have a lot of hypotheses at this time. It could be that maybe more than one kind of product is manipulated and that's causing them to more likely be contaminated. It could be as Martin pointed out. It could be stuff coming in from the retail environment that came from the outside into the retail environment. There's a number of things.

At this time, the purpose of this risk assessment is to better understand what is going on at the retail environment. A lot of researchers are doing studies, but what they're doing is they're doing -- like, I'll do a slicing study and get a

transfer coefficient. That's helpful, but that's not a very holistic look at the system. So I think what we're asking people to do is take a look at the models we're going to present to you today, think about the kind of data and information that you have, and start thinking about what might match up.

So the objective of this risk assessment, the new one that we're initiating, is to ascertain the impact on public health of current practices and potential interventions that reduce or prevent LM contamination in ready-to-eat foods, sliced, prepared, and/or packaged in retail facilities.

The type of risk management questions that had been posed to us are what is the exposure of *Listeria monocytogenes* from consuming ready-to-eat prepared in retail facilities; what are the key processes that increase ready-to-eat foods' contamination at retails; and how much is the relative risk per serving reduced according to the specific risk management options?

So with that said, I'm getting ready to turn it over to Sherri, who will talk -- who will introduce

the rest of our speakers, but this is a new risk assessment, a new *Listeria* risk assessment. It's one of several. As I explained, we're getting closer and closer to understanding the challenges and implementing various actions to address it. And in this case, we're wanting everybody to be engaged, both the public and the stakeholders, to help us come to a better understanding as to what exactly happens at retail.

Currently, we're collaborating with the Department of Health and Human Services, Food and Drug Administration on this retail cross-contamination model. We want to develop data specifically for the risk assessment. We are working with Cornell University, Virginia Tech, as well as the University of Maryland, and the Joint Institute for Food Safety and Applied Nutrition. And we're also asking that stakeholders to participate early and often and be actively involved with us in this process. Thank you.

(Applause.)

DR. DENNIS: We have time for one or two questions. I'll take one from the audience, and then

we'll see if anyone on the phone has a question.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. I guess I'm just sort of hypothetically trying to think through this, but in looking at the information you just shared with us, there was -- you could see a significant decline. Once FSIS implemented its programs, its control programs, the alternatives, you can see the drop in *Listeria* in deli meats at manufacturing. And that product, I'm assuming, is for the purposes of both pre-packed and retail-sliced. And then Ann presented data that showed from 2001 to 2005, both pre-packed and deli-packed had a reduction of almost 50 percent in the number of positives. Yet Fred has said during that same time, we sort of flat-lined on incidence.

I guess that leads me to raise the question of do we think the risk ranking, in fact, may no longer be accurate. If we're lowering *Listeria* more than 50 percent in this category, but the cases of listeriosis haven't changed, are we maybe looking at the wrong product?

MS. KAUSE: I think at retail we're going to

look at a number of products in this particular risk assessment, not just deli meats. There'll be a wide variety. I think one of our hypotheses at this time is that, yes, we're seeing a reduction in LM contamination in at least FSIS-regulated products. But since listeriosis is plateauing out there, it draws us to think that something is going on at retail, in terms of cross-contamination, which is consistent with what Joe Corby and Martin Wiedmann and Ann Draughon showed this morning. And so we're thinking that people are making headway in the manufacturing plant, and then it goes downstream and gets contaminated since *Listeria monocytogenes* is an environmental contaminant.

UNIDENTIFIED SPEAKER: I'm coming, Jill. One sec.

DR. HOLLINGSWORTH: But I guess I'm going back to Ann's data that shows a 50 percent reduction in LM positives both in pre-packed and deli-sliced. So if LM, overall, in the whole meat category has declined by 50 percent, but human cases of listeriosis have not, can we -- do we need to go back and look at

the risk ranking and say is it the deli meats that are causing that same -- I mean, why did we plateau on listeriosis if the meat levels are going down?

MS. KAUSE: Thank you, Jill. I think I better understand your question. You're wondering about listeriosis cases overall, and we're looking at relative risk. And you're saying, well, you know, you're looking at relative risk of about -- I don't know -- what was it, like, 1,600 cases are attributed to deli meats, and going back to that original 2003, I guess, risk assessment that says deli meats are probably the primarily responsible. We can revisit that, and we certainly will. With the more current data, of course, we are still seeing a higher challenge with deli meats sliced at retail than those in the plant, but the overall number of case, we certainly can revisit.

And that's a good point. Of the public comments -- we're now just starting to wade through the public comments on the comparative LM risk assessment, which will cause us to go back and revisit both risk assessments, both the 2003 and the 2009 risk

assessments for *Listeria*. I'm not sure if it will change the relative risk, per se, but we certainly can look at overall cases.

DR. DENNIS: We'll take one more question here, and I'd like to go onto the folks on the phone and give them an opportunity. Amir?

DR. MOKHTARI: Amir Mokhtari, RTI International. Just have a comment about reduction in the number of positive cases and then how it's associated with the reduction in risk of listeriosis. Maybe we can reduce the number of positive cases, but we are not talking about the contamination level of those positive cases, which is actually we talked this morning about how that's going to impact the magnitude of risk because we're all talking about number of positive cases. Yes, we are reducing those positive cases. But maybe the ones that are remaining are highly contaminated, and that's why we are seeing this increase in the level of risk. Just a comment.

MS. KAUSE: Thank you for your comment. And for that reason, that's why we have interest, of course, in enumerated data, as we might be changing

prevalences. Maybe the problem is from highly contaminated product. We, at this time, we're still in the exploratory stage to better understand the sciences to how that links. Thank you.

DR. DENNIS: Okay. We'd like to just check and see if there's anyone on the phone that would like to ask a question.

OPERATION: Again, if you'd like to ask a question, press star, one.

DR. DENNIS: Okay. We'll go onto our next speaker, Dr. Dan Gallagher, who will give you a much better idea of what this model is going to look like as we have it conceptualized at this time.

Dan Gallagher is an Associate Professor of Civil and Environmental Engineering at Virginia Tech, with a specialty in computer simulation and statistics. He was one of the co-authors of the 2003 FSIS risk assessment for *Listeria monocytogenes* in deli meats as well as the FSIS comparative risk assessment in ready-to-eat meat and poultry and deli meats that Janell discussed. Dan?

DR. GALLAGHER: Thank you. And thank you

for this opportunity. I'd like to spend about the next half hour, if I can find it -- sorry.

DR. DENNIS: I'm neglecting my duties, here.

DR. GALLAGHER: That's it. Thanks. Thanks, Sherri. Trying to give you an overview of what the cross-contamination model might look like and what some of the considerations for it are.

There's three main topics I'd like to talk about. One is just some basic cross-contamination concepts, what do we mean when we use that term, how might we start to apply that at retail, and then how might we use this type of model to add sort of risk management questions. How do we integrate the policy into it?

Cross-contamination is the physical movement of a bacteria, or other contaminant, from one location to another, all right? That definition right off means we've got to start tracking locations. We've got to start tracking counts at locations over time. So that's pretty much defining the framework of what a cross-contamination model needs to start from. Bacterial concentrations will change because of growth

that would normally increase them. They will decrease because of cleaning or sanitation-type issues, and then we also will account for the additions or losses because of this cross-contamination process. So the model needs to be able to track bacterial concentrations at different locations over time.

Let's do a quick and easy example. These numbers that you'll see from my talk is just conceptual. They're all made up, all right? So they're purely hypothetical. We're going to slice a chub. Let's assume that face of that chub starts off with ten CFUs, ten organisms. And the slicer starts off uncontaminated, and we have what we call a transfer coefficient, how easily the bacteria moved between two locations of 40 percent for this example. So 40 percent of those organisms will transfer to that uncontaminated slicer. The remaining organisms will move on to the consumer, to the customer, all right? So that's an example of a cross-contamination. We started off with only the chub contaminated. Now we have some product contaminated and a slicer contaminated.

Now, when the next customer comes along and we start off -- let's say we start off with a chub that has no contamination, no organisms at all, but we've still got four organisms on the slicer. So when we slice that, roughly 40 percent, and I'll round that to two for this example, we're going to get transferred to the product leaving with the customer, all right?

So see, this becomes a bookkeeping process. Where are the organisms? What are the transfers? What concentrations do they move to? We also need to account for growth and death, so maybe the slicer is sanitized, so that'll reduce the concentrations. Then maybe overnight in the niche area, the organisms will grow up overnight and increase a little bit.

So those are kind of the mechanisms that we're tracking in the cross-contamination model. We've only really been looking at the slicer. We need to do that for multiple sites.

So why is this a problem? Why are we concerned about this? If I start with an uncontaminated chub and slice it through an

uncontaminated slicer, hopefully, I'm getting an uncontaminated product to the consumer. The same thing starts off with a contaminated chub, I get contaminated product -- not surprising -- but in this case, because of the cross-contamination, we've now contaminated an additional site. So now the slicer is contaminated. And if I come along with other chubs that start off clean, they can pick up some of the organisms from this slicer and leave with contamination.

So the cross-contamination tends to spread the bacteria concentrations across many more servings than if it wasn't present to begin with, and now the problem is these might be low levels leaving the store, but if that's a product that supports growth, we can have several orders of magnitude increase in the concentrations before the consumer uses it.

All right. So how might we apply some of those concepts more specifically at retail? Again, we need to talk about sites, where are our bacteria levels we want to track, and events that move the bacteria from one site to another.

So sites are just locations that we're going to track. We could talk about slicers, countertops, hands, gloves. We'll talk in a little bit we probably need to simplify some of these. We might have a generic non-food contact surface that would be a lot of these individual sites because we don't have enough data to track them individually. But we saw in some of the earlier talks from Joe Corby, floor drains might be heavily contaminated on a long-term basis.

The next question is does bacteria in these sites ever transfer to any other site? So what event might take a bacteria cell from one of these locations to some other? What are the events that will cause that kind of transfer, all right? So slicing a chub, wrapping the chub, cleaning it, opening the case, that might allow the bacteria to transfer among those different sites also needs to be tracked.

Just conceptual retail environment, the case, here, the worker, the slicer, the food preparation area in the back. Okay. Maybe these are the sites that are contacted when a customer is served. So the worker is taking them out of the case,

slicing it, and there's the table they're laying it on. So cross-contamination can occur for this event across those different locations.

Then maybe they work with some deli salad for a while, so they're not using the slicer, but maybe their gloves get contaminated and they forget to change them. So contamination from other food areas. Then maybe they do some food preparation, area back in the sink. Now, if there is a chance that the bacteria can get out of that sink and onto the worker, that's an event that we would be concerned about. The fact simply that there is bacteria in the sink, but not in and of itself enough to know that cross-contamination is occurring.

All right. So then this becomes a bookkeeping process. The blue examples here are locations that we're tracking, so different types of chubs, different slicers, a food contact surface, a non-food-contact surface. These are the events that will track we'll call exchanges.

So we start off in the morning, and we know from the previous day the concentrations at each one

of those locations. Maybe the first thing they do is they come in and they'll clean the locations they can access. So they'll clean and reduce the concentrations on the slicer and maybe the floor, the non-food-contact surface. Then they'll serve a variety of customers, and let's look at some of these.

So in this case, a contaminated chub comes out, customer leaves with some contamination. Here, a non-contaminated chub comes out. The slicer was contaminated, so they leave with a low level of contamination in the product now.

Here is an example where a heavily contaminated chub comes through. In this case, it's also able to contaminate both the slicer and the food contact surface area, and the customer leaves with a contaminated serving.

Another customer coming in, this was an uncontaminated chub, but now because they're using the contaminated slicer, they're leaving with some.

Each one of these, then, is a time series, and we will have those kinds of time series data for all of the locations that we're tracking. And between

each event, then, we're looking at does growth occur, does cross-contamination occur across those different events, or locations. Maybe they'll clean it again for the sites they can get. Maybe overnight when the store is closed, some of those locations some growth can occur. And then this becomes our starting status for the next morning.

So we can run this for a series of computer-simulated times for as long as we need. In each case, we're tracking this time series at each one of those locations. So we can answer things like how long is a slicer typically contaminated for?

The ones that will move on is this column with the customer serving. We want to relate this back to a public health outcome. That's the one that will eventually lead to consumption. So this is the same example but in a more flow diagram kind of process. These are the different major events that might occur, so contamination from a non-food-contact surface, the floor, the sink, all right? There's some probability that will occur.

