UNITED STATES DEPARTMENT OF AGRICULTURE

PATHOGEN REDUCTION: A SCIENTIFIC DIALOGUE

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P R O C E E D I N G S

9:05 a.m.

Welcome and Administrative Matters

DR. HULEBAK: Good morning. If everyone can please take his or her seat, we're ready to begin now.

I'd like to welcome you all to this Symposium on Pathogen Reduction: A Scientific Dialogue. My name is Karen Hulebak, and I'm the conference chairman.

I want to thank you all very much for coming to this symposium, for your interest in the substantive scientific issues that are the subject of this meeting that are so central to the formulation of public health protective policy, and for your willingness to participate actively in discussion of these issues through your participation at these tables up at the front where the panelists will sit and through your participation at those tables where the audience participants in this meeting will sit.

FSIS's organizing principle for this symposium was to generate new ideas for strengthening the effectiveness of HACCP, microbial testing, pathogen reduction measures, interventions, performance standards, inspection, risk assessment, and voluntary measures on the farm. We want to engage in dialogue at this meeting about how pathogen reduction is achieved through such measures.

My first duty at this symposium and a pleasurable duty it is is to introduce our Under Secretary Elsa Murano, Under Secretary for Food Safety. Dr. Murano will then introduce Secretary Ann Veneman, Secretary of Agriculture.

Dr. Murano, Under Secretary for Food Safety, was sworn in as Under Secretary by Secretary Ann Veneman on October 2001. As Under Secretary for Food Safety, she oversees the policies and the programs of the Food Safety and Inspection Service. She has had extensive public and private experience with food safety as a manager and as an educator. Immediately before joining this Administration, since 1997, she was Director of Texas A&M University's Center for Food Safety within the Institute of Food Science and Engineering.

Dr. Murano?

Welcome and Introduction of the Secretary

DR. MURANO: Howdy. Good morning, everybody.

I want to welcome you to this symposium entitled "Pathogen Reduction: A Scientific Dialogue". Thank you for joining us to hear leading experts from government and academia discuss the current science behind pathogen reduction and how we can take food

safety to the next level. That's why we're all here. So, I'm very happy to see all of you.

I am pleased to say the least to have the honor this morning of introducing Secretary of Agriculture Ann Veneman. Secretary Veneman has made improving food safety one of her highest priorities. In fact, she was so excited about this symposium during the early planning stages in January, that I know for a fact it was difficult for her to wait until today to see it come together. We have to keep reminding her that we're mere mortals and couldn't plan the conference in just a few weeks. So we did the best we could, and I thank all of you for coming because you're making me look good.

Secretary Veneman has made a lifelong commitment to food and farm issues. She grew up on a family farm in a small rural community in California and even was a member of 4-H. I wish I had been a member of 4-H myself, but this was not one of Castro's priorities back when I was growing up. So, I wasn't able to share that experience with the Secretary.

She has spent much of her career dedicated to advancing sound U.S. farm and food policies. Just listen to this list of positions in which she has served. She served as the USDA's Deputy Secretary, the

Department's second-highest position, during the Bush Administration from 1991 to 1993. Earlier, she also served as Deputy Under Secretary of Agriculture for International Affairs and Commodity Programs and as Associate Administrator of USDA's Foreign Agricultural Service. Most recently, she served for four years as Secretary of the California Department of Food and Agriculture, the nation's largest and most diverse agricultural-producing state.

Throughout her career, Secretary Veneman has been an advocate for food safety and research programs to ensure that consumers have a safe and wholesome food supply, and she is committed to ensuring that this nation has a strong infrastructure to protect it.

So, without further ado, please join me in welcoming the Honorable Ann M. Veneman.

(Applause.)

Opening Remarks

SECRETARY VENEMAN: Thank you. Thank you, Elsa, for that very kind introduction.

Good morning, everyone. I am very pleased to join you at this symposium this morning.

This is one of several public meetings that we are hosting over the next several months to talk about an issue that's very important to this

Administration, and that is the safety of our food.

Food safety is a complex system of inspections, surveillance, intervention, technology, and much, much more, but ultimately our goal is quite simple: to protect the public health and to assure Americans that what they eat is safe and free from harmful disease and bacteria.

This is one of the U.S. Department of Agriculture's most important roles and one that we take very seriously. Dr. Murano's doing a great job and she's fortunate to have a strong and dedicated force of career employees throughout the country, employees who are committed to safeguarding consumers and our nation's meat and poultry supply.

We have made significant strides in food safety in recent years, but we cannot rest on our laurels. Much remains to be done. The implementation of the Pathogen Reduction HACCP Rule stands out as a major achievement, and it has played a vital role in reducing pathogens. Data released just last month by USDA show that Salmonella prevalence levels are well below the product baselines that existed prior to HACCP. This decrease correlates with reports from the Centers for Disease Control and Prevention indicating a decline in Salmonella-related human illnesses during

the same period, tangible evidence of our success.

We must remember that this achievement has behind it decades of hard work and dedication from individuals who have spent lifetimes in the pursuit of making food safer to eat, people, such as Dr. Bauman, who we honor here today.

HACCP began in 1959, a collaborative effort originally intended for the production of foods that could be used under zero gravity conditions in space shuttles. Perhaps this is where the term "lite" food came from. But the critical part was making the effort useful to more than just those in space. Hard work and determination by numerous scientists, government officials, academicians, consumers and the private sector contributed to building this system.

Another top priority at USDA is keeping BSE out of this country by maintaining a vigilant system of protections. USDA's BSE Program is a good example of how we are utilizing science to continually update our policies.

Last November, we released a landmark study by Harvard University that shows that the risk of BSE occurring in the U.S. is extremely low. This is a result of many years of vigilant effort. The report clearly showed that the years of early actions taken by

the Federal Government have been largely responsible for keeping BSE out of the U.S. and putting a structure in place to prevent it from spreading, if it ever did enter the country.

We continue to strengthen our BSE Prevention Programs by taking science-based steps in areas such as surveillance and inspection. However, we must remain vigilant, and we must continue to work closely with other federal agencies, states and all stakeholders to ensure that we maintain strong programs that not only protect consumers but our livestock as well.

Let me emphasize that our goal is not simply to generate science for academic exercise. Our goal is to generate science that is useful in protecting the public health of the United States.

This symposium brings together leading scientific experts from government and academia, consumer interests, professionals and the private sector, to discuss scientific data and issues associated with pathogen reduction and HACCP. Our aim is to stimulate thinking and generate new ideas that will hopefully become the foundation for future efforts to make our food safety systems even stronger and more effective than they are today.

We've hired two of the country's finest and

most respected scientists from the food safety science disciplines, Dr. Murano and Dr. Pierson, and have charged them with taking food safety in this country to a new level. In fact, just last month, Dr. Murano announced important new steps to control pathogens in ground beef. Ground beef plants will now be expected to use effective decontamination strategies for pathogens or require their suppliers to do so. Plants that do not include this decontamination step as part of their HACCP plan will be targeted for increased verification testing by FSIS inspectors above that which is already conducted.

We will continue to use scientifically-based decisions to strengthen HACCP systems and move food safety forward. There is a strong commitment to food safety programs by the Bush Administration. We have proposed record-level spending for food safety programs in two consecutive budgets and strengthened inspection systems to ensure regulatory compliance and safety. This includes, among other things, funding for additional food safety professionals, such as veterinarians and consumer safety officers, who, along with the rest of our inspection workforce, are ensuring the plants have effective HACCP systems.

Those of you who have heard me speak before

know how strongly I believe in the importance of partnerships in achieving real improvements in all areas of the food chain, including food safety. None of us can do the job alone. That's why we've invited speakers from government and academia and welcome the input of consumers, industry representatives, and other interested parties as we continue to examine ways to make our systems stronger. This process involves scientists and non-scientists alike.