The one that we're spending the most time at

this point on is serving customers because that's where most of the transfer and the contact sites occur. Pick the -- get the chub out, remove it from the case, unwrap it, slice it, wrap it back up, put it back in the case. There is potential cross-contamination in each one of those kind of events. All of this -- represents a time so there is some growth at any one of those, and the one that we'll track for public health input, slicing the chub means the customer is then leaving with a sample that has a certain concentration.

For all of those locations, but in particular for the customer leaving them, we will have a series of concentration versus time. So each one of these little data points here -- I can't hold it steady enough, but there is customer 1, there is customer 2, there is customer 3. They're leaving with known, or simulated known concentrations. And we can run this on the computer for as long as simulated time as we need to be able to get enough certainty on what those concentration profiles might look like. But this is done just for one store and one set of how

much do they pre-slice in the morning, what are their sanitation procedures like.

We need to think about a variety of situations that might occur. Now, normally in this type of model, we don't formally account for every possible situation explicitly. We don't say there's a 1 percent mom and pop store that pre-slices 3 percent in the morning, the rest is sliced to order, the sanitation process, they change their gloves 87.3 percent of the time. We don't have that level of detail. The terms you'll see us use are variability and uncertainty. And it's our hope that that accounts for the range of situations that we're interested in mimicking from the real world.

Variability is where we know what the values are, but they change from time to time or from site to site, okay? I don't expect the growth rate in a product with growth inhibitor to be the same in the product without a growth inhibitor or between a dry sausage, non-growth type, and a ham, right? So I expect variability across those different types of products. But we have some numbers for what those

growth rates might be.

There's other things that we really don't know, that we're uncertain about, that further data would help us. We call those uncertainty values, right? The way this will work is here is an example of variability. Now, instead of just one time series leaving, I'm going to track in this case, just hypothetically, three. The red line is for product without growth inhibitor. Then maybe the blue is non-growth-supporting. The black is with growth inhibitor.

So now I've accounted for some of that variability by subdividing the different types of products I might be mimicking. But again, this is still for one store. There is variability across stores, so I have to repeat that whole process but for a different store, where a store might be what types of sanitation procedures do they use, how much do they pre-slice in the morning, do they pre-slice in the morning, how many different slicers do they use.

So I'll do that for different types of stores and have that same kind of time series

analysis, both accounting for variability, where I think I know what the values going in are, but then I've got to repeat that multiple times for data that I wasn't sure of and how to make a best guess about, all right? Those are the uncertainty distributions.

So this is all my variability that we saw from before. But maybe I wasn't really sure on how much that kind of store pre-sliced. So we'll pick a different value for it and run the whole thing again and run it again, and we'll literally have hundreds or thousands of this. So when we talk about computer run times being an issue, we're not making that up or whining. That's real. I mean, this is days of computer run times, frequently.

We summarize that in what jargon we'll call a CDF plot, cumulative distribution function. We have our variable, our quantitative variable on the X scale. For us, for right now, that's going to be an LM concentration. And then we have a cumulative probability on the Y scale. The way you'd read it off is the 50 percent value. You'd read over and down. Fifty percent of the values are at that concentration

or lower. That's why it's a cumulative plot. Ninety percent we'd read over and down. Ninety percent are that value or lower. All right. That's how CDF plots will work.

I'll have one of those curves for each of my variability sets of runs. And then because I run lots of them across uncertainties, I can look at the uncertainty distribution across those different types of CDF plots. So what's an average CDF plot look like? What's an extreme on the low side and what's an extreme on the high side. Again, we're not interested in just saying we expect five people to die or a hundred to get ill. I want to be able to say plus or minus how certain am I about that value.

The focus on this model development is in the retail environment, but we do need to link it to public health. So there is a module to take it out through consumer storage time and temperature, and so there is some growth allowed for there. There's a serving size module, so we get a dose at consumption. How many cells are they actually consuming when they eat? And again, growth can be enormous here. We can

have orders of magnitude increase from what's leaving the store to what the consumer is actually eating.

We'll also combine that with a dose response model, all right, so we know how many cells are being consumed. We know that risk of illness from a given dose. So we will get the mean number of illnesses plus or minus that uncertainty. So we'll be able to say the incidence is not just two in a million but two plus or minus 1.8 or two plus or minus 0.01 in a million. That's important for the types of risk management questions and decisions that we might be able to make from these kind of risk models.

So the key data needs for sites. What sites should we consider? How big are they? Sometimes that's a mass, sometimes that's an area, but a size measure. What temperature are they maintained at? What are the growth rates for each site? Think about that for a minute. What's the growth rate of *Listeria* stuck on a steel blade on a slicer? What are the transfer coefficients? So during an event between the slicer and the chub or the slicer and the glove, what are the transfer coefficients? How many cells will

get transferred across those different sites? What different types of deli meat products or deli salads, or other food groups are being used in the deli area? Is it 90 percent is turkey and ham, 5 percent is dry sausage? How much of that exists in the deli case and how fast is it being moved through the store. And then a question we'll talk a little bit more about: how does *Listeria* get onto the site outside this transfer process?

For the events, okay, what's the probability of an event occurring? Customer serving hopefully we can get some data on. What's the probability that a cell inside a sink is going to transfer to a food contact surface? We need those kinds of numbers. What's the sequence of events, serving a customer, for example, how long does it take? What sites get contacted when serving a customer or opening up a chub work?

And then the model will be able to do all of those time series type analysis, the LM concentrations at different sites over time. We can also back-calculate some other things. How long is a chub

normally held in there because we're tracking chub sales, so the model will tell us. That's something we can sometimes compare to external data to make sure the model is working reasonably well.

You can begin to get the sense this is a data intensive type model. There are some data gaps. So one example might be where does LM come from in the store, into this deli area? We have from Ann Draughon's data some evidence that some of the chubs coming in are contaminated. So that will start the process, all right? And that we have some quantitative numbers for. We know from Joe Corby's and Martin's work that, you know, cases, shoes, floors also might be sources of it, but we don't have good quantitative numbers for that at this point. So a big question, how does LM enter this retail environment.

The transfer events, again, there have been some good studies recently about, say, transfer from a slicer to a chub or back and forth, but how about some of these rare events? How about high concentration in a floor drain, where we know it's there long-term, how likely is that to come back to a food contact surface

or get into somebody's hands? Those are still kind of open questions at this point.

In terms of getting into risk management type questions, keep in mind, lots of times we're asked, as a modeler, did you consider this very specific kind of case? We need to simplify this to be a generic type approach, okay? So if the model can't answer the questions we're asked, the model is not complex -- not good enough or, flat out, it doesn't work. But it's easy to try and make models that get to be too complex that try and answer questions that aren't asked. The problem there is, as you can see, run times are a real issue. But the data needs, as you get more complex, increase exponentially, all right? And lots of times, it may not be worth the effort to make a more complex model if you're simply making up the numbers that go into it.

So there does need to be this balance between complexity and simplicity for the model. Make it as simple as possible, but it needs to be complex enough to answer the questions we're being asked. The way it generally works is a question will come to

us -- we'll see some examples in a little bit. We need to translate that into the variables the model is actually tracking. So what changes are we considering in terms of the variables that we have as control knobs on the model, or we run the model for that new scenario and then evaluate did the health impacts change at all.

Let's look at two examples, one that's fairly straightforward just as an example. If I required that two different slicers were used, one for product that supports growth and one for product that doesn't support growth, does that make any difference in the public health? Maybe not. I don't know. We'll let the model go run it. But it's easy to evaluate in the model because I can easily model more than one slicer at a time. When a chub is picked out, we say does this chub support growth or not, and we sent it to the appropriate slicer. That's one that's a question that would be easy to evaluate.

Here is another one that's harder to evaluate. You'll know that at most deli counters, there's broiled chicken and maybe some seafood very

close to the deli area. If we move those farther away, okay, because in many cases, they're dealing with raw chicken. Does that make any difference? We don't have good numbers for how that interaction might be occurring. So I can go into the model and change the probability that that transfer is going to occur, but that's more bit of a guesswork for what numbers should go in there.

So a better framework for some of those type questions is something called a sensitivity analysis. That's where if I don't know what the right number is or how it might change, I can run it across a wide variety of values and plot the effect. And that will at least tell me if that value makes a difference or not and how significant that difference might be. And you can do that for things that you'd never want to try in the real world as well by making the situation worse.

If you think about a food code, where gloves should be used and changed every time the product is handled, what happens if we don't do that 10 percent of the time or 20 percent of the time or 50 percent of

the time? You'd never want to try that in a real deli, but we can run that in our model fairly easily, right, because that's some of the variables that we're tracking. So we could look at the relative impact of those kinds of changes.

So what the model will be good at and what it won't be good at, we have -- we are currently developing a mechanistic event-driven model, transfer coefficients, specific discrete events occurring, tracking where the bacteria are at any given time. Questions related to mechanisms and events the model should be able to handle fairly well. Changes in sanitation practices, changes in slicers, changing in the amount that gets pre-sliced in the morning versus sliced to order, those are things that we can handle in the current approach to the model.

More administrative type practices might be very important and might be critical to reducing listeriosis, things like better record-keeping or better consumer education. They might be important, but our model doesn't deal with those kinds of issues very well. Those aren't specific mechanisms or events

that we're tracking. So those types of questions we're not going to be able to help too much with.

All right. So just in conclusion, we can build a cross-contamination model at retail. It is very data intensive, all right? So the more data we can get, the better the quality of the predictions that will come out, okay? We can look at different scenarios, and we think we can develop the relative importance of some of the different controls that might be studied for LM at retail. All right.

This was the first part of a two-part discussion on the model. Regis is going to come up and talk a lot more specifically about the data that we have available and some of the data needs. So again, hopefully, this has left you with some of the conceptual issues that we're grappling with at this point. And now time for questions. So any questions?

(Applause.)

DR. DENNIS: Question over here.

DR. MOKHTARI: Just to better understand the data that you showed here. If you look at the graph you show for a store-to-store variability, I mean,

yeah, you -- we see, like, substantial variability when you are looking at products that do support growth. But when you're looking at the products that do not support growth, it's basically a flat line.

DR. GALLAGHER: Now, keep in mind, this data is completely made up at this point to simply illustrate it.

DR. MOKHTARI: Okay.

DR. GALLAGHER: Okay.

DR. MOKHTARI: So you basically, when you start with some initial contamination, more or less, you are not changing it to the end of the, like, several days that you're modeling here. Does this mean that basically cross-contamination is not an issue here so you're not introducing new contamination to the product --

DR. GALLAGHER: No.

DR. MOKHTARI: -- because everything is coming from growth based on this data.

DR. GALLAGHER: Right. Again, this was just simply to illustrate that we can track different product types, and I wanted the lines to be different.

So this was me sitting in my office making different kind of average points for it. These are not model runs.

DR. MOKHTARI: Okay.

DR. GALLAGHER: Okay. We would suspect that because chubs are held for a certain amount of time in the case that growth can occur on those chubs if growth is permitted for that particular product type. So growth and transfer would both be important, and for non-growth-supporting product, I mean, growth gets cut out. If I have a dry sausage, even if I contaminate it, that contamination level shouldn't change enormously during the course of the retail environment. If I contaminate non-growth-inhibitor turkey or ham, the growth might increase inside the retail environment, the concentrations on those products.

DR. MOKHTARI: So basically, surrounding environmental contamination by itself is not a major factor, I mean, when you have -- I mean, if you eliminate the growth, you're good to go?

DR. GALLAGHER: No. I mean, I'm not sure I

fully understand, but if all I ever sold was dry sausage, maybe. I'm not even sure I'd buy it then. But once I start to put in a growth-supporting product in there, I think environmental contamination is critical because if it ever does transfer and then we get three or four log increases during the consumer storage, you've got a health problem at that point.

DR. MOKHTARI: Okay. Considering the growth, do you think that your model supports what data was shown in the morning, as far as, like, seeing 1.2 percent prevalence of positive numbers?

DR. GALLAGHER: One of the calibration or one of the things you do with a mathematical model like this, you ask yourself where is the real-world data that I can make sure my model compares to. So one of the things that we'd like to do -- we will do is make sure that our model predictions are coming up with roughly the same prevalence in concentration distributions.

DR. DENNIS: We'll have more time for question at the end, but we had one more question in the back. We'll take that one, and then we need to

move on.

MS. TSUI: I'm Flora Tsui from FSIS. It's been a pleasure to use your 2003 models. I'm very much looking forward to this new model. Just want to clarify, is this model product-specific or location-specific or both?

DR. GALLAGHER: We will pick specific locations in the retail that we will track over time, slicer, case, probably gloves. At some point, we need to consolidate and simplify it. So we might not track floors versus walls separately, for example. We might just say there is a generic non-food-contact surface, okay, where we will have the time series for those particular locations. Then we will track different product types. And again, the level of detail is something under discussion. But clearly, deli salads, non-growth-supporting, growth-supporting with and without growth inhibitor would be the minimum that we would consider at this point.

Your call.

DR. DENNIS: She said it's just a quick question.

DR. GALLAGHER: Okay.

DR. HOLLINGSWORTH: Can you go back to your slide that had the example of the gloves?

DR. GALLAGHER: Yes. That one?

DR. HOLLINGSWORTH: When you're looking at a scenario like this, just so I understand, what kind of information do you need to already know about the effect or impact of changing gloves or not changing gloves in order to assess what will happen in the model if you do it 10 percent of the time? That's what's not clear to me.

DR. GALLAGHER: Okay. Since this is under a sensitivity, that's generally where I don't have a good feel for how important or what that value might be in the real world. So think about the end result of this being a plot. Number of people getting sick on the y-axis, percent of glove proper use on the x-axis. And then I can see is it flat? Well, then maybe glove use doesn't matter. Is it increasing continuously? Then gloves does matter. Is it flat and then jump up? You know, then you need to be above that jump-up point. So we'd look at this as a

continuous scale for glove use, plot the public health impact, and then evaluate that curve.

DR. DENNIS: We'll have time for questions later. Thank you, Dan.

I just want to emphasize that where we are in the process now is this is a conceptual model. And what we're looking forward to is for the submission of data and information and your comments that will help us in building this model.

So our next speaker will talk a little bit more about the data that we currently have available and the kinds of data that we would seek in order to build the model. Our next speaker is Dr. Regis Pouillot. He is a visiting scientist at FDA's Center for Food Safety and Applied Nutrition, in the Office of Food Defense Communication and Emergency Response. He has worked on risk assessments for ten years in France at the French Food Safety Agency and also as the head of epidemiology at the Pasteur Center in Cameroon.

DR. POUILLOT: Thank you, Sherri. Good afternoon. So, yes, we'll spend the 30 minutes to

speak a little bit more about the data, the data sources, the data review and the data gaps, all the data that are needed to -- the model that we are building with Dan Gallagher.

The outline is as follows. We'll first provide you a comprehensive review of the data needs. And then in the second part I will explain why we need those data. And for that I will spend more time on the different basic processes we use in the model; that is the cross-contamination, bacteria growth, cleaning and sanitizing. And for each of these basis processes, I will try to use the data we have, the data we need, and also the data gaps we still have.

First of all, we published two Federal Registry notices for this project, one in January and the second one in May. And the first one was a request for comments and for scientific data and information, where we gathered all the data needs and we asked any stakeholders to provide us data we need for this model.

The area of that is very wide. And for example, here we have the -- we asked for the

characteristic of the ready-to-eat food markets in the United States, including the volume of cheeses, deli type salads and deli meats that are sliced and prepared by manufacturers compared to the volume that are sliced and prepared in retail facilities. That would help us to try to balance those different kind of products.

Second kind of data are the characteristic of deli department in groceries, including the proportion of separated seafood, meat -- deli department in groceries. This question, we have to say that this question is quite vague, but we have to know a little bit more about the different characteristic of deli department in the groceries in the United States.

The second set of data we ask is *Listeria monocytogenes* levels and frequency in products at both level -- when they arrive at retail facilities and when they are sold by retail facilities. So first one will help us to -- will be used as an input in our model, and the second one, as Dan told us, could help us to scale the model and to compare the output of the

model with the real life.

Another kind of data we need are the factors that influence the growth of *Listeria* in cheeses, deli meats, and deli-type salads, which includes the growth rates of *Listeria monocytogenes* observed in specific products, the chemical characteristic of cheeses, deli meats and deli-type salads, where I will show you why in the next slide, and the proportion of deli meats that are treated with growth inhibitors, the inhibitors used, the level of growth inhibitors and their efficiency. In fact, we have seen that there is an increasing proportion of product that includes some growth inhibitors, and we really have to model it in our project. So last kind of data for this growth are the data on temperature to which cheeses, deli meats, and deli-type salads are exposed at retails.

I continue rather an exhaustive list. We also need some data on the environmental contamination, which includes data and information on the prevalence and levels of *Listeria* in the retail environments and kind of data we have been presenting this morning, and also data on the growth of *Listeria*

on non-food surface, including environmental biofilm growth.

What will really be a very important factor for this model is the factors that influence the environmental contaminations, the cross-contamination of food by *Listeria monocytogenes* in retail facilities. And we ask for data on the potential transfer of *Listeria* to food from the retail environment from our experimental studies or our real data and also data information on food -- activities. So that means that even if we knew that the environment is contaminated, we really have to know what is the impact of this contamination on the food by knowing the potential transfer of *Listeria* from this environment to the food.

Last of all, we ask for data on the effectiveness of control measures or interventions that are currently practiced in the retail environment, which includes the environmental sanitation procedures that are used and the worker sanitation procedures, including frequency protocols and efficiency of it.

And we finish our Federal Registry notice asking any other data related to the occurrence, growth, and control of *Listeria monocytogenes* in retail facilities. So you see, we need a lot of data in very wide areas, and we have asked in this Federal Registry notice all this kind of data.

I will now focus on some of them, on the major data needs, and in fact, these major data needs are linked to the factors that impact principally -- contamination that are the initial contamination in products, the cross-contamination, the bacterial growth, and cleaning and sanitizing procedure.

Initial contamination in products have been presented by Janell Kause this afternoon. That will be the contamination of chubs in coming in the retail. We hope to get some data in the docket. And I will focus, then, on cross-contamination, bacterial growth, cleaning and sanitizing.

We defined the -- as Daniel told us, we defined the cross-contamination as the transfer of *Listeria monocytogenes* from any object to another, which is not the classical definition of the cross-

contamination in the risk assessment domain.

So if you want to model one cross-contamination, you have one contaminated object which is in contact with a non-contaminated object, and then at the end, object B is contaminated from a transfer of bacteria. To be able to model this cross-contamination, you need the initial contamination of A and, of course, the transfer coefficient from A to B, that -- proportion of bacteria that shifts this from A to B.

In fact, there are more and more literature studies on this kind of definition of transfer coefficient, and I present you one example that was published by Chen in 2001. She put on one skinless chicken breast meat ten to the eight bacteria and asked a participant to cut the meat, to handle faucet, to wash hands and then to cut a lettuce, and at the end of this experiment, she made a bacterial count on the hands, the faucet and the lettuce.

From this kind of study design, she was able to evaluate the transfer coefficient from the chicken to the hand, the impact of the fact that the

participant wash hands, and then the final transfer to the lettuce. I provided here the transfer coefficient she obtained and you can see that there is a huge variability. For example, from one experiment to the other within the same study, you can have from 0.36 percent to 100 percent of the bacteria that are transferred from the chicken to the hand.

We gathered all this kind of different transfer coefficient from the literature, and we currently have more than 900 transfer coefficients. And we really observe a lot of different study, a lot of different protocol and a huge variability in the transfer coefficient. This variability is a function of the source, the recipient, the kind of contact, and also the bacteria.

And here, I provide the results obtained from a transfer from meat to stainless steel surface. And you can see that for this 100 transfer coefficient, you can obtain some very low transfer coefficient up to 100 persons. So a huge variability. But we have some data on this specific area.

A special case of this transfer coefficient

that is well-studied, too -- we have now seven publication on this kind of -- with this kind of protocol -- is the use of a slicer. And for example, for this publication from Vorst, 2006, they placed ten to the eight *Listeria* on the blade and then start slicing turkey, salami, or bologna. And here you have, according to the sliced number, the concentration, the number of CFU on each of the slice of turkey, salami and bologna. So you can see that you have a slow reduction in the number of bacteria on each slice and that could have a real impact on the number of slices that are contaminated.

You can see also here that when you reach ten to the three bacteria, you begin to have something that is more -- to the low number of bacteria, which is much more difficult to count than very high number. So we have also some specific data for the slicer.

I was speaking of one cross-contamination, but, in fact, as Daniel showed you, we work with multiple cross-contamination within our retail. And this is a kind of schematic of -- we can do of this cross-contamination, and you can see that we'll have

to consider not only one cross-contamination, but multiple cross-contamination from clothes to hands, from hands to gloves, from gloves to chubs, from chubs to food contact surface, and from non-food-contact surface to chubs before these chubs begin ready-to-eat food that is sold to the consumer.

So things are much more complicated than for one only cross-contamination, and the additional data needed is the frequency and the probability of contact between objects within the retail. For example, if the food worker sliced chub and then replaced chubs, there is non-zero probability that he had a contact with his hand on a non-food-contact surface and then from his hand to the chub. And that could be the origin of cross-contamination.

So one question is how frequent is this contact? How frequent is the contact on non-food-contact surface, and if there is such a contact, what is the probability that the food worker changes his glove, as he should? And before changing his gloves, what is the probability that he also washes his hand, and so on. So we have a lot of question about what

really happens in a retails to be able to simulate such an environment. This was a -- that I got because no data existed in the United States on this kind of issue.

So we first developed with the helped the JIFSAN, the University of Maryland, GFG, and the FMI. We developed the pilot observational study, where, in nine or ten facilities, we go there and observe food worker behaviors just following the food worker and noting everything that he does. You have here an example. At 11:20, he opened the deli case and using his gloved hand, he pick up a ham and close deli case. His hand rubbed the ham, and so on and so on and so on. So Mary LeBrin (ph.), which is in the -- here today, is currently doing in the retail and note all the food worker behaviors just to see what happen in the retail.

We only work on nine retail facilities, but the first results -- the study is not finished yet -- but the first results seem to show a very standard practice for a given food worker. A food worker always does the same thing. And there is a

variability between food workers within single retail facilities. And there is a variability from a retail facilities to other one.

So this is the very first results. We do not have finished yet. And this is only a pilot observational study, but once scaled on a realistic set of parameters, we will be able to begin to work on our model and to try to find more deeply which parameters are really important, really sensitive, and this will help to define the objectives for a more complete study.

To finish with the cross-contamination, we have a remaining data gap, which is the probability and level of transfer from and to the niche. And you saw this morning, we have some data -- study, Cornell's data, a very interesting set of data. But question remains on the real impact of this contamination of the environment on the food contamination.

What is impact of a contaminated drain? Is this contamination only the indicator of contamination or is it the real origin of a potential contamination?

We don't know, currently. We can ask the same thing for the cart wheels. We don't know if it has an impact on the food contamination. And more than that, we are working in the quantitative risk assessment, so we have to do a quantification of the probability and the level of transfer of bacteria from this niche to this product. This is a very important data gap.

The second basic process we have to consider is growth of bacteria within the environment. So as you all know, *Listeria* can growth and the result of this bacterial growth can lead from very few bacteria to very huge amount of bacteria, which pose a risk. The bacterial growth is a function of the time the environment and the bacteria -- and you all know, also, that *Listeria* has the ability to grow even as such a low temperature as 29 to 40 degree Fahrenheit. This is what is currently said, but you have to remember that at this temperature, the growth rate is really low and it's not nil, but it's very low. *Listeria* can also grow at a low and higher pH, from 45 to 96.

And so we have to consider all over the --

variation in the environment that allow or not *Listeria monocytogenes* to grow. As we told before, we have an increasing proportion of products resulting in microbial growth factors, and we have to consider them.

To that, we have to some very interesting tool now in the literature, which are all the predictive microbiology models. You have here some examples of models that fit, more or less, to observe data. All these data are the evolution of the population of bacteria according to time in very various conditions. These models have made a huge improvement the last 20 years, and we are now more or less able to simulate the interaction between the parameters, for example, the presence of growth inhibitors and the temperature. What happens at low concentration? What about the -- of the bacteria? What about varying environments? And what about the growth/no growth interface? So there is a huge literature, lots of models we have to dig in them to see the ones that will help us to predict the bacterial growth in our deli meats.