We are committed to seeking input from all parties who have an interest in improving the laws, the regulations and the systems that enhance public health and help protect our nation's food supply. So, I want to thank all of you for being here today and in participating in this very important conference.

Today, I am very pleased to have another honor and that is to unveil the Howard E. Bauman Award for Significant Achievements in Food Safety. We honor the achievements of his life by providing this award to his daughters Victoria Zobel and Kay Rose, who are with us today.

Dr. Bauman was working for the Pillsbury Company when he received a phone call from what is now known as Natick Laboratories and was asked whether Pillsbury would be willing to produce foods that could

be used safely under zero gravity conditions in space capsules. He recounted in a 1993 lecture how the most important part of the program was to come as close to a hundred-percent assurance as possible that the food products would not be contaminated with pathogens and would not result in an aborted or catastrophic mission. Then he joked, "such as the loss of his own job".

Working in the best traditions of creativity and cooperation, Dr. Bauman worked collaboratively with government scientists to find a new approach to the problem. They concluded after extensive evaluation that the only way to succeed would be to have control over the raw materials, the process, the environment, personnel, storage and distribution, beginning as early in the system as possible.

It was using this approach that Dr. Bauman and his colleagues developed HACCP. We owe much to Dr. Bauman for his creativity, and I'm sure he would be pleased to know that HACCP is now in place in meat and poultry plants nationwide. It is because of his vision and foresight that American consumers have a higher level of food safety protection.

USDA is presenting this award annually in his honor to recognize the achievements of others with similar vision and commitment to improving food safety

and public health. So, I want to thank you both again for being here today.

(Presentation of 2002 FSIS Bauman Award for Food Safety)

(Applause)

MS. ZOBEL: Thank you very much, Secretary Veneman, for those kind words about my dad. That was wonderful.

I'd like to thank Dr. Elsa Murano and Dr. Will Pearson, Dr. Karen Hulebak and Mr. William Hudnall for all your efforts to create this award and to invite us to accept it. Thank you.

I know my father was really proud of the work that he and his group at Pillsbury did that led to the development of HACCP. I know he believed everybody in the world deserves a safe food supply. He promoted HACCP whenever he could in this country and abroad and was very happy to see it begin to be used here as well as in other countries.

It's an honor not only for this award to be presented to him but to be named for him, and it's an honor for us to accept this award. Speaking for my family, I want to thank everybody here who did anything to make this award possible and for inviting us here. It's such an honor to be here. It's good to know that

achievements in food safety can be recognized this way from now on.

Thank you very much for all your efforts and for your great hospitality.

(Applause)

(Pause)

DR. HULEBAK: Thank you all very much. Thank you again, Secretary Veneman.

We'll continue the conference now with just a few administrative announcements. This meeting and its agenda has been designed to maximize discussion of the four major scientific subject areas in the agenda and that discussion needs to take place among the panels, the panel chairs, and the audience participants, as I mentioned earlier.

If there is a ground rule for this symposium, other than the need, of course, to maintain civil discourse, our goal is to focus on the science associated with the issues on the agenda. It is often tempting to talk policy, at least for some of us, but we want to emphasize science for the next two days, and we need to try to keep this goal in mind.

Now, how will this meeting work? I will introduce each panel chair. Each panel chair will then introduce his or her panel members and then panelists

will each give short presentations. We'd like you to hold questions that you might have for individual panelists until the end of the panel session because moderated discussion periods will follow each one of those panel sessions, and it's there that we'd like to concentrate the discussions and get dialogue going.

Now, we encourage participation from all participants in this symposium. If you wish to ask a question from the floor, there are mikes on the floor. We've also created cards on which you may write out a question. If you don't particularly care to identify yourself, you don't need to. You may identify on the card whether your question's for a specific panelist or for the panel generally. The cards are available at the registration desk out front. When you fill out your card, you can either return it to someone at the registration desk or to me or to a panel chair. I just have one request. Please, please write legibly or, you know, your question could be garbled beyond your wildest imagination.

We do intend to produce proceedings of this meeting, including the discussion sessions. So, when you ask a question from the floor, if you do, try to identify yourself.

We do have an excellent agenda, I think,

really excellent speakers, scientific experts all of them, all of whom work for either government, including our sister public health agencies, or from academia. The agenda has been planned by a really creative and hard-working planning committee with representatives from several USDA agencies, and we gratefully acknowledge Tonya Roberts from the Economic Research Service, Jim Lindsey from the Agricultural Research Service, and Ram Rao from CSREES. Pardon me for using the acronym there. It's just a long name.

We also had participation on the planning committee from a number of FSIS program offices. Lenville Johnson, Phyllis Sparling, Pat Schwartz, Charles Edwards, Danielle Shore, Matt Vaughn, and especially Sharon Sachs who carried the heaviest burden of all, thought of everything and worked with wondrous effectiveness.

We had the enormous help of FSIS' professional planning staff without whom none of this would have taken place really. Sheila Johnson, Mary Harris and Sally Fernandez.

Thank you. Thank all of you.

The agenda, as you will see, leaves ample time for breaks and for lunch and for those productive sidebar and hallway conversations, if we adhere to our

schedule, more or less.

A few final notes. There are reprints, press releases and some other written materials that are relevant to the symposium's topics out on tables next to the registration table. You're welcome to take however many you want. The restrooms are back near the main entrance to the conference center. So, you go right out of this room, right down the main hall and then right again. You'll find the restrooms. Also pay phones for those of you who still use them, I should say those of us who still use them, right down at the end of this hall and back by the restrooms.

Lunch is on both days and on your own, and there are a number of good buffets and cafes and restaurants all along this outer gallery.

Now, let's begin with Panel 1, "Introduction of Hazards, Farm to Table", Michael Doyle, Chairman.

I have the pleasure, the great pleasure of introducing the Chairman of Panel 1, Dr. Michael Doyle, Regents Professor of Food Microbiology and Director of the Center for Food Safety at the University of Georgia.

Dr. Doyle is an active researcher in the area of foodborne bacterial pathogens and focuses primarily on the study of microbial pathogenicity, development of

methods for pathogen detection and identification of means to control or eliminate pathogens in foods.

He's a graduate of the University of Wisconsin, Madison, where he received his B.S. in Bacteriology, his Master's and Ph.D. degrees in Food Microbiology. He has served with many scientific organizations as contributor and advisor, among them World Health Organization, Institute of Medicine, Food and Drug Administration, Department of Agriculture, Department of Defense, and U.S. EPA. He has published more than 400 scientific publications and has been editor of two authoritative texts, "Foodborne Bacterial Pathogens" and "Food Microbiology: Fundamentals and Frontiers".

Dr. Doyle, welcome.

Panel 1: Introduction of Hazards, Farm to Table

DR. DOYLE: Thank you, Karen, for that very kind introduction.

This morning's session, Panel 1, is going to focus on the Introduction of Hazards from Farm to Table, and we're going to principally focus on microbiological hazards that contaminate meat, poultry and eggs at different locations in the food continuum.

What our speakers will address include risk factors for acquiring meat- and poultry-associated

foodborne illnesses, where the pathogens originate, how pathogens are introduced into foods, including the influences of environmental and management factors, also identify the challenges for pathogen control presented by the microbiological ecology of meat and poultry pathogens, not only on the farm but also in processing facilities, and then describe hazards that are introduced during transportation in layerage of animals.

To give you an example of some of the risk factors that have been identified as being associated with many of these harmful microorganisms that can be found in foods, I'm going to share with you two case control studies that were done by the Centers for Disease Control as part of the FoodNet Program that was introduced about five years ago, and I laud the CDC and the state health departments for the work that they have done in this area because I think what they are doing is giving us some guidance and scientifically-based guidance and direction to identifying those risk factors that are largely responsible in influencing the transmission of foodborne pathogens.