So the growth rate are observed in the published literature. We hope to get some response to some of these growth rates in response to our Federal Registry notice for specific products because we can either use a growth rate specifically according to the product or take growth rate and then evaluate the impact of other characteristic of the product on this growth rate using the pH water activity and -- microbial growth factors of this product. We need also the storage temperature at retail, the storage duration at retail, and we need some data on these parameters.

The last basic process is the cleaning and sanitizing procedure. Same thing as cross-contamination. For one cleaning, it's quite easy. You need to know the initial contamination. And then you need to know the reduction in the number of bacteria during the cleaning/disinfection. And there's a huge number of -- reductions that have been published specifically to avoid -- a lot of publication have been done in hospital to avoid contamination from one patient to the other.

Here is an example, DiSolters (ph.) in 1990. Use some bacteria in suspension and some bacteria dried on stainless steel and for a different batch of products evaluates the log reduction. Here, you have with ethanol a five to six log ten reduction when you apply this product for a given duration with a specific protocol on a surface.

So we have some of this data from the literature. But what we need to know is the product that are used -- that are really actually used in the retail, the frequency of cleaning operation from a simple wipeout to complete cleaning. We really need this data. And also the protocol, the reprotocol -- not only the one that is supposed to be done, but the one that is actually done with the duration of the cleaning and the frequency.

For all this data, we have the data from the food code, which could be used as a baseline, but we need some real data from our observational study, and we hope to have some response to the Federal Registry notice.

I focus mainly on the retail, but in order

to be able to compare and to see the public impact of the different risk mitigation, we'll have to go to the risk. So we'll follow the products from the retail to the consumer when they eat and when they eventually get ill -- from the contamination when sold, what happened when the product is eaten, they might be home storage, a very long home storage with the bacterial growth, and we have to model this.

We will not consider cross-contamination at the consumer steps because it's not the main question of our project. Usually, we have this data because they have been used for the FSIS/FDA two or three risk assessments, and there are some new data on this home storage.

Once eaten, we have to use -- to evaluate the probability of illness, and we have two concurrent dose response model. We could take a whole meeting speaking about those dose response model because they are not perfect, but we really think that they are sufficient to try to evaluate our different risk mitigation.

Here is an example for the transport and

home storage. You have here the different temperatures that have been measured in consumer fridge from two different publication, one from 2008, the second one from 2007, and you can see that we are -- some consistent data with a very high -- at 40 degree Fahrenheit and some very low or very high temperature for the consumer. We know that this has a real impact on the risk, but this is not the main focus of our project.

As conclusions, I tried to tell you all the data we need, some that are available but not all, and to conclude, we have all what we can call the white literature, that is, what is published, officially published in the different review. But we need some data which is called gray data or black data, which are all the data that stakeholders could have and that they could share with us to try to improve our project. Two dockets are currently open for comments and data until September 29th. That's it. Last day, September 29th, and you can obtain them. You'll have the number on the presentation.

Some data gap will hardly be filled, for

example, the probability and the level of transfer niche to products. We'll try to derive some specific data to get some data using specific study design. But this may be some limitations of the model, and we'll have to deal with that. Thank you for your attention and waiting for question. Thank you very much.

(Applause.)

DR. DENNIS: Questions? I'll take some from the audience, and then we'll go to the phone. We have one right here.

MS. KLEIN: Hi, I'm Sarah Klein from Center for Science in the Public Interest. We have suggested, and I want to get your thoughts on gathering data from the European Union, where a zero tolerance policy has not been the standard, so that the products coming into the retail environment are subject to the 100 CFU per gram standard. And we just kind of want to hear more about your thoughts on looking at that data since that will most likely provide a more realistic picture of what's happening, you know, in terms of cross-contamination from

products that are coming in carrying some load of LM.

DR. POUILLOT: Okay. As you can guess, I have some information of what happened in Europe.

(Laughter.)

DR. POUILLOT: And there is a real increase that is observed in six or seven different countries in Europe, currently, but everyone in Europe really asks some question about what is the cause of this increase, because the 100 LM tolerance has always been there, in fact. So the current increase is not an impact of this policy. As it was told this morning, there is a huge impact on the elderly, on the people with immune compromised status, and we really don't know. So using our literature review, we'll take, of course, Europe and data from all over the world. But I'm not sure that we can make a direct link, and the research from France on retaining -- do not do this link between the 100 CFU tolerance and this increase. So I don't know if you want to --

DR. DENNIS: Any more questions?

MS. COZAD: Good afternoon. My name is Townley Cozad from Lockheed Martin. My question is

about last week's news, there were a couple of articles that China decided that they were going to build their first national food safety risk assessment system. Is there an ongoing collaboration process or sharing of information between FDA and FSIS and what China is trying to do, and if so, is that shared also off the information for your Federal Registry notice?

DR. POUILLOT: I'll have Janell --

MS. KAUSE: This is Janell Kause, the director of the Risk Assessment Division for FSIS. I believe that that's newly formed. For the most part, the risk assessment community, at least in food safety, is very, very tight. People do share information and data because the field is very, very small. Predominately, they do this through codex and codex committees, but we look forward to seeing if the Chinese risk assessment group does invite us to provide or share information and if they're willing to share information that they have as well.

DR. DENNIS: We'll take a question from the phone if there are any questions, and then, if not, we'll open it up to the full Panel.

MS. KAUSE: Larry Kohl?

DR. DENNIS: Oh, I'm sorry, Larry? I didn't see you. Go ahead.

MR. KOHL: Regis, my question is --

UNIDENTIFIED SPEAKER: Hold on one second. Let me bring you the microphone. I didn't see you. Excuse me. Make sure everybody hears you.

MR. KOHL: Larry Kohl with the Food Marketing Institute, and my question is for Regis. Have you thought of or considered the types of criteria that might be needed for the data and how you might use that data, then, or if you'll use the data? And I guess it goes back to the question about a lot of data that might be available at the state level from a regulatory standpoint and whether that data would be acceptable in using within the model, and there might be other data that would fall into that category or a category from an industry standpoint, and there might be some confusion whether that data would do you any good or if you could use it.

DR. POUILLOT: Yeah, it's a complicated problem because as many kind of data as the number of

the kind of -- yeah, there is a difference in the quality of data according to the kind of data we need, but I don't know what --

DR. GALLAGHER: Let me break that up into two responses. The first and the harder one, is the quality of the data. I mean, typically, we think pure journal publication data is a higher quality, and in some cases, we try and take that into account. We can easily take it into account when we have multiple versions of the same type of data. Then we can go with the better one, what we think is the better one.

The second one, though, is would we consider other data. I mean, clearly, the New York-type data is important to us because it's giving some indication of where LM might reside in a retail environment, and that's not data we have elsewhere. So in that case, certainly. The key point is we'll look and consider any data that we can get our hands on. Whether it's useful or not, we've talked about some of the limitations that that New York-type data has. It's mostly prevalence. There are some sites that were consistent across all locations, others that were more

judgmental. So trying to track -- build some of those issues in is a little more difficult.

DR. POUILLOT: Looking at representativeness and quality of the bacteria logical data, if it's bacteria logical data. But we want -- representative. And of course, literature data are very interesting, but from time to time, a batch of raw data is better than this kind of statistics that we obtain in the white literature. More and more people try to publish their raw data on some website, and Cornell do a great job on this issue. But that will help us a lot for these kind of risk assessments when we really have to get the raw data and work on them and get some other statistics. This is important because in risk assessment, we don't just want the mean as in a usual study, but we really want all the variability of all the different situations that occur in an environment.

DR. DENNIS: I just want to add to that, that it's really important to have access to all of the raw data so that we can evaluate the quality of it. And one really wonderful place to post data is on JIFSAN's Web page, www.foodrisk.org. And we'd

encourage researchers to post their information there.

MS. KAUSE: And this is Janell Kause. It is the website where a lot of the federal food safety agencies are collaborating and providing access to their models, to their data, and so on, to make it easy for everyone to find out a one stop shop where to get that kind of information. And we're encouraging our stakeholders to also provide the data and information that they can there. Of course, some data will have to be blinded for obvious reasons, but we do encourage people to collaborate, because I think it is our goal that if all of us have a common understanding of the problem, then it can be addressed more readily.

DR. DENNIS: Join me in thanking Regis.

(Applause.)

DR. DENNIS: Okay. Now we will open up questions to all of our speakers, and I would like to start and see if there were any questions from folks on the phone.

OPERATOR: Once again, to ask a question, please press star, one.

DR. DENNIS: Okay. And we'll come back at

the end to anyone on the phone. I open the questions up to our participants here.

MS. KLEIN: Hi, Sarah Klein from Center for Science in the Public Interest. Just two quick questions of clarification. Are you considering data on bacterial growth in consumer homes and just not cross-contamination in consumer homes or are you not looking -- I mean, is the risk assessment not going to reach into consumer homes at all?

DR. POUILLOT: We would consider growth at the consumer home for different reasons. The last risk assessment showed that this was a major -- factors on the *Listeria* risk assessments. This is really important. The other thing is that it appears that people store the deli meats that are sliced at retail a shorter time than the ones that are sliced at the manufacturers. So we have to consider this in terms of risk. People know -- consider that -- well, in fact, they keep the product a longer time.

MS. KLEIN: Great. And then the second question was when we refer -- the last couple of presentations referred to chubs and talking about the

study of contaminated chubs that are coming into retail. Are we talking only about meat to meat contamination, or are we also looking at meat to cheese contamination on the same slicer or meat to seafood contamination, where that could happen, cheese to seafood, et cetera?

DR. GALLAGHER: Meat to cheese, yes. Deli salad areas, yes. Seafood, raw chicken, broiler-type issues, we're aware of them. We're not quite sure at this point how to properly build them into the model. Okay. The question becomes if there is a seafood counter ten feet away from the retail deli area, how would *Listeria* transfer from that location back into the deli area. We're not saying it's not -- it can't happen. We're trying to think our way through that one at this point.

MS. KAUSE: This is Janell Kause. I think we're going to learn a lot from the study the University of Maryland is carrying out, the observational study. I think it depends what we see. If they're seeing observations where it looks like there could be a transfer, maybe then it can be

included. Right now, as Dan points out, we're not seeing how that's going to happen. But again, it's in the early stages of development. So what gets included in this model depends quite a bit on what data we're able to garner from folks here, folks that provide comments to our docket, observation studies, research that academia and CDC and others do, and so on.

DR. DENNIS: Other questions?

MS. SMITH DeWAAL: This is Caroline Smith DeWaal. I just have one, and Janell, I'm sorry if I missed your earlier presentation. You may have explained this. But can you describe how Dr. Gallagher and Dr. Pouillot are going to be working together. I mean, are you working out of the same office? Is all the materials going into the same docket? Is FDA -- I mean, I'm interested that FDA is managing the data gathering portion of this exercise and USDA is doing the modeling. But I just want to know how the data actually is going to be managed.

MS. KAUSE: Thank you, Caroline. That was Caroline Smith DeWaal with Consumer Science in the

Public Interest. And this is Janell Kause with the FSIS. Just to be really clear, this project was initiated between FSIS and FDA last fall. And from the get-go we decided that we'd both have modelers. And actually, Dan Gallagher is on contract with me, and Dr. Regis Pouillot works with Sherri Dennis. So we have both agencies building the model. We have both agencies collecting data, both agencies meeting on a weekly basis on this risk assessment. Both agencies have sponsored this public meeting, both with money and resources. And so in terms of the docket, we do have two dockets. In the future, it will always be just one docket where it'll be a one stop shop, and we'll have the same number.

So it really isn't divided between us. We actually work like a single unit in this case. And that was decided because when we talk about cross-contamination at retail, we're not talking about just FSIS-regulated product or FDA-regulated product. We're talking about retail products. And so we're wanting to work together from the beginning to the end and also engage consumer groups, industry groups, the

public in general early in this process because we really do believe that while everything is pointing to retail and it's a place for us to go, what exactly people need to do depends on what we can understand about the retail environment as a system. Does that help, Caroline?

MS. SMITH DeWAAL: Yeah, thank you.

DR. GALLAGHER: This is Dan Gallagher. Can I add just a little bit of a geek answer to that as well just to show you how the modelers work? The question about sharing code and data, we maintain on the Web what's called a subversion site. That's a piece of software that tracks when you make changes to code. So Regis and I both have access to the full model, can make changes to it, and the website and the subversion software are keeping track of the changes that we make. So we're interacting as a repository for the code that we're writing together.

MR. MARTIN: Hi, Chuck Martin from SuperValue. Question for Regis or Dan. In terms of transport and home storage, handling of products by consumers, I see that there are some studies listed

from EcoSure and RTI 2007. Are there any other plans for additional consumer behavior studies with respect to handling products after purchasing from retail and with respect to how long deli meats are held at home and at what temperatures?

DR. POUILLOT: We have the RTI data from 2007 for what happened at the consumer. We have the EcoSure from what happened before, and for transport to the consumer, we have the -- to my knowledge there is no other set of data. We made some initial work that shows that this transport from the retail to home do not have -- does not have an impact on the final risk because you, in two hours, you not going to have a very significant growth for --

DR. GALLAGHER: So basically, there's no additional studies currently being planned where we'll use the existing data that we have. And again, most of the risk assessment questions that are being framed at this point are focusing at the retail deli counter, not changes that might be occurring in the home.

DR. DENNIS: Just to add to that -- this is Sherri Dennis. Certainly, if you are aware of other

studies, we encourage you to submit the information to the docket and if you have an opportunity to encourage further research, that's something that, obviously, continuing to update that information will be really important.

MR. MARTIN: Just a follow-up. Did I hear correctly that at this point, the model does not see a impact on growth of LM due to handling and storage time by consumers?

DR. GALLAGHER: You had to listen very careful what he said. It was the transport. So from the time you buy it at the deli counter until you put it in your fridge, that time doesn't seem to be terribly significant. From the days to weeks it might stay in your fridge, we can have enormous growth and it makes a big difference. So that two-hour period driving home from the supermarket and getting it in your refrigerator doesn't seem to be critical even though the temperature might be a little high. But, you know, keeping it for a week to 14 days in your refrigerator does have a very significant impact.

DR. DENNIS: Additional questions? So we

will reconvene.

(Off the record.)

(On the record.)

MR. TYNAN: It's almost 3:00. It's exactly 3:00. I wish I had that much influence in my home.

(Laughter.)

MR. TYNAN: Good afternoon. My name is Robert Tynan. I'm with the Food Safety and Inspection Service, Office of Public Affairs and Consumer Education, and I have the pleasure of having the opportunity to moderate this portion of the public meeting. It's an expert panel to talk about some of the scientific information and data that we'll need as part of the study. This also gives Janell and Sherri an opportunity to sit and listen and not be in the -- right up here trying to manage and monitor the meeting itself.

The session we have today -- I'll introduce the Panelists in just a few moments. But we do have three questions that was at the registration table that you probably all have in your packets. We also have a little bit of a slide. So there's the three

questions. I won't read those to you. For purposes of this Panel, we'll also not have a introductory remarks, in the interest of time. So we'll have the questions. We'll pose them to the Panel. And then at the end, if there's still time, we'll allow the Panelists an opportunity maybe to elaborate a little bit on their own thoughts about the issue, and that will end the Panel, and then we'll go into the public comment portion.

And let me introduce the Panelists to you. I have some bios here if you'll bear with me. And these, I hope, are approved bios as opposed to the unapproved version.

(Laughter.)

MR. TYNAN: Down to my far right, I have Dr. John Butts. John is the Vice President of Research and Development at Land O'Frost, Incorporated. He joined Land O'Frost as the Director of Research in 1974. He's a member of the board of directors of the American Meat Institute and is an active member of the Scientific Affairs Advisory Committee for over 25 years. And John, you're only

29, is that correct?

DR. BUTTS: That is correct. And the only one here with gray hair, too.

(Laughter.)

MR. TYNAN: To my immediate right, I have Dr. Jill Hollingsworth. Dr. Hollingsworth is the Group Vice President for the Food Safety Programs Department for the Food Marketing Institute. Her fields of expertise include food safety and microbiology, epidemiology, food-borne diseases and public health. Dr. Hollingsworth previously served as the Assistant Deputy Administrator in the Office of Public Health Science at FSIS, and she's also served as the FSIS Special Assistant to the Administrator where she was directly responsible for providing scientific and technical advice and guidance under four administrations. And I've had the pleasure of working with Dr. Hollingsworth, so it's nice to see her today.

To her right is Ms. Caroline Smith DeWaal. Ms. DeWaal is the director of Food Safety Program for the Center for Science in the Public Interest and is

the co-author of *Is Our Food Safe: A Consumer's Guide to Protecting Your Health and the Environment.* She represents CSPI with Congress and in the regulatory arena on a broad range of food safety issues, including meat and poultry safety, seafood safety, food additives, pesticides and sustainable agriculture and animal drugs. Ms. DeWaal is a leading consumer analysis on reform of laws and regulations governing food safety. And prior to coming to CSPI, Ms. DeWaal was the Director of Legal Affairs at Public Voice for Food and Health Policy.

And to Ms. DeWaal's right, we have Dr. Amirhossein Mokhtari, and I did pronounce that correctly?

DR. MOKHTARI: Perfect.

MR. TYNAN: Excellent. And Dr. Mokhtari is a senior risk assessor and modeler at RTI International. He's worked on many research projects sponsored by USDA, FDA, and EPA. He currently provides risk assessment support to various clients on a diverse array of projects, including developing a methodological framework for the fate and transport of

pathogens in the environment, modeling consumer phase risk assessment for microbial pathogens, quantifying transmission dynamics of infection, diseases in the population and evaluating the role of food handlers in the spread of microbial diseases. That's very impressive.

Okay. And with that, that is our Panel. And so we'll begin by going over the questions. And the first question we have has to do with information or data as well as unpublished data or data sources that the Panel is aware of regarding the transmission and movement of LM at retail that might assist with this risk assessment. And what we're looking here is for information that is not -- identifying information that we're not currently aware of.

For example, I think Dr. Draughon this morning mentioned that consumers keep deli meats in their refrigerators for certain periods of time, and the risk increases. As an example, is there data on how long deli meats might stay in the consumer case at a grocery store? There are some limitations. But within those regulatory limitations, how long does it

take to turn over? Would that data be available and would that be helpful?

And so with that, I may ask Dr. Mokhtari if he might start off the discussion of data and what data we may need.

DR. MOKHTARI: Okay. Well, I would like to answer this question in a different way. I mean, I would like to share some of my experience about what kind of information is useful to include in these type of models, actually.

I talked with Dr. Gallagher after reading his draft about the risk assessment he's developing. I was so excited because recently, Dr. LeAnn Jakis (ph.) and I worked on a norovirus risk assessment in the retail food establishment, which is basically more or less the same approach that Dr. Gallagher is using, mechanistic model looking at temporal variation of contamination.

So some of the outcomes that we learned from that research was basically the importance of food handlers' behavior, how we have to include that into the risk assessment modeling, and the importance of

conducting observational studies and look basically how food is handled inside retail stores. I mean, one of the outcomes that we learned from that study was just one of the major reasons for cross-contamination is basically how food handlers are handling the food inside the food establishment.

The other point that I'm interested to mention here is the impact of looking at spatial distribution of contamination at retail. There is another work that RTI is doing with Michigan State. Dr. Ryser might be part of that and Dr. Iain Todd (ph.). We are looking at transmission of norovirus in daycare centers. And in order to do that, as a part of the research, we assigned a significant amount of budget for doing sampling at different locations in a daycare center to basically identify the hot spots, as Dr. Wiedmore [sic] mentioned in the morning.

There are many different locations that we are suspicious that might be a source of *Listeria* in the retail store. So what we did in that study, we are going to do a lot of sampling inside daycare centers, different locations, like diaper change area,

kitchen, or even toys that children are playing with. So basically, we want to include that into the model to identify what sources of -- what locations inside a daycare center might be a hot spot for introducing contamination into the model.

And I think Dr. Gallagher, I didn't hear that you're going to include, like, product-specific gross data. There's significant studies that Dr. Ryser is a part of at Michigan State, and instead of looking at gross data, which, like, basically the PMP model that we have for gross is using that, they're looking at the product-specific data -- I'm sure Dr. Ryser can mention that -- for a specific deli meat product and how gross is going to be estimated, just time and temperature in those products. And that's what I wanted to share.

MR. TYNAN: Okay. Thank you, Dr. Mokhtari. Dr. Butts, did you have a comment or some thoughts on the data, please?

DR. BUTTS: I think adding to those concepts, we call the factors GMPs, or good manufacturing practices, which we use to control the

transfer of the organism basically from the growth niche to the product. And those GMPs are very important. And we have seen situations where we had a contamination incident that occurred, although we didn't know it when it was happening, but with good, strong GMPs, we were able to keep the contamination away from the product. And this happened at a time, you know, many years ago before we had redesigned our plant. And that contamination was spread throughout the floors, but we were able to keep it there by having strong GMPs.

One rule that we have, for instance -- and it's not like your mother taught you at home. If you drop something on the floor, you don't pick it up. You know, we have people who -- that's part of their responsibility to do. But if you're handling product, you don't reach down and pick it up. So there is a number of hard-fast things that we must do whether it's in a meat processing plant making ready-to-eat food, a raw slaughter facility or in a retail deli. The GMPs must be strong.

I've heard a lot today about the

contamination from the chub to this to that, but I heard a little about growth niches. Growth niches are the root of all evil. These are the reservoirs where the organism is hiding. And it's perfectly logical to me to see a clean retail store, clean deli, and still have a high amount of contamination. Surface cleanliness is important, but the growth niches are below that. And as that organism grows, they come out and can contaminate product.

This is a serious issue in retail deli compared to our processing plants because of the temperature difference. That temperature difference does enable the growth niches to grow faster. So I think we're going to see them exude quicker.

MR. TYNAN: Thank you, John. Dr. Hollingsworth, did you have any comments you wanted to make on that?

DR. HOLLINGSWORTH: Getting, I guess, back to the specific question about is there data out there published or unpublished that can be used. I think there are other sources of data that we can explore together. And in all honesty, the likelihood that

that data will just be submitted to a Federal Registry notice is not that great for a couple of reasons. One is just the time and resources it takes to gather and assemble it, and then also even understanding in what format you need it. And I think a lot of the data that might be available can best be transferred or handed off more in a one-on-one setting, where we specifically understand what the risk assessors need and how we can get you that information.

For example, we know that and we saw Joe and Martin's data today from New York State, but we know other states collect samples. We know that other states have quite a bit of data on *Listeria,* both product and in environment. And we can get that information, I think, if we work together.

Also, there is industry data. We do have retailers, some of them, who collect samples, some on products, some on environments, some for *species*, some for LM. But also, they do a lot of sampling. We have a lot of stores that do generic sanitation sampling, ATPs, and what have you or coliforms. And I think even though that may not be *Listeria*-specific, I think

that kind of information will give us some good ideas to what we see as sanitation problems, areas that are more difficult to clean, for example.

The other thing, and this actually came up quite by accident, I guess, in a discussion the other day, that retailers can get sales volume, what products turn over quicker. They know which products get sent to the stores daily or weekly, which products stay for the full seven days because it's not a high-volume turnover product, versus something where the chub may turn over in a matter of hours, let alone days. And that kind of information we can get. So I think it's just a matter of us understanding what data would be helpful and then us looking at how we can get that from the retail sector to share.

There are some other things, too, that I think we should look at. One is chemical use, what types of cleaning products. And I guess it was Regis, maybe, who brought this up. What kinds of chemicals are used in different parts of the store? We have all different chemicals. Some are used for countertops versus the chemicals we used on floors. They may be

very different. And we can get information on the different chemicals that are used, how they're used, how they're being monitored, who verifies whether or not the procedure for using them, the concentrations, are correct. We can get that information.

The other thing I'd like to suggest, too, is that we think of some innovative approaches to gathering data if there is information that's missing that we need. And I think that you will find that the retails are willing to get -- collect data if they understand what it is you need and also if they have some centralized way of submitting that information.

For example, I think someone just mentioned hot spots. We can certainly prioritize hot spots. And even do across the nation a sample collection of a particular hot spot or a piece of equipment and have multiple retailers take samples, pull the samples, and submit them. For example, to a centralized lab to have those analyses done. So I think there's ways we can identify what those data gaps are and work on getting them done.

And other thing we'd like to think about is

collecting before and after data. If we can collect, you know, several hundreds of samples prior to making a change, we make that change, and then we recollect the samples, because too often, we're asked to identify a problem, make a change, and then no one ever really comes back and says did that change really have an impact. So I think we can do both before and after sampling, too, that would help. And I think when we get to Question 3 and talk about how do we do that together, I've got some other ideas. But I do think there is data out there, and I think there's ways to get some new data.