So, the first case study here has to do with campylobacter, and this was headed up by Sidney Friedman at the Centers for Disease Control with the

help of the state health departments and our colleagues at CDC. It's a very large study done between January 1998 through March 1999, where they identified as risk factors for acquiring campylobacter infection, first of all, foreign travel, but if we exclude foreign travel, domestically-acquired campylobacter enteritis was largely associated with eating undercooked poultry which has been identified as a leading vehicle in many other case control studies.

Also identified was eating chicken or turkey cooked outside the home, eating non-poultry meat cooked outside the home, eating raw seafood, drinking raw milk, living on or visiting a farm, contact with farm animals and contact with puppies. So, many of these go back to the farm in identifying vehicles such as poultry and perhaps cattle and other farm animals as being instrumental in transmission of campylobacter to humans.

Another type of study which was done to identify risk factors for sporadic E.coli 0157 infections in the United States was a study that was done between February '99 and April 2000, and the primary risk factors identified in this study were swimming in a pond, lake, river or stream with cattle nearby. This one had the strongest risk factor, 15.8.

The matched odds ratio was 15.8.

Secondly was drinking pond, lake, river or stream water, and then drinking from water fountains or pool water, visiting a farm less than 12 times a year. Here we get to the food aspects, eating pink hamburgers in the home, living on a farm and thawing ground beef in a microwave.

Now, following the presentations made by our panelists, and this will be immediately after lunch, we're going to have a moderated discussion that will include the panelists but also you in the audience and hopefully you will have lots of questions and comments that might be germane to the topic of addressing issues associated with the introduction of microbiological hazards in meat, poultry and eggs.

So, with that, please save your questions and comments until after lunch because we're not likely to have time before that to address them. With that, we're going to move on into the program, and our first speaker is going to be Dr. Dave Dargatz, who is an epidemiologist with the USDA Animal and Plant Health Inspection Service at the Centers for Epidemiology and Animal Health in Fort Collins, Colorado.

Dave coordinates the beef cattle activities of the National Animal Health Monitoring System, and

Dr. Dargatz is going to address the Introduction of Hazards on the Farm, including Prevalence and Distribution of Potential Pathogens in Livestock Operations.

Dr. Dargatz?

DR. DARGATZ: Well, thank you and good morning.

It's my task to start us on that continuum or start us on that journey from the farm to the table and to look at pathogens, and what I'm going to do, focus primarily on this morning, is looking at some of the data from the studies of the National Animal Health Monitoring System, and I'm going to primarily focus on Salmonella and E.coli as two of the pathogens of most interest.

The National Animal Health Monitoring System is a program of USDA/APHIS. Our primary goal is to collect on-farm information about animal health and production practices, but we've taken advantage of our presence on farms to also collect some samples and some data that are relevant to pathogens, primarily in characterizing the prevalence of pathogens on farms as well as potential risk factors for why those pathogens might be on the operation.

I'll take you through four production systems

this morning very briefly and some of the studies that we've done to look at feedlot cattle, dairy cattle, layers and then also the swine industry. We'll begin then by looking at the feedlot industry, and in 1994, in the Fall of 1994, actually from October through December, we collected data from a hundred feedlots in 13 states. These feedlots were participating in a cattle on feed evaluation that we had underway, and we selected a hundred of those feedlots in which we collected samples from either two pens of cattle, in the case of trying to characterize prevalence of Salmonella or four pens of cattle in the case where we were trying to characterize prevalence of E.coli 0157.

I would point out that in this particular study, we used the historical culture methods or the methods that were present at the time for culturing 0157. In subsequent studies that I'll discuss in a moment, we used more sensitive methods, and I think that will become important as we begin to look at the results.

As far as the Salmonella results then from this study, 38 percent of the feedlots that we collected samples in had one or more positives. Overall, of the nearly 5,000 samples that we looked at, about 5.5 percent of those were positive for one or

more Salmonella isolates. The most common serotypes, and I've just listed the five most common serotypes here, accounted for 65 percent of the total number of isolates that we looked at, and they included Salmonella Anatum, Salmonella Montevideo, Muenster, Kentucky and Newington, and I think importantly these five serotypes are not the most common serotypes that we see relative to either animal illness or human illness as we look across surveys that have been done in the past.

We also in that study then turned to look at risk factors. So, why? What sorts of management strategies or animal-related factors might be related to the presence of Salmonella or our ability to recover Salmonella on those operations? Out of all of the risk factors that we looked at, we found two factors that were associated with increased likelihood of identifying Salmonella in that pen of cattle. One was the feeding of tallow, in which case those animals that were currently receiving tallow in the ration were 3.5 times more likely to be positive, and also feeding whole cottonseed or cottonseed hulls to those animals was associated with a 2.3 percent or 2.3 times increase in the likelihood of identifying Salmonella.

Factors not associated with a pen being

positive for Salmonella included things like region, the size of the operation, use of sprinklers for dust control, the amount of time that the cattle had been on feed, the type of cattle, that is beef versus dairy-type animals, cattle density in the pens, and then all of the other feed ingredients that we looked at.

As far as E.coli 0157, 63 percent of the feedlots where we collected samples from those four pens of cattle had one or more positive samples. Overall, 1.8 percent of those nearly 12,000 samples were positive for E.coli 0157. Factors that we identified that were associated with an increased likelihood of pens being positive for 0157 included being on feed for a period of time shorter than 20 days. So, early in the feeding period, we were 3.3 times more likely to find an 0157 in that pen.

Barley feeding, 2.7 times increase in risk. Light entry weights, regardless of what the current weight of those cattle were, was associated with an increased risk and steers being the predominant gender of the pen as opposed to heifers was associated with an increased risk as well.

Factors not associated with the pens being positive included region, operation size, animal density, ionophore use, and all of the other feed

ingredients that we looked at.

Five years later, in 1999 and 2000, we repeated a study of feedlot operations. In this case, we looked at 73 feedlots in 11 states. Each feedlot was visited twice over the course of the year. We collected samples in three pens for both Salmonella evaluation as well as for E.coli 0157 evaluation.

Results for Salmonella, 51 percent of the feedlots had one or more positive samples. Recall that we're looking harder. We're finding more of it. 6.3 percent of the 10,000+ samples were positive for Salmonella. So, somewhat consistent with what we had seen previously at 5.5 percent. Again, the five most common serotypes of Salmonella that we saw accounted for the vast majority of isolates, in this case 72 percent. Again, Anatum, Montevideo and Kentucky were in the top five. This time, we also found some Reading and Newport isolates as well. Risk factor evaluation is underway for this study to repeat the sort of analyses that we had done in the 1994 study.

One point that I would make is that in some preliminary looks at the data we have now since we collected data across an entire year been able to look at time trends. So, again recall that our last study looked at this time period over here, October to

December. We've been able to demonstrate the seasonal distribution of Salmonella which is not any great news but is consistent with other data that we've seen out there for Salmonella and for other pathogens as well.

As far as 0157, over the course of the year, a hundred percent of the feedlots had one or more positive samples. Overall, 11 percent of the samples were positive, and again we saw the same sort of distribution; that is, early-fed -- animals that have been on feed for a shorter period of time were more likely to be positive than animals that have been on feed for a longer period of time.

Now, why the dramatic increase in the percentage of samples that are positive? In this case, we're using the immunomagnetic bead separation technique to look for these 0157 isolates, and it's a dramatically-more sensitive technique to identify those. So, we think that that is reason for the increase of the recovery of 0157.

Here again, since we collected data across an entire year, we're able to plot out some of the time trends that we see. Notice that in the colder months, we see a lower prevalence as opposed to the warmer months, we see a higher prevalence in these samples.

If we turn our attention to the dairy

industry then, and we look at our 1996 study, we conducted a survey of 19 states, 91 dairies, 97 markets that were handling cull dairy cows. Overall, we collected samples from milk cows on the farm, cows to be culled on the farm, and also then culled cows in the markets. We looked at those samples for Salmonella as well as for 0157, and this is back to the traditional sort of historical culture techniques. So, the lower sensitivity techniques for looking for 0157.