MR. TYNAN: Well, I was going to ask a follow-up question if you had some ideas on how we would get the data that you're saying --

DR. HOLLINGSWORTH: That's number three.

MR. TYNAN: That's Question 3. Okay. We'll wait until Question 3. Ms. DeWaal, did you have a comment on that particular question?

MS. SMITH DeWAAL: Thank you, Dr. Tynan. I want to talk about really three different components of data gathering for this project. First of all,

it's the incoming load of *Listeria* on the product. Just to remind you, I mean, part of the reason this exercise is going on with FDA and USDA is because there is a change in policy at FDA about their zero tolerance requirements for the food products going into the deli counters that are regulated by FDA. USDA has not changed its policy.

So we think that when you are looking at data on the amount of *Listeria* entering the retail environment, it's critically important that you be looking at data from countries which are already utilizing the 100 CFU per gram standard. Most of the countries in the European Union, I believe, are already using this. It may be true, also, Australia or New Zealand. I actually haven't checked.

But I think critically important is not measuring the amount of *Listeria* that might be on products coming into the retail environment based on U.S. data because we've been operating under a more stringent standard. So I think you really do need to utilize the European data especially on that question.

With respect to cross-contamination, I just

want to note that you don't need to rely strictly on retail sampling or studies for that amount of data. I mean, we're talking about food contact surfaces, often which are the same in processing as they are in retail.

You may actually look at some of the data from the Canadian outbreak last summer from *Listeria*. I believe that may have been a contaminated slicer. But it caused a very large outbreak, and you should gather the data from outbreaks that may have occurred both in the processing as well as in the retail sector to see if you have data on contamination at these key points.

The other note here is that there may be data -- I know that New Zealand had a system for checking -- at different points, they checked environmental surfaces, products, end product testing. They checked at different points. And again, in the processing environment, it might be interesting to get that data if the surfaces are comparable and see if you can't get data on cross-contamination.

And the final data-gathering point I want to

raise is on the consumer -- what the consumer is doing with a product. So if you've already done your estimates for incoming product and cross-contamination, you also want to know what the likelihood is that consumers may handle the product or use the product in such a way that will facilitate the growth of *Listeria*.

So what are the storage temperatures on products after they leave the retail environment? What are the handling and holding patterns? I think you've already discussed the study coming out of Britain saying that elderly consumers may hold these products much longer than perhaps they were intended. I don't know if we have similar data here, but the bottom line is these are high-risk consumers, and we need to know how they're planning to hold the products and, similarly, how these products may be used in institutional settings. Thank you.

MR. TYNAN: We have a little bit of time on this Panel and we gained some time this morning. So I might just before we go on to Question No. 2 ask the Panel if there are any additional comments based on

what they heard from the other Panelists before we go on.

(No response.)

MR. TYNAN: There being none, we'll go to Question No. 2. Question No. 2 is what risk management interventions, control measures, mitigations or other technology to reduce the risk should the risk assessment evaluate? Do you have data or information concerning these interventions that could be provided to the risk assessment team?

And here we're looking for changes in practices relating to *Listeria* in the retail settings. The study, as I understand it is a baseline -- it has a baseline model and it's going to incorporate scenarios using new interventions. So what are the interventions that should be addressed in the study? And regarding the data, is there manufacturer data, things of that nature, that we could incorporate into the study as well?

And I'm going to ask Dr. Butts, perhaps, to start the discussion and talk a little bit maybe about the AMI experience and some of the success they've had

with interventions. Dr. Butts?

DR. BUTTS: Thank you. This organism has caused more change to the processed meats industry than any other event in the last 30 years. The ubiquitous nature and virulent nature of *Listeria* has led us in the processed meats industry to recognize the need for an effective and attainable product protection plan.

Before we experienced DNA linkage and the things that Martin was talking about, our former leader, Bruce Tompkin, taught us about the three scenarios that we had to deal with as an industry. And those were the isolated case, where one product, one package was contaminated, versus cases due to a single lot or a single event, where, in our situation, it would be one shift or between cleanup and cleanup, versus the situation where we had clusters or isolated cases, which were from the growth niche. And particularly, if we have a virulent growth niche that was living in our plant, that growth niche needed to be eliminated.

So that really preceded, in our situation,

the DNA linkage. And we learned this morning that it can persist over years in the plant. So let's look at our history and what we've learned from our history. In the early '90s, product and contact surface sampling dominated. Growth niches were discovered in hollow rollers. The industry recognized the benefits of separation. We painted lines on the floor to separate.

In the mid-'90s, equipment teardown became common. That's when we developed the seek and destroy concept, to really find and isolate the growth niches. We did a lot of internal equipment redesign. And our suppliers, equipment suppliers, were informed, but during that period, our floor problems persisted. We could not clean the floors. Drains were not expected to be *Listeria*-free.

Also in the mid-'90s, we discovered the persistent deep growth niches and recognized them as the root cause of our problems. Also, we found facility areas were primary sources of *Listeria* harborage. These are walls, freezer walls, absorbent materials indoors, wet floors, and cracks in floors.

And at that point in time, we found that mid-shift cleanups -- and I liken a mid-shift cleanup in our plant to your wipe-down -- that spread more contamination than it solved.

So I would challenge you to look at these wipe-downs and cleanups. Are they really benefiting? You know, I understand the need because of temperature, but we found it to be a problem.

In the late '90s, we realized the benefits of dry floors. Cooking and pasteurization of equipment became commonplace. The DNA linkage then evolved, methods for construction process control. That's a unique special cause. And spread of the organism from the growth niches to the product become more well understood. And at this point in time, the painted lines gave way to absolute physical separation in the plant.

In 2000 we held our first AMI workshop. And again, Bruce was a strong leader in that, and I've heard Randy Huffman's name a few times today. He was with AMI and put it together. And he got us speakers together to reach consensus on what we considered the

best practices. We went forth and taught that. To data, we've held almost 20 workshops and trained over 1,200 people in industry, really, from all over the world. Our last one was just a few weeks ago.

In 2001 the AMI board of directors met and declared food safety to be non-competitive. That was a breakthrough in our industry because it really allowed our science peers to really talk to one another and openly share best practices.

And from 2001 to date, many lines have been brought under control. Elimination of single growth niches brought new levels of control and more aggressive sampling was deployed. To date, pasteurization of large chubs are commonplace. That's why I believe that the incoming load from meat processing plants in the United States today is very low because the technology is there for the manufacturer to eliminate that problem. And of course, the use of DNA and ribotyping really allowed us to understand the growth niche situation.

In 2003 the AMI had a report from their equipment design task force. They gave us ten

principles of sanitary design. And in 2004, our facility design group gave 11 principles of sanitary design. Both of those documents provide proven guidance as to design of equipment and design of facilities. We've seen them sited far beyond the meat industry into other applications where food-borne pathogens have become a problem. So we encourage you to look at those and use them in helping define the criteria for the transfer that you're seeing.

Lactate and diacetate -- many, many products now have growth inhibitors, and we believe that they're providing a higher level of assurance to you and to the consumers.

And now we've got some plants that have attained real high levels of control. It's not uncommon for a meat processing plant to have 100 drains in it, be sampled monthly, and have no positives for over a year. So we know that control is available. We're not going to say that we can eliminate *Listeria* from the RTE environment. It is ubiquitous and very aggressive. But by controlling the plant environment, we know that we can very

dramatically reduce that.

And here is a little-known fact. Over 90 percent of the *Listeria* recalls that you see in federally inspected plants come from plants who failed to hold the product when the test is ongoing. These are typically smaller plants. So, you know, we can just virtually almost eliminate the publicity if plants would just hold that.

So what do we learn from our history lesson? Our history and practical hands-on experience teaches us to eliminate and manage growth niches. A growth niche is defined as a location harboring the organism after the routine sanitation process has been completed. We also learned that there were critical factors for sanitation process control. We've heard a lot about the situation in Canada this last year, and that one situation clearly demonstrated one of the key factors, one of the key critical factors, and that's degree of disassembly of the equipment.

Is the equipment in the retail delis capable of being disassembled on a routine basis so that the growth niches are exposed and can be eliminated? We

have others, chemical sanitizer treatment, hand scrub, contact surfaces, heat treatment. When we clean a piece of equipment, small parts come off. They go into what we call a COP tank. Yes, we can apply soap. We can apply some chemical sanitizer at food contact concentration, but we cook that, we pasteurize it so that we know that we've removed it.

MR. TYNAN: Dr. Butts, could I interrupt for a second -- and I know you probably have many gems of wisdom there to share, but in the interest of time, could you summarize maybe the interventions for us and allow the other Panelists to --

DR. BUTTS: Sure. Since 2003 there have been no federally inspected plants that processed deli meats linked to *Listeria* investigation. The tools that we have used have been very effective. We hope that we can have the scope of control -- and here are the pitfalls that we need to avoid. And that's punishment by either regulatory or corporate for finding a problem, investigative sampling must lead to positives being found, and that's a win/win situation. The other is prescriptive government programs. We got

to have room for continuous improvement. We're forming habits here. So too quick of regulatory action is going to cause problems.

In summary, declaring food safety non-competitive, ensuring process control best practices within the industry has been one of our keys. We've seen that there are missing links or gaps in the data. Janell showed that between where we've been and where CDC's data is at. That's very concerning to the meat processors. And AMI and the processed meats industry remain committed to solving the food safety problems associated with our product from farm to fork.

MR. TYNAN: Thank you, Dr. Butts. I'm going to ask Dr. Hollingsworth to follow up, and if I could, if I could ask all the Panelists to make sure they speak into the microphone so that the people on the phone can also hear. Okay. Dr. Hollingsworth?

DR. HOLLINGSWORTH: Thank you, Robert. Couple of things on the risk assessment interventions. We believe that especially if you look at some of the data that has been collected, for example, some of the work in New York, we were very intrigued by the

repeated findings of *Listeria* in floor drains, and I think, as John had pointed out, too, that that's not uncommon.

But the question that we have is if, in fact, it is that common in drains, is that a point or a source of contamination, cross-contamination, to other locations. And one of the things we would be very interested in working with the risk assessors on is looking at the current techniques that are used to clean floors and floor drains. We have everything from someone coming out with a high pressure hose and blasting the floor to clean it, which may be the worst case scenario, to those companies that don't even use brushes anymore or liquids. They use foams or chemical rings to try to keep down the moisture level and also not to spread the contamination.

So I think that's one area and one example of a place where we can identify here is a potential problem. What are the retailers doing now to address it? What are the good practices and maybe the not so good practices? And can we assess if they're really making a difference in the environment to spread

Listeria or not.

The other thing is that we need to also keep in mind -- I think sometimes when we look at what might be a good mitigation strategy, we end up causing unintended consequences. And I'll give you a couple of example of those that we've been talking about internally in the retail sector that we're concerned about.

Right now, there is a requirement, for example, every time an employee changes their gloves, they have to wash their hands. Now, some stores have a policy, for example, if you're making sandwiches on a line, that you should change your gloves for every customer. It's not required, but it's a policy -- customers like it. They like to see their sandwich being made with a fresh pair of gloves. But to do that, the store employee has to take off their gloves, leave their workstation, go over, wash their hands for 20 seconds, dry them, come back, put on new gloves, make a sandwich, take those gloves off, go back, same procedure.

So what we end up doing is almost pushing

employees not to change their gloves because the consequences of changing them actually cause disruption in the environment dealing with customers. And so one of the things we'd like to look at, for example, is changing gloves more frequently a good practice and does it make a difference if you haven't changed the job task that you're doing, is it necessary to wash your hands every time you change your gloves -- just something we'd like to look at.

Another example of this is opening up door cases, the deli case. There have been some attempts to say, all right, once the employee puts their gloves on, which we want them to have the glove on to pick up the meat out of the case, but they shouldn't open and close the door with the same gloves. Well, short of changing your gloves five times to get the door open, the meat out, close the door, put the meat on the slicer, open the door, put the meat in, close the case, they'd have to change their gloves five times to do that. But so what they do if they're told that's the alternative, they leave the door open, and now we have a temperature problem.

So I think we need to really realistically look at these. There are things that happen in a deli environment that will never happen in a processing environment. And so as much as our friends in the meat industry have been sharing information and helping us, we have practices that are just different. But we have to be sure that we don't have these unintended consequences trying to solve one problem and, in fact, create another.