Overall, what did we find? 5.4 percent of the milk cows were positive. About 18 percent of those cows expected to be culled in the next seven days were positive. This was a fairly small sample but some increase there. About 15 percent of those culled cows going through markets were positive. Here, I've listed the top six Salmonella serotypes because Anatum and Meleagridis each had 6.1 percent of the total, but again these represent nearly two-thirds of the total number of isolates that we saw. Again, these are not typically the most common isolates that we see associated with animal or human illness.

21 percent of the operations had milk cows that were shedding Salmonella on the day that we visited and collected these samples. 25 percent of the operations had expectant culls that were shedding

Salmonella.

Risk factors for why we might identify Salmonella on a dairy included large herd size, nearly a six-times likelihood increase for finding Salmonella, the southern region, the use of recycled flush water, and the feeding of brewers products seemed to be associated with an increased likelihood of finding Salmonella on the operation.

If we turn then and look at 0157 from these animals, again notice that as we go from the colder months, February through April, to the warmer months, May through July, in each class of animals that we look at, we see a bit of an increase in terms of the percentage of samples that were positive for 0157 and a higher level in cows to be culled. Overall, again that lower number, that lower prevalence in the, say, 1 to 2 percent range or up to 3 percent range, as opposed to the level that we saw in the last feedlot study, again probably reflecting a lower sensitivity of the test methodology.

If we look at the percent of operations where we were able to identify 0157, again as you have more samples that are positive, you're able to identify more operations that are positive. Overall, about 24 percent of farms identified as positive and about 31

percent of markets where we were able to recover a positive 0157.

Risk factors for 0157 being present on the dairy, samples collected after May 1st, so that later period, we saw more 0157, and also the use of flush water in the alleyways for manure removal. Factors not associated with 0157 on dairy farms included all other manure-handling practices, the chlorination of water tanks, whether they grazed any cattle or not, housing type and then all sorts of diet components that we looked at, including protein fat sources, by-products, probiotics, the use of alfalfa in the ration and a variety of other dietary management strategies were not associated with our ability to find 0157 on the operation.

We turn then to a study we did looking at the layer industry. In 1999, we collected environmental samples in about 200 layer houses. These included manure samples, samples from the egg belt elevators, and the walkways. Also in a subsample of those, a 129 layer houses, we also collected rodents out of those samples and then evaluated the rodents for the presence of Salmonella enteritidis. So, all of these environmental samples as well as the rodent samples evaluated for SE.

Overall, we found that 7.1 percent of the layer houses were positive and about 3.7 percent of the mice were positive, and factors that were associated with positive houses, including flocks that were less than 60 weeks of age, not cleaning the feeders or hoppers between flocks, and a higher number of rodents. So, as we had that rodent index or the number of rodents that were trapped over a seven-day period of time, as that rodent index went up, we were more likely to see SE on the operation. Just to characterize that then from a regional standpoint, there are some regional differences in terms of our recovery of SE, whether it be from the houses or from the mice.

Finally, then, if we turn and look at a couple of studies that we've done looking at the swine industry, 1995, we collected samples on a 152 operations in 16 states. These operations were -- had at least 300 grower-finisher pigs. We collected up to 50 samples per site, and these were all from the late finishers. So, we were looking at that as those animals were approaching the end of the finishing phase.

A total of 660 samples collected. In 2000, we repeated a study looking at a 124 operations in the 17 primary pork production states. These operations

had at least a hundred head of inventory and again 50 samples collected from the late finishers, about 5,500 samples collected then from these operations.

Overall, if we look at those for Salmonella prevalence, the herd level prevalence in 1995 was 38.2 percent; that is, that percentage of herds we found one or more positive isolates in. In 2000, 34.7 percent of the operations had a positive. Overall, at the sample level, about 6 percent of samples were positive for Salmonella, 6.6 percent in 2000. So, these numbers are very consistent with what we have seen in the feedlot industry as well as the dairy industry as well.

The common serotypes here, I've listed the 10 most common serotypes from the '95 study as well as the 2000 study. A good bit of agreement between those two studies, particularly as you focus on the top five serotypes that we were able to identify.

As far as risk factors from the 1995 study for finding Salmonella on the operation, if the farm mixed their own feed on the operation, they were about half as likely to have a positive Salmonella sample. If, when they marketed their animals out of the finishing barn, they tended to market everything out of the finishing barn at once, they were about two and a half times more likely to have a Salmonella positive.

If they had some respiratory colds, that is, they were culling animals in that finishing phase for respiratory disease, they were less likely to have positive Salmonella isolates. If they had split sex feeding, that is, they separated pens of pigs by gender, they were more likely to have positive Salmonella isolates.

As far as the region goes, if they -- the comparison being the Southeast region. If they were located in the North or the Midwest, they were less likely to have a positive Salmonella sample, and if they used -- if they didn't use a meal-type feed, so these feeds would include things like pelleted feeds, they were much more likely, in this case 26 times more likely to have a positive Salmonella.

As far as 0157, of those total samples, about 4,200 were evaluated for 0157 and all of those were negative from this study.

So, if we talk about pathogens on the farm, what are the conclusions that we can draw from these studies, and there are more studies out there that we could talk about, but I think these would be my conclusions.

One is that the pathogens tend to be widely distributed geographically and by operation type. Region is generally not a factor that we see in our

ability to recover some of these pathogens, and we have similar prevalence, say, of Salmonella across different types of operations.

Mostly, the pathogens are present in low numbers or at low prevalence, so relatively low recovery of those organisms and the low numbers. As we move to more sensitive techniques or more sensitive methods for identifying those organisms, we find that prevalence starts to come up, which would seem to indicate that they're present at some levels below our historical detection threshold.

We have inconsistent risk factors across epidemiologic studies. So, as we've gone back to some of these operations or these types of operations in different studies, we found inconsistencies between the risk factors that we identified. Likewise, we find inconsistencies across operation types in terms of what seems to be related to the presence or absence of those pathogens, and data from these large epidemiologic studies, I think, are very useful in terms of generating hypotheses for where we might look further under more controlled environments, and I think that that work is certainly underway, and a lot of people picking up on various aspects of what's been identified as a risk factor in some of these larger epidemiologic

studies and investigating those in more controlled experiments.

We really need more research to evaluate interventions as well, things like biosecurity interventions for the operation as well as active interventions into that process, things like vaccinations or competitive exclusion or those types of active programs to try to limit the presence of pathogens on the farm.

I'd just point you then at the end. This is our contact information, our website. Most of the information that you saw presented this morning is available on the website as well as information from a variety of other studies, focusing perhaps on some of the different pathogens as well.

(Applause)

DR. DOYLE: Thank you, Dr. Dargatz, for that excellent presentation and sharing with us some of the cutting edge research that's being done at your facility at Fort Collins.

Our next speaker is going to address the Introduction of Hazards at Slaughter, and Dr. Gary Acuff, who's a Professor of Food Microbiology, and I think he's world-renowned as an authority in the area of meat microbiology, Texas A&M University, College

Station, Texas, is going to share with us some of the observations that he has made relative to the introduction of hazards at slaughter.

DR. ACUFF: Okay. Well, I'm happy to be here this morning. They asked me to talk about Introduction of Hazards at Slaughter, which I'm sure there are quite a few people here who work with this every day actually know more about it than I do, but I'm going to try to set the stage for our discussion and cover some of the basics in terms of what microorganisms are there and how they're introduced and where they're coming from.

Well, I saw this morning that we're covering meat and poultry and eggs, and I just prepared mine on the meat and poultry. I don't know anything about egg slaughter. They only gave us 15 or 20 minutes. That's the best I can do on an icebreaker.

All right. Well, to begin with, when you look at slaughter processes across the board, the beef industry and the poultry industry appear basically to be a little more uniform in their slaughter processes maybe than what goes on with the pork processes, and there are differences from plant to plant. So, you can't just say okay, this is the process across the board because they all change just a little bit, but there's some major points that you can consider, of

course.

The hazards, of course, we've already mentioned are enteric pathogens as our primary concern, Salmonella and enteropathogenic or Enterohemorrhagic E.coli, campylobacter in some cases are a hazard, more in some cases than others, and we can do all kinds of things with strict sanitation and hygiene through the process. The problem is that we can limit some of the contamination but we can't absolutely assure the absence of the organisms with the current situation.

The primary sources of contamination are the ones we've always talked about, primarily feces is the biggest concern and that can come from several sources. Probably the major source is from the hide or from the feathers or skin in some of the other processes, aerosols and sprays throughout the facility, contaminated hands and equipment in the workers and within the facility and the potential spilling of body fluids.

Now, there are a whole list of major and minor potential sources in this process, but probably the two major sources that we're concerned about are the potential for fecal contamination, and it appears in a process where you remove the hide. Hide contact appears to be the primary source.

Well, I want to take these one at a time and just kind of go through a basic flow diagram and talk about where the hazards are coming in and how they get there, which ones we're concerned about. First, cattle slaughter, and we'll move from a process where we remove the hide to later processes where the skin remains on the carcass for the final product.

In cattle slaughter, of course, we bring the cattle in to the facility and they're held waiting for slaughter, and there's quite a bit of cross-contamination that potentially can happen in that area. So, from animal to animal, we can come into the facility, cross-contaminated with various pathogens.

The animals are stunned, and in beef or in cattle slaughter, the animals usually come in contact with the floor, and there's quite a bit of potential cross-contamination on the hide that can occur at that point. We've done some studies at A&M where we've looked at campylobacter through beef slaughter operations, and we've found that you can expect a consistent cross-contamination of campylobacter on the floor after stunning, when the animal comes in contact with the floor.

Bleeding is generally assumed to not be a major source of contamination at this point. There was

awhile when it was considered to be a major point because there is potential for microorganisms to enter the bloodstream and then be transported throughout the carcass, but the system is pressurized, and upon contact with this pressurized system, the flow is usually out. So, there could be a small amount, but for the most part, it's not considered a major contamination source.

Now, once you begin the process of removing the head, the shanks and the beginning process of removing the hide, lots of manual contamination can occur at that point. So, and it appears that the more manual processes that are involved, the heavier the contamination. When it becomes automated, the contamination appears to be at a lower level.

When the hide is removed, there's an initial incision along the brisket and there's typically -- that's a point of major concern because that's when we first begin to break this skin surface barrier to the surface of the carcass which should be sterile at this point as we begin to remove the hide, and so this is going to be one of the major differences in this process and some of the others we'll talk about later, is that we expose the sterile surface and inoculate it with bacteria that have been freshly placed on that

surface and that creates some opportunities and also some problems later on.

Aerosols and dust are going to be generated whenever we're moving the hide away from the carcass because sometimes it flops or dust may fly off of the carcass, then back on to that carcass or a closely-adjacent carcass. Workers' hands are going to contact the exterior surface where we have extensive contamination and then possibly touch a sterile surface later on. So, it's important to work with the employees on how important their hands are in contaminating this process, and then just the hide can actually contact -- the exterior surface of the hide can contact the surface of the carcass itself and supply quite a bit of contamination there.

Evisceration is another major potential contamination point, and probably the most important thing here is proper bunging, which is making a cut around the anus, including the adjacent part of the rectum, and then enclosing that in a bag before dropping into the body cavity. If that's done correctly, it can limit contamination quite a bit. It can't absolutely exclude it, but it can limit it significantly.

Of course, there's all kinds of potential for

cross-contamination during evisceration. So, that's a concern, and obviously the major concern is that you do not puncture the gastrointestinal tract and allow the contamination to contact the carcass.

Okay. Carcass splitting is not a major contamination point, but I wanted to take the opportunity at that point to remind us all of all the potential sources in the processing environment that could contact this surface that has now had the hide removed, had the viscera removed, and we have the surface that was previously uncontaminated and may now then be contaminated with anything in this environment which would include potentially microorganisms from the walls, from the floors, if the carcass were to come in contact with that, airborne contamination in the facility as well as contamination from water sources and the utensils and personnel.

So, a whole host of potentials but all fairly minor, still something that we have to consider as well, though. The carcass goes through a wash, and we have the potential to reduce some of this contamination that has been placed on the surface freshly, it has not had time to attach hopefully, and this is going to be covered later on by Dr. Sofos, so I don't want to get into this extensively, but we have sort of a unique

situation with cattle here that we don't necessarily have with the other processes because we've had a sterile surface that's been inoculated, and we may have then the opportunity to try to remove some of these guys that you may not have in other processes.

Finally, the chill process. We have the potential for carcass-to-carcass contact where we may have some cross-contamination. Also, if carcasses are allowed to contact in the chiller, then that surface may stay warmer for a longer period of time and allow some replication of the microorganisms over a fairly short period of time.

All right. Well, considering hog slaughter, we have two basic different operations here. One is not that different from cattle slaughter in that we're removing the hide or the skin and producing a skinned carcass or the other process is scalding. Here are examples of carcasses that have produced this. One is a scalded carcass where we remove the hair but leave the skin on.

So, since with the skin removed, it's not all -- the introduction of hazards are not all that different than what we talked about with cattle, I want to talk a little bit more about the scalding process because that creates a little different situation.

The same thing with the animals receiving, coming into the process, coming into the slaughter plant. We can have cross-contamination from one animal to another, and we expect some of that to occur at some level, and it should be fecal contamination which will be present on the surface of the animal, on the skin.

Now, contrasting with cattle and the stunning of hogs, we don't see as much of the contamination that we may have with contact with the floor with the cattle carcass. The hog carcasses usually don't have this similar problem, although there's a lot of variation in hog slaughter. Bleeding again is not considered a major contamination point, and scalding creates a unique situation.

Now, we take the animal, take the carcass and put it into a hot water or a hot temperature situation to try to loosen the hair. This is usually at a temperature around 60 degrees C, could be for five minutes or so. So, there's an assumption that we would have a pretty significant reduction in bacterial contamination on the surface of the skin. There could be some cross-contamination but what we see for the most part is a reduction at that point.

Now, following that, we have a dehairing process where there's a lot of potential for fecal

contamination to leave the carcass and then to come in contact with the surface, contact the equipment and then cross-contaminate other carcasses. So, we can see some fecal contamination there, and we're also going to see microorganisms that have been protected from the heat and the scalding process begin to contaminate the surface as well.

Now, singeing. I don't know how many of you have seen this, but the carcass actually goes through a flame to try to get rid of any residual hair that may be remaining on the surface, and it looks like it should just flame sterilize the carcass. You do have some kill, but it's rather uneven because there's some areas that are more protected from the flame than others. So, it looks like it should be really effective, and it may or may not be is the bottom line.

Following that, there -- and you know, one thing I should point out in hog slaughter, these steps may not be in this order. We may be doing things in different order. We may be repeating steps. We may be singeing and scraping and polishing numerous times. So, this is sort of a generic flow diagram, but like I said, in hog slaughter, the processes are fairly varied, and you may see different variations on the same thing.

Now, this process is designed to remove any burned surface, and in the process spreads contamination. If there's bacteria that the equipment comes in contact with, then it'll spread it around on the surface of the carcass.

Evisceration again continues to be a concern. Proper bunging is really important again in this process where we would try to make the cut around the anus and the rectum and drop that into the body cavity. As far as I know, in hog slaughter, the bunge is not bagged like it is in cattle, but that may be something that's picking up more often. I'm not sure about that. Obviously again cross-contamination and the concern that you might puncture the gastrointestinal tract and cause some leakage.