And those are the kinds of things we'd like to work on. For example, in looking at what kinds of -- in doing the risk assessment, would we want to put in a mitigation and run the risk and see if that mitigation factor would have an effect? One thing to consider, for example, is what if we just said the handle on the deli case is a food contact surface? So now you can touch it with gloved hands. The only real difference for us is you never can bare-hand touch it, and you have to clean it twice a day. So now it's a food contact surface, and that may solve the problem.

So I think there are some solutions that might work for us at retail, and we'd be happy to talk

about them and also share how can we measure them and assess them if they really make a difference.

Another issue that was raised was one of training. And I thought that particularly in Joe's discussion -- we have lots of training programs, training videos for retailers, but I thought his idea of actually watching maybe in a real-world situation some things that go on daily without anyone really thinking about, this could be a potential problem for *Listeria*. And actually creating a short little video that -- I guess people don't watch videos anymore. DVD. I know, I say eight-tracks, too, so just bear with me.

(Laughter.)

DR. HOLLINGSWORTH: So maybe one of the things we could do is have this short little video that we show to deli employees, and it's just common sense things that you can do in a deli to reduce the risk of listeriosis. And I think something like that would be doable, and we could actually put that in place and measure does it seem to make a difference in behaviors.

And the other piece I wanted to refer to, and Caroline brought this up, and that's the consumer piece. And we at retail certainly do not want to say this isn't our problem, it's all the consumers, it's not. They're our customers. And we also feel that we have an obligation, though, to do everything we can to help the consumer to do the right thing.

And some of the things that we've been talking about -- and again, we'd be interested in even assessing will this help -- and that is, if we put best if used by dates on deli meats that are sliced in the deli. Some stores already do that. Others don't. Some put the actual day that the product was purchased, but then we don't educate consumers what does that mean. Does that mean once you've purchased it, keep it for five days, seven days, until it's slimy?

But I think that there are ways that we can help educate consumers even with simple things like educating them -- and we did a great job, if you think about it, with cooking temperatures for ground beef. We can also do this, I believe, with handling deli

meats, both time and temperature.

And lastly, I think, the one thing we will have to look at when we do this risk assessment, and that is the variety of different types of products. One of the things that we don't have is an advantage that a processing facility has, is running a particular product in bulk at one time on one line. And we don't. We're handling everything. We're handling cured, uncured products, meats, poultry, cheese. We have deli salads often in the same case. God forbid the person who does have raw chicken. If someone sees that, let me know. I'll go visit them personally.

But we do believe that we're going to have to look at these products as individual entities because they're handled differently, and the way they respond to the growth of pathogen and the way consumers handle them all varies. So we'd like to also talk and look at how can we look at these different categories of products not in big clumps, but almost product by product.

MR. TYNAN: Excellent. Thank you very much.

Ms. DeWaal?

MS. SMITH DeWAAL: Thank you. I like the concept of moving a problem from one place to another, because in a way, we may be shifting the controls for *Listeria* from the processing plants that can manage it differently into the retail environment. So they may have to be hiring people like Dr. Butts or Bruce Tompkins to come in and help assess their environmental controls.

And so let me explore a couple of ideas. One mitigation strategy would be for retailers to require their suppliers to test and hold their products for LM before they bring them into the deli and whether actually shifting it back to the supplier might be one risk mitigation strategy that a retailer could use.

But the second thing that I think the agencies need to look at as they pursue this risk assessment is the fact that the regulatory touch point for retailers is at the state and county and local level. And if anyone here has studied the implementation of the food code, you will know there

is a high degree of variability from the level of what standards are being enforced to the qualifications of the people enforcing them at the state or local or county level to the frequency of enforcement.

So think that as part of your risk assessment, you need to factor in that variability of the regulatory component of retailers. And CSPI has done work -- I think we did a report in '96 and we did a report last year on -- where we looked at the variability in this system because it's very broad. I mean, you don't know from state to state who is actually regulating it. And at some points, the food code is adopted at the state level but not at the city or county level where it's being enforced. I mean, it's pretty complex. So I do think that's got to be part of your risk assessment. Thank you.

MR. TYNAN: Thank you, Ms. DeWaal. And last but not least, the last word will be Dr. Mokhtari.

DR. MOKHTARI: Just a couple of quick points. I mean, I want to mention again the importance of the consumer phase risk assessment for this practice. Consumer phase is not all about the

storage time and temperature, in my opinion. I mean, there are many different practices, food handling, involved during the consumer phase, including the potential for cross-contamination inside the refrigerator or the issue of leftover deli meat and -- or even the countertop, if they put the deli meat on the countertop.

And we are doing research with Michigan State on best consumed by risk dates for deli meats, actually, as mentioned here. One thing that we learned from that research is basically how people handling their deli meat inside homes, basically impacts how long they can hold their deli meats. So irregardless of what is the initial contamination of deli meats purchased from retail store, the way you're handling your deli meat at home, the potential for cross-contamination in your own refrigerator or the issue of leftover, that's going to be a very decisive factor for the best consumed by dates.

And the other issue that I wanted to raise here, as John mentioned, the question might be at the end how aggressive we need to apply these risk

mitigation strategies to make sure that, for example, the final contamination is within an acceptable range. One of the really cool features that Dr. Gallagher implemented in his model is the whole issue of two-dimensional models, looking at both variability and uncertainty.

And I think USDA has practiced this already in the -- bacteria risk assessment for -- chicken, that they looked at the issue of food safety objectives, FSOs. And basically, by enforcing a specific standards, at the end coming back and look at what kind of ranges of acceptable levels for, for example, sanitation practices, we need to ensure at retail or at home to make sure that our contamination at the end are within this acceptable range.

So I think it's a good feature that you already included that two-dimensional, which is a key requirement for that kind of analysis. So you might want to take a look at that and already include that in your modeling because at the end, that's a very important feature that you have in your modeling. It can answer a lot of good questions.

MR. TYNAN: Okay. Thank you. I'll ask the Panel if they have any questions or comments about the other Panelists' remarks?

DR. BUTTS: Yeah. I appreciate Caroline offering my job up for consulting. I have a pretty good fee.

(Laughter.)

DR. BUTTS: I want to talk a little bit about test and hold and the great misconception of product sampling. We have a lot of statisticians here in the room, and I hope that you go back to those basic tables we had years ago in our first statistics classes when we looked at attribute sampling and, you know, take those to heart.

The real sampling that we must use is not product sampling, but it's process control sampling. And process control is really -- really enables us to have a high level of assurance that we are delivering the product to the consumer. So product sampling and test and hold is not going to provide the assurances. What's going on when that product is being processed will. So I strongly encourage that.

MR. TYNAN: Okay. Thank you, Dr. Butts. With that, I'm going to move to Question No. 3. And Question No. 3 is what suggestions do you have to make the process more transparent and allow participation of stakeholders in the development of this risk assessment?

And I'm going to ask Dr. Hollingsworth if she wouldn't mind starting off on that and maybe look back and tell us how we're going to get some of that wonderful data she talked about. Dr. Hollingsworth?

DR. HOLLINGSWORTH: Thanks, Robert. I think that one of the simplest and easiest ways is just to sit down with the people who you want to talk to and talk to them. I think one of the things for the retailers is that they're not always clear on exactly what kinds and types of data you're looking for. So I think if we had an opportunity, and of course, meetings like this where we, you know, we have speakers and we share information, that's great. But I think a more one-on-one type of conversation even if we have to have more than one in several different locations across the country on a regional basis, we

can certainly bring retailers to the table who'd be more than happy to talk about tell me what it is you want to find out, what is it you need to learn?

And I also think that they would be very willing to share especially if they know that there were no regulatory ramifications. But information like, you know, I watch this practice in my store and it's always bothered me. What do you think? And just kind of an open sharing of best practices of what information they have of what kinds of data they would be able to collect and gather. And I think they'd be very willing to do that. In fact, I can tell you they were because I've talked to them recently. We've had a number of conference calls. And they've all said let's just get together and talk about it.

I think the other thing that they would be very willing and interested to do and I think it would help all of us is even if we had a meeting between the risk assessors and the retailers talking about what data they can share is to have additional groups come into those meetings. And there's two groups in particular that come to mind. One, of course, is the

meat producers, the suppliers who send us these products, and have a joint talk between the retailers and the suppliers and get some information on who is buying products with and without growth inhibitors and why. There is a very good reason why a lot of retailers are not purchasing products with growth inhibitors. And I think we need to talk about that.

And the other group that I think would be very important to have in these meetings are the companies that provide the cleaning chemicals because often those companies also do monitoring of the sanitation practices. They train the employees how to clean the equipment, how to test the chemicals, their strength, and what have you. And I think having those companies in the meeting would help, too, because they can really share with you the information they have. They have tons of research that they do on, you know, kill steps and contact times and what has to be rinsed and what equipment can and cannot be cleaned.

And another would be, at the same, time you could have equipment manufacturers. We've seen a lot of good ideas coming out from equipment manufacturers,

I mean, and everything -- we had a meeting with the three major deli slicer companies. Now, the companies that make deli slicers at retail aren't necessarily the same slicers that you have in processing. But we talked about if we could build -- you know, money was no object, space was no object, what would be build in the way of the slicer. And there were amazingly great ideas that came up. Some of them were not affordable. They weren't even realistic, but they were great ideas.

And so I think bringing in these equipment design companies both for slicers and also those people who design things like the deli display cases. Are there ways to make that a better environment or to keep the temperatures down even more?

And I think all that's very doable. And I'd like to almost, you know, just offer that as an invitation right now that we'd be willing to help organize those meetings and get those groups together.

The other thing that I think would help -- and I know doing the behavior studies right now that we're participating in I think has been, hopefully, a

valuable exercise for the people who are out in the stores looking at routine behaviors in a deli department, but we would more than happy to arrange other store visits.

The only thing stores that usually do have a problem is bringing visitors around during peak hours, and of course, that's when you want to be there, because if something is going to go wrong, it's when you're rushing. But we could work around that. We could find ways to get people into stores and visit what really goes on behind the counter or even in the cooler and behind the scenes. But that way, we could look at it together.

And there is one other piece to this that always gets, I guess, a little sensitive, and that's talking about cost benefit because I think if you look at, you know, what is the cost of somebody getting sick or a woman losing her unborn child, and there is no dollar value you can put on that, and we realize that. But on the other hand, what we want to really do is to say at retail, if there is something we can do that's really going to lower listeriosis, then we

need to know about that and we need to figure out how can we do it.

I think our frustration right now, and I raised this before, and I'll mention it again, is we have a guide to best practices at retail for controlling *Listeria*. And we feel that the retailers have done a really good job putting those procedures in place. And if you look at the data from 2001, the Gombas study, to 2005, Ann Draughon's study that she presented, we've achieved a greater than 50 percent reduction in the positive LMs in deli-sliced meats. But the incidence of listeriosis in the population has not changed in those same four years. And that's a huge frustration for us.

And the question we have is if we can even lower it another 50 percent in deli meats, are we still going to have the same level of listeriosis because if so, we haven't done what we've set out to do. So I want to try to remember -- to remind everyone we need to keep our eye on the target, and that is lowering the illness in humans. Just getting it out of meat and getting it out of the stores, if

it's not reducing the human illness, then we haven't done what we've set out to do. So let's not lose sight of that.

And the one last thing I meant to mention is I brought up this guidance document that the retailers put together for retail best practices. We've distributed hundreds and hundreds of copies of that document to retailers all over the country. We would like very much to provide that document to the risk assessors, to FDA, FSIS, and get critiques back on it. Are there things in that document that we could do different or better, because that is our best practice guide. It's been out there since, I believe, around 2005, and we're certainly ready and willing to update it if there's other best practices that we should be advocating.

And I forgot one other group that I do want to mention, and that is the difficult time that even FMI has reaching out to very, very small stores. Even little country stores and bodegas and little tiny shops, but they are retailers. And they're just as important to us whether they're members or not because

they totally impact on the whole perception of are retailers doing the right thing for their customers.

And I think one way that we can reach out and involve them more that we could certainly work with you on, and that is almost every state has a state retail association. The state retail association members are usually the very small stores that are only in that state. They're not national or multistate companies that belong to organizations like FMI. But every retail state association is a member of FMI. So we can reach out to all of those associations and get you all those little stores, too. And we think we need to bring them into the loop on this because they're just as important.