During chilling again, carcass-to-carcass contamination again is always going to be a concern because we can cross-contaminate or have a situation where the carcasses prevent another one from cooling rapidly enough, and we may have some bacterial growth at that point.

All right. Poultry slaughter. Now, this is not all that different than hog slaughter in the effect of the microorganisms on the surface. The process is obviously different, and we have a larger number of

carcasses going through the process and more rapid, but the microorganisms and the points of contamination are fairly similar.

Cross-contamination during transport, bringing in on trucks, we expect to see quite a bit of that, and when they're held awaiting slaughter. When we shackle, we should see some flapping of wings and aerosol is created. We may see cross-contamination between carcasses at that point. The animals are stunned and then bled. So, similar situation to the other processes that we've talked about, and then these birds are sent through a scald process.

The overall is that we see a reduction in contamination during scalding, but there is some cross-contamination, and what the poultry industry has tried to do to prevent that as much as possible is create a counter-current flow where the carcasses are constantly moving towards the cleaner water and the dirtier water exits at the entrance of the carcasses. So, this is done quite a bit to help prevent some of the carcass-to-carcass spread.

Now, the temperature that's used here is a little bit lower than what we see with hog carcasses because of the potential damage to the skin surface. So, generally, this is with broilers, we would probably

expect to see a temperature less than 55 degrees C, probably around 50 or 52 C, and this can be for two or three minutes. Maybe with turkeys or a carcass that would be frozen, we might see a harder scald where we'd have a temperature greater than 55 degrees C.

In any case, a reduction in contamination at this point is not something that we significantly rely on to improve the safety of the carcass because following scalding, we go through a defeathering step where any reduction would be pretty much eliminated. The carcasses are cross-contaminated in removing the feathers. They go through a system of cylinders with rubber fingers that remove the feathers, knock the feathers off the carcass, and fecal contamination is frequently squeezed from the carcass and then contaminates the fingers and cross-contaminates the carcasses. So, we expect to see some probable fecal contamination of carcasses through this process.

Well, after defeathering, actually we go through -- usually we go through a wash, an in-line wash prior to evisceration and that helps remove some of the potential contamination on the surface as well, but the next major point of introduction would then be evisceration.

Because these are smaller carcasses, it

presents, I think, a little bit harder situation in trying to control the potential for gastrointestinal leakage. So, it's something we want to try to control. Again, the more manual the process, I think, the more likely that we're going to have leakage on to the surface of the carcass. Most of this is automated as much as possible, and I think that helps, but you have to consistently and constantly look at the equipment to make sure it is clean and sanitary and not cross-contaminating carcasses as much as possible.

The last thing you can't see there is that we have cross-contamination by equipment, workers handling the carcasses, and when the viscera are presented for inspection, we may have cross-contamination of the carcasses actually by the inspectors as well. So, that's something to be concerned about.

Carcasses are spray washed following the defeathering evisceration process which reduces contamination. Of course, we're concerned and talking about introduction of hazards. The next possible place for introduction would be chilling. We see an overall reduction in contamination at this point because -- and there's several chilling possibilities here, but probably the most used process is an immersion chilling process where we would have some contact with an

antibacterial or sanitizing solution, usually chlorine in these situations, but we would have an expected reduction in contamination through this process.

Also, if we have an immersion chill process, we're going on a counter-current flow situation for the most part, so we're moving constantly to cleaner water, which should reduce contamination, but we do see the potential for cross-contamination between carcasses.

Now, -- and then cross-contamination by equipment and packaging. Overall, through all these processes, what we see are the animals bringing in the organisms themselves as the primary source. We see an attempt through the process to try to contain the contamination that those animals bring in from the surface of the product, the food product that they're trying to produce. It's not possible to absolutely prevent all of that, but the process is designed to try to eliminate as much as possible.

What we see overall is a low level of pathogens on a raw carcass and fairly varied and spread. So, we see cross-contamination, sort of an evening of contamination, usually low levels and varied.

Well, we can talk about a whole boatload of minor sources, and I think that the key to the process

is that the major sources far overshadow most of the minor ones. You can spend a lot of time trying to control minor sources in a slaughter operation, and if you don't control those major sources, then all of that is pretty much wasted time. So, concentration on the dehiding or the skinning operations, concentration on controlling evisceration, when those are under control, then one can begin to look at some of the minor sources and maybe have some impact there.

And then, I wanted to add these reminders here at the end. Apparently healthy animals can enter this process and contain microorganisms obviously that can cause very serious illness in humans from the product that's been improperly prepared, and the other thing to consider is that while this may be one of the major contamination points, there is potential for contamination of these products from stunning through consumption. So, it's not just the slaughter process that supplies the contamination, although it's probably the major point, once you consider that contamination can occur across the board throughout the process all the way to consumption.

Well, in summary, looking at the whole process, at all of these three systems, beef is a system that allows a sterile surface to become

inoculated with bacteria, and I think that creates some opportunity for removal of some of those organisms because they may not have had time to be actively attached to the surface. Of course, they'll be talking about that some tomorrow.

In processes that have the skin on the surface, then we're looking at a slightly different situation because the bacteria are present on the skin, attached, fairly tough at that point, not freshly exposed to a new surface. So, it creates a slightly different environment for both processes. Now, that doesn't mean that we expect to see one necessarily have a higher contamination level than the others, just a different process. In fact, in beef, one of the concerns that has to be addressed is that there are lots of small cuts on the surface that -- where bacteria can become inoculated underneath the surface and be protected then from later on decontamination procedures.

So, each process has positives and minuses, and they basically probably even out in the end as far as the contamination with pathogens is concerned.

Thank you.

(Applause)

DR. DOYLE: All right. Our next topic will

be hazards in the area of processing and post-processing, and Larry Decker, who is a Chief Food Inspector, with the very strong background in meat, with the New York State Department of Agriculture and Markets Division of Food Safety and Inspection, in Albany, New York, and is also the Chair of the Meat and Poultry Committee of AFDO, which is the Association of Food and Drug Officials, is going to enlighten us as to the hazards associated with processing and post-processing of meat and poultry and eggs.

DR. DECKER: Good morning. I -- thank you for the invitation for attending this morning, and I'd like to preface my comments by saying that I came from the trenches, started at the bottom as far as regulatory issues go, meat and poultry inspection and have grown through the business. Actually, I started before that in processing meat on the industry side.

The industry has changed, and my comments are not only going to be addressed from the point of a processing plant, quote unquote, but also processing at retail. I don't know how it is around your area, folks, but in New York State, we've got an awful lot of larger and even smaller retail markets that are actually mini-processing plants, and we've run into some serious concerns with those. We've run into some

foodborne illness outbreaks unfortunately.

In fact, a recent study by our department and New York State Health suggests that 17 percent of the food illness outbreaks were traced back to either beef, pork or poultry, a total of 17 percent, and those of you who'd like to keep track of minute data, as I recall it, 7.9 percent of that was beef, poultry was 7.9, and pork was 2 percent. Mainly Salmonella, E.coli 0157:H7, and some campylobacter in there as well.

What's scary to a certain extent -- this study, by the way, ranged from 1980 through 1998. That's quite a long range. But 31 percent of the cases, they couldn't trace it back to a causative product or ingredient. Of course, times have changed. Our laboratory techniques have improved drastically.

What caused the problem? This is way -- from my standpoint, what I see as an area that we really need to concentrate on, and I'm going to start at the beginning. We've come from the farm. We've gone through the slaughter. Now, we're into the processing, and the first part of that is the incoming ingredients. Okay. How are they handled? We find that the product's coming in unwrapped, exposed, in vehicles that are less than desirable to transport meat products, and I'm using this based on my experience.

Can everybody hear me, by the way? How about the back row? Okay. Fine. Thank you.

Unapproved sources. I have a great slide which I really wish I had brought with me, and this is a poultry product, I call it a poultry product, we found in one of our better, I use the word "better", better stores in the New York City area, a nice -- actually, it was two dried bats sticks through it, and now that's a meat product. Somebody was processing that and they were using it as a flavoring in a product. This is an ethnic type of thing, and that's one of the situations that we're running into as far as we have a diverse background and we're becoming more so. As folks migrate to certain areas of the country, they're bringing with them their family dietary requirements or needs or wants.

I think, also, the Number 1 -- to me, the Number 1 cause of foodborne illness outbreaks or hazards, whether it's in a processing plant or in a retail situation, is actually the foodworkers themselves. We're finding that -- well, first of all, and it's getting better and better over the years, we're not finding so many infected workers as we used to in the past.

Many years ago, if you were sick, you went to

work anyway. If you didn't work, you lost a job. That has all changed, and I think we've got management pretty well responsible in that area, as long as the employees tell them that they do have a problem.

Poor hygiene, I think, is the next area as far as foodworkers go. I think it's a lack of knowledge. Washing hands after using restroom facilities, changing outer garments when going from one area of the establishment, let's say -- and I'm going to use the word "the slaughter processing area", the slaughter area of the establishment to the processing area of the establishment. Lack of education from the standpoint of not being properly trained by establishment operators.

We know the industry has a rapid turnover, but what we need to do is take the time, and I say "we", that's all of us, we need to take the time to educate those who are responsible for handling and processing our meat and poultry products.

The processing procedures themselves. We in New York State require that anybody that processes a shelf stable meat and poultry product, plus other food products, are required to obtain what we call a scheduled process. In other words, that's an approved processing procedure. It's signed off by a recognized

expert in that particular field. Usually it's somebody from the land grant colleges as well as some excellent consulting services around the country. That's our Number 1 concern. If they don't have an approved process, they shouldn't be processing that product.

Next, they have an approved process, they're not following it. Okay. That's an educational situation. Next is the concern of actually processing the product, and I'm going to address cooking or heating or drying. If that's not done in a manner to which will reduce pathogens, we've got a problem. They need to reach specific temperatures for the specific product, and again that gets back to following scheduled processes.

Also, if it's a shelf stable product, where is our pH and water activities? Are they to the point where this product has been processed in such a manner that when it becomes shelf stable, the pathogens are not going to reenter and reproduce and grow?

Lastly, I think in this particular area, it's actually the cooling of the product. Is it properly cooled? Do we have a chance for cross-contamination? We've got a nice product. We've probably worked on it hard. We sterilized it, quote unquote. How is it handled from the point of cooling to storage? Do we

have our gentleman who was in the slaughter house come in because they're shorthanded and wheel the product into the coolers with his nice dirty aprons and so forth or do we have the proper training there and procedures?

Packaging. That's become quite an issue at the state level anyway regarding vacuum packaging. When should we vacuum package, when should we not? I'll give you a perspective from New York State. We will not allow processed meat products to be vacuum packaged in New York State at retail, and I have to qualify that, because of Listeria. That's one of our main reasons. Of course, we could get into Bot in some cases but mainly Listeria.

Our rationale for that is there's too many activities going on at the retail level, too many various processing activities that could cross, get that cross-contamination. So, we will not allow them to do that.

Another issue, and I think this is coming to the forefront, is irradiation. We have a product that will enter into the processing plant or into the retail level that, quote unquote, has been irradiated or it's been processed in such a manner that we've reduced the pathogens drastically.

Our concern is the establishment that receives this product now opens up the packages, reprocesses it, and then offers it for sale. Do we have the proper protection there? Have we recross-contaminated? Have we cross-contaminated that, quote unquote, sterile product?

Lastly, in my comments, is transportation, and I don't know how many of you folks are in the industry or regulatory and have seen the way some of our products have been transported. It's getting better and better because we're going to vacuum package box-type meat and poultry items. Used to be open and exposed. It still is to a certain extent, especially in the rural settings, the smaller-type slaughter facilities, slaughter processing facilities.

Condition of the container itself that the product is shipped in. We find that it's somewhat less than desirable. The vehicle transporting the product, what kind of condition is that in? Does it have the proper refrigeration? That pretty well does it from that standpoint.

There's one other area that probably needs to be addressed, and it's a growing concern not only with New York State but I know of AFDO as well and other states. We have an arena of custom processing

slaughtering. The folks have -- if you're not familiar with the custom processor of slaughter, it somebody that provides a service for a producer. If I raise an animal or I raise a bunch of birds, and I don't want to slaughter them myself, I just want to take them somewheres and somebody'll do it for me, they'll slaughter it and package it up, usually freeze it, give it back to me, and I put it in my freezer. They don't really require much, if any, regulation at all. Some states have a little something they can lean their hats on but most of them don't.

These folks have now become more than just providing the service, they're becoming mini-processors. They're starting to make the beef jerky. They're starting to get into dried sausages. They're making hot dogs and hamburgers and -- well, they always did have ground beef but sausage-type products, and I'll be honest with you, there needs to be an educational process there because some of them don't have a clue as to what they're doing.

On top of that, once they make these products, they're vacuum packaging them, and then they're going back to the ultimate consumer, and by prayer, we're hoping that everything is working out all right on that. But that's an area that I think we need

to address.

I know I've gone down a little different road from what you had previously this morning, but it's just somethings I think we need to talk about. We want to talk about hazards. I think I've given you a few hazards.

Thank you.

(Applause)

DR. DOYLE: Your program says it's time for a break, but Dr. Hulebak says maybe we want to go on and you can have a longer lunch time, is that all right? All right. Yes, no?

DR. HULEBAK: Show of hands?

(Show of hands)

DR. DOYLE: Would you prefer to take a break now? Yes? No? I see more nos than yeses. So, I guess we're going to go on.

So, next, we're going to have Dr. Robert Tauxe. Heaven forbid, I don't want to misrepresent Dr. Tauxe. Dr. Tauxe is the Medical Epidemiologist at the Centers for Disease Control, which is part of the U.S. Public Health Service. He's the Chief of the Foodborne and Diarrheal Diseases Branch, which is largely responsible for the surveillance and investigation of foodborne disease outbreaks, and Rob is going to kind

of bring us to the final end of the food continuum and talk about hazards that are introduced during the preparation and consumption of food. Basically, he's at the end of the food chain.

So, once we get the computer changed, Rob will give us his perspectives on those hazards that we have to deal with in food service and at home and other areas of the end of the food chain.

DR. TAUXE: Well, good morning. Thank you very much, Mike, and good morning to you all. It's a pleasure and an honor to be here and to join you. We're swapping out computers after the zip drive sort of consumed my zip disk and refused to either give it back or show it. The back-up Plan B should be operational here in just a moment.

(Pause)

DR. TAUXE: All right. Well, good morning.

The public health burden of foodborne disease is substantial. Each year, an estimated 76 million cases occur. That's one in four of us, one in four of Americans. An estimated one in a thousand are hospitalized each year, and minimum estimates would start at 6.5 billion in medical and other costs.

As I'm sure the audience is very clear on, prevention depends on efforts from farm to table to

reduce contamination of food. I need to explain to my public health colleagues sometimes that this isn't like measles or polio where a simple vaccine is the issue but that it's a much more complex partnership.

Now, another thing that makes it complex, of course, is that we're talking about infection with a variety of different pathogens. Illness as recognized and dealt with by the public health authorities may occur in large focal outbreaks, but actually a vastly greater number of illnesses occur as sporadic cases, individual cases, perhaps part of unrecognized disbursed outbreaks.

We talk about the reservoir for our pathogens. That's the locus of sustained transmission and persistence where it really continues its housekeeping. Some of these pathogens have a human reservoir, well adapted to the human host, Shigella, hepatitis A and Norwalk Virus, for example. Many have an animal reservoir and are zoonotic, basically zoonotic, Salmonella, campylobacter, E.coli 157, Listeria, Vibrio, if we call shellfish an animal, Yersinia, and Toxoplasma.