MR. TYNAN: Thank you, Dr. Hollingsworth. Ms. DeWaal?

MS. SMITH DeWAAL: Thank you. First of all, I think Dr. Butts is right that, actually, the statistical process control has proven most effective for these products. But I will note that in the ground beef industry, they actually are utilizing test and hold more. And what we don't know here is the

issue of seafoods or cheeses that may be coming into the deli counters with an increased load of *Listeria* is actually what we're talking about here. Perhaps there is data on whether the most effective monitoring tool there is statistical process control or some other technique. But I think the retailers are going to have to get an answer to this to know how to manage and control these products coming in.

With respect to getting greater stakeholder involvement as well as being more transparent, I would recommend a couple of things. The National Advisory Committee for Meat and Poultry Inspection is one tool that USDA has for regularly consulting with its stakeholders. It's an opportunity for the risk assessment to present its work and to get feedback. And in addition to the members of the Advisory Committee, it's also a public -- there is a public comment period that happens there. So I think that's a useful tool.

Secondly, I think you need to really be aware of what consumers know, especially those in the high-risk population. We were pretty surprised last

year when one of our staff was pregnant and was monitoring what was happening on a variety of pregnancy boards on the internet. And when there was a *Listeria* outbreak or a *Listeria* problem, she would highlight it to the discussion group and a lot of time got feedback like, oh, it's a voluntary recall. That means it's not very serious or what are you talking about there's this pathogen that causes miscarriage.

So I think you do need to understand what is known by the high-risk population. I mean, this is a very severe pathogen, and a lot of consumers just don't understand the consequences of messaging around *Listeria*. This is not just food-borne illness in its classic form. It causes severe illness, hospitalization, death and miscarriage. So I think you need to test the knowledge of the consumers who are going to be purchasing the products and bringing them home.

And, secondly, this is always an interesting test. If you go into the retailers and start asking questions -- I do this sometimes at grocery stores in my neighborhood, even very, you know, well-informed

ones, Whole Foods, and places like that. And at different stores, I'll test things like, you know, are these cheeses made from pasteurized milk because sometimes they're not labeled to indicate that. And then I'll say, well, what's the risk if it's not made from unpasteurized milk. And basically, you could do tests of actually the knowledge of the counter help at these retail delis. Can they actually answer consumer questions about the risk of these products and what the handling -- what handling should be done to make sure they stay safe.

So I think those are a couple of opportunities, the use of focus groups, the use of surveys, as well as the National Advisory Committee on Meat and Poultry Inspection. Thank you.

MR. TYNAN: Thank you, Ms. DeWaal very much. Dr. Mokhtari, can I ask you to weigh in?

DR. MOKHTARI: Okay. Couple of quick points. I think one of the final application of this risk assessment model, as Dr. -- mentioned, is going to be a virtual lab for FDA and USDA, which is very important.

As far as, for example, the guidance document for the retail best practice, I mean, if we implement the major component of that guidance document into this model, definitely you can go back and see whether those recommendations are practical or effective in reducing the risk. So eventually, this risk assessment model can be used in that purpose.

But as far as a suggestion for having the stakeholders involved in the process, just a quick point based on my own experience, I think it's really important to include the stakeholders at very early stages of the process even developing the key questions that we want to answer with a risk assessment. I mean, I've been involved in many situations that I presented my research in a conference, and I got very basic questions from participants, which were, like, practical questions, did you include this and that in your result or can I learn about this problem from your findings. And my quickest answer was, like, unfortunately, we didn't get enough finding from USDA and FDA. We're going to do it the next situation. But that was not the

correct answer. The correct answer was we didn't think about it because we didn't discuss with the stakeholders.

So maybe a better approach is, like, since we are in the beginning of this process of risk assessment, we basically ask the stakeholders, the retailers, what kind of questions you want to answer with this, what kind of information. Maybe they're not interested in temporal variation of contamination. Maybe they just want to see if they're cleaning their slicers on this frequency, is it going to impact contamination or not. So it's very important to get the actual feedback from the stakeholders in the very beginning.

MR. TYNAN: Thank you. Dr. Butts, I'm going to give you the last word.

DR. BUTTS: Jill, on behalf of the AMI and the meat industry, we want to accept that invitation that you extended. We greatly appreciate that.

As a stakeholder to be really transparent in this situation, we have developed three pillars of what we call microbiological process control

technology. And the first one, very simply, eliminate or manage growth niches in the exposed product area. The second, control transfer of the organism. And the third one, deploy process management techniques.

To eliminate or manage growth niches in the exposed product area, that requires knowledge of where the growth niches are at. We've used investigative sampling to get there. That's told us. I think that can be done very simply and very easily. Sometimes it can be done almost visually. I think it can be done without a great expense once you realize what you're looking for.

The control of transfer vectors, again, most of our discussion today has been about GMPs or control of transfer vectors. That's only one of the three pillars.

And the third one is develop interventions. And these are really process management techniques. In the meat processing plants, each piece of equipment that is in the RTE area is required to have an intervention in our facility. And that intervention goes from packaging machines that are longer than

these tables -- we have to be able to assure ourselves that we can completely remove the organism from that. We've done many strange things, you know, large slicers that will fill up the area from here to that wall. In fact, we believe that most of the things in the retail situation can have those interventions and are supporting research to hopefully help accomplish that.

I'll tell a quick story on the cost/benefit ratio.

MR. TYNAN: Dr. Butts, can I interrupt for just a second?

DR. BUTTS: Sure.

MR. TYNAN: I think our question we were talking about the process for making it more transparent and for participation.

DR. BUTTS: Okay.

MR. TYNAN: Were you tying into that?

DR. BUTTS: That's okay.

MR. TYNAN: Okay. That's it? Did you have some other comments on that?

(No response.)

MR. TYNAN: Okay. I think that ends the formal questions. I wanted to allow the Panel maybe to take one minute each if they have some additional comments they want to make at this particular point.

(No response.)

MR. TYNAN: We're all done? Okay. I want to thank the Panel for participating and helping us out, and I'm going to turn it back over to Sherri if I can to moderate the Q and A session.

(Applause.)

DR. DENNIS: Our final component of our meeting today is to invite individuals who have signed up for public comments to please come forward. And we would ask that you do restrict your comments to three to five minutes, and if we have some additional time, we can open up further to folks that did not sign up but would like to make some comments. So I'd like to first invite Lisa Ross of Shopper's Food.

MS. ROSS: I apologize. I thought that was a sign-in sheet.

(Laughter.)

DR. HOLLINGSWORTH: She's here.

DR. DENNIS: Well, you'll join the other individual who signed up because they were in the other meeting. So --

(Laughter.)

DR. DENNIS: You weren't the only person confused. Dr. Elliot Ryser.

UNIDENTIFIED SPEAKER: Excuse me. I was scared to put you up there. You might --

DR. RYSER: Just talk from here? Okay. Thank you for this opportunity. Got a few areas I'd like to cover very briefly. I've been working with *Listeria* for the last 25 years, and over the last seven or eight years been heavily involved in *Listeria* in ready-to-eat meats. We've done a lot of work with slicing, as people have alluded to.

In terms of slicing, again, we have some additional data that has not yet been published. We've done a fair amount of work with slicing of ham, of different moisture and fat contents, and we can tell you that the higher the fat content, the greater the spread of *Listeria* during slicing.

In addition, slicer design has a impact on

transfer. We've looked at several different commercial slicers initially, when they were new, and then after continuous use at a retail deli, and we also saw more extended transfer with the used slicer. So, again, wear and tear in the blade increases the roughness of the stainless steel, which, again, enhances the spread of *Listeria*.

Let's see. We've done some environmental sampling at a delicatessen as well along the lines of Dr. Martin Wiedmann and the other work at New York State, and we also have found *Listeria monocytogenes* present in floor drains, in the seals around coolers. Again, primarily, non-food-product contact areas, but we have seen *Listeria* on some food-product contact surfaces as well, including a deli slicer on occasion. So again, all evidence seems to support the slicer is the primary mode for cross-contamination.

The industry has been doing an excellent job. I applaud the industry for their efforts over the last few years. We've seen the incidence of *Listeria* decrease in the products coming from the manufacturer by 50 percent. But again, the

contamination rate at the retail is still seven to eight times greater compared to what's coming from the manufacturer

And along the lines of *Listeria* transfer with Dr. Draughon's study, which I was involved in, you need to also be aware that when we found positive samples, a lot of these positive samples came in clusters, which again suggests that *Listeria* was transferred from the slicer. A client would purchase a pound of ham. Then they'd purchase, say, another pound of ham or a pound of turkey. So the next product tended to be positive, and we've seen that out to three or four samples, on occasion. So again, the positive samples came in bunches.

Last item, we've been doing a lot of work on growth of *Listeria monocytogenes* in delicatessen meats at different temperatures, namely 4, 7, and 10 degrees Celsius. Looking at deli meats both with and without preservatives, being lactate and diacetate, and we can tell you that we have seen considerable variability between different lots of the same product with supposedly the same formulation.

So just because the product contains *Listeria* growth inhibitors, that does not mean that the growth curve for *Listeria* is flat. We have seen growth in some of these products that contain growth inhibitors.

This work is being done to develop a best consumed by data for consumers, and Dr. Perry is involved in some of this work as well at the risk assessment level. And again, this is going to be a difficult challenge since, again, we've seen some of these products with growth inhibitors that support growth, so it's not clear from the package label as to what data you would place on this package.

And lastly, I think some of this is going to be a problem for consumers as well. I mean, I'm not sure how well consumers are going to be able to adapt to the best consumed by date. I'm sure that Caroline Smith DeWaal would agree with me that consumers expect a safe product regardless as to how long it's going to last. They expect the product may spoil in the refrigerator, but they don't expect to encounter a serious illness from consuming that product. So

again, from the consumer standpoint, I think people want a product that is free of *Listeria*. So the best consumed by date is certainly a precaution. I'm hopeful that consumers will accept this, and it's become a problem with the elderly as well. Obviously, they tend to keep their products much longer, and you've seen that in the UK. So that's a whole 'nother issue that complicates this matter. So thank you very much for this opportunity.

DR. DENNIS: Thank you, Dr. Ryser. If you did not sign up but you have a statement you would like to make, we do have some additional time. I would ask, though, that you please try to keep your comments to about three minutes.

(No response.)

DR. DENNIS: If none, as you're driving home tonight and you think of some comments, I really encourage you to send your thoughts into us. And before we leave --

UNIDENTIFIED SPEAKER: Can we check our phone line one more time --

DR. DENNIS: Yeah, before --

UNIDENTIFIED SPEAKER: Check the phone line.

DR. DENNIS: Oh, I'm sorry. Before --

UNIDENTIFIED SPEAKER: The operator.

OPERATOR: Once again, star, one on the phones to ask a question.

DR. DENNIS: Go ahead.

OPERATOR: At this time, I show no questions.

DR. DENNIS: Okay. Thank you for inquiring. And for last comments, I want to turn this over to Janell Kause to close us out today.

MS. KAUSE: Well, Sherri, thank you. We want to thank everybody who is here today, as well as our panelists who stayed and participated in this process. This certainly is an opportunity for us to come out to you early in the process to garner input. And we wanted to thank each and every one of you. We've heard a lot today from CDC, from the various agencies, from various universities, and from the various stakeholders and what the current state of knowledge is about *Listeria monocytogenes* in retail. We also had a number of wonderful ideas come out of

the Panel just even this short session. And we think that we're going to be following up on a regular bases with them.

We want to remind folks that you may have seen our constituent update, which did say that, you know, we're going to close the docket in just a few weeks. That is the docket that somebody asked me that we're referring to that actually closes on September 29th. So I want to reiterate that it's open for three months, and we can go a little bit longer. Our goal really is the same, is to give each and every one of you the opportunity to contact us, follow up with us. I especially like the idea of even coming up with new questions, questions we may not have asked ourselves because that will help us tremendously as we go ahead and try to work on the issue of *Listeria* at retail.

With that, I close us out, and thank you very much.

(Applause.)

(Whereupon, at 4:15 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:

PUBLIC MEETING ON THE INTERAGENCY RETAIL *LISTERIA MONOCYTOGENES* RISK ASSESSMENT

Washington, D.C.

June 23, 2009

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.

_____

TIMOTHY ATKINSON, JR., Reporter

FREE STATE REPORTING, INC.