Finally, it's complex because a given pathogen, say E.coli 0157, can be transmitted by several different pathways, by several specific foods,

like water, direct contact with animals, direct contact with other humans.

Now, here is a listing of the major identified foodborne pathogens in the United States as of now. It's a list that is long and actually continues to grow. The little asterisks indicate ones that have been flagged as foodborne in the last 30 years. Listeria has been known for a long time, so has Vibrio Cholera as pathogens, as human pathogens, but the real importance of the foodborne component of that has just been recognized more recently within the last 30 years.

You'll notice over on the right, I've added a new one, the Prion. The medical community in this country is quite alert right now. We've had our first case of variant CJD in a 25-year old woman in Florida who had moved here from Great Britain about five years ago. That means we have a case. We're on the look-out. She was certainly exposed in Great Britain, however.

Now, here's the same list, and in addition to showing which ones are recently identified as foodborne, I've indicated in yellow those which have a zoonotic reservoir, and there is a certain amount of overlap there. A substantial number of these are

zoonotic in origin, enough in fact that I would propose that there is sort of a syndrome of the new foodborne zoonosis.

The infected food animal typically looks healthy, and there is a sustained or repeated cycle of infection in the animal that keeps it persisting there. The contaminated food looks normal, and the pathogen can survive standard processing and preparation. An easy example is a raw oyster which doesn't get much processing or preparation but also lots of recipes for eggs and undercooked beef are quite popular. These pathogens are missed by current inspection strategies and often spread silently around the globe causing a pandemic of which the United States may just be part, and they require new control strategies. Clearly, there have been a number discovered in recent years, and there are certainly more to be discovered.

Now, if the chain of production from farm to table, as we've outlined it this morning, goes from production at the farm level or feedlot processing, then I'm going to focus on final preparation and cooking in the final kitchen. Now, the kitchen is not just one kitchen. A kitchen is a lot of different kitchens and a lot of different kinds of kitchens, and in fact, an enormous array of different issues occur in

the kitchen.

We have actually surprisingly limited information about all the things that go wrong in kitchens, but let me summarize a small amount of what's available. Outbreaks between 1993 through 1997 reported to CDC, that's about 2,700 of them, 43 percent of which occurred in restaurants or delis or other commercial food establishments, include in many cases reports noted by those who investigated it of contributing factors that are typically events that happen in the kitchen and not surprisingly, the poor holding temperatures is the most common noted in 73 percent of those, poor personal hygiene in 38 percent, inadequate cooking in 21 percent.

Now, this is the impression of the person doing the investigation, who may be looking into issues depending on what he thinks the problem is, but these are -- at any rate, it's very common to find that there are problems in the kitchen.

In a separate review with more detail in it, between 1980 and 1995, 1,800 outbreaks investigated in New York State were summarized recently by people from New York State, and they identified 32 percent of the outbreaks being related to contaminated ingredients, 24 percent consumption of raw or lightly heated foods, 23

percent food from unapproved sources, we just heard, and in 23 percent an ill foodhandler played a role, and I would think that that 23 percent is probably a minimum estimate, and especially as we get better and better at identifying Norwalk-related outbreaks, that that is going to increase because those are particularly likely to be related to ill foodhandlers.

Now, it's important to remember, however, that outbreaks really are multifactorial events and no one contributing cause can be pointed to and say, well, gee, that one thing, that's it. I mean, the pathogen has to be present in the first place. Problems in foodhandling are often reported in foodborne outbreak investigations. Certainly investigators are looking for them, but, however, they're probably frequent in kitchens where outbreaks have not occurred and that sort of control group of kitchens is an interesting question.

We hope to have much better information about this within a year or two as part of -- as an adjunct really to our FoodNet active surveillance program and new network of environmental health sanitarian network has been formed which is now going to start looking very systematically at what's happening in kitchens, both those where there are outbreaks and those where

there are not, and we hope to have much better information about this to compare those practices.

It is clear that training focused on better foodhandling is important and so is handwashing and other measures to reduce direct bare hand contact with food. However, reducing the arrival of the pathogens into the kitchen is really a critical point and that's what I want to talk about a little bit more.

What are the sources for introducing pathogens into food during the final preparation? The most important one, I think, is that foods arrive contaminated, and we're talking particularly about raw foods of animal origin. However, at least 23 percent of those outbreaks in New York were attributed to a foodhandler who was infected with the pathogen and that's how it arrived into the kitchen, and there are other environmental sources.

Well, it's no surprise that when contaminated raw foods of animal origin arrive in the kitchen, lots of things can happen after that. Handling may further amplify the risk. Lack of adequate refrigeration facilities or mixed refrigeration facilities or all sorts of other time and temperature problems may amplify the risk.

Those foods can easily cross-contaminate

other foods via hands, utensils and services. Recent interesting practices identified in outbreaks included a large sink where vegetables are routinely dumped in the water and the sink was changed once a week. I think the same water was used -- this is in a very large hotel. The same sink was used occasionally to wash hands in and who knows what else was in that sink. Lots of cross-contamination possibilities there that might explain a complicated outbreak.

Another example is -- and this one's more subtle. We have a problem with Yersinia infections in this country that's very specific and selective, and it affects particularly infants who were drinking baby formula, bottle-fed infants, that are being taken care of by somebody who is handling raw tripe, pork tripe, especially chitlings, making a seasonal dish for a family gathering around their winter holidays, and we see these infants who are very ill with Yersinia and the common link is that whoever it is that's taking care of the chitlings and cleaning the chitlings, which involves a lot of cleaning of the pork intestine, if that person is also the designated bottle feeder, we see cross-contamination and the baby with the formula is the one who gets sick, although the chitlings themselves are very well cooked.

Now, there's also obviously a direct risk if the food is uncooked, and I'd like to point out that undercooking is common, that even right now after lots and lots of efforts, including Fightback and other education efforts, to try to alert people to the problem, labels on foods, a lot of people eat undercooked food and like it that way. We just completed a survey in our FoodNet population, approximately 15,000 persons surveyed in the year 2000, and 2.5 percent said that they've had raw oysters in the preceding month. That doesn't really change very much by month. 26 percent knew that they had had a pink ground beef and actually about 31 percent say that's the way they like their ground hamburger, is on the rare side, and 27 percent said that they'd had runny egg dishes.

So, our population may be aware of some of the issues but this is how they like to eat their food, and we have to take account of that. Three percent, unfortunately, only 3 percent, said that they used a thermometer to make sure that the burgers were cooked to the right temperature. So, these practices that we would like to see are not all that common.

Now, let me move to the second introduction. When an ill foodhandler arrives in the kitchen, they

work by and large often because they have no paid sick leave. Sick leave policies in rapid turnover industries, like the fast-food restaurant business, are pretty minimal. Although they all will say, gee, people who are ill should not work, they do not make it necessarily very easy for them not to work.

The ill foodhandler may be shedding the organism in feces or vomitus. I think the risk of vomitus may be underappreciated. It certainly was by a baker in the Netherlands who early last year felt rather poorly as he was preparing a vast number of sandwich buns, vomited in the sink, sort of cleaned it up, and then went on to load each bun on to the tray to make the sandwiches, resulting in several hundred people getting Norwalk virus infections.

Lapses in personal hygiene can definitely contaminate food. Particularly for pathogens with human reservoirs, and that's the Norwalk viruses, the Shigella and hepatitis A, but also occasionally for pathogens with animal reservoirs, there are instances, certainly well-documented instances, of foodhandlers with Salmonella, 0157 or campylobacter contaminating food.

Now, there are other environmental sources that food can -- that allow food to become

contaminated. We're worried particularly about food that's prepared or consumed around animals, and there are a lot of different ways this happens, particularly in the summertime. There's a school trip to the petting zoo where you share your ice cream with the calf. There's the county fair where kids, concession stands and cattle are often all sort of indistinguishable or in the same place, and then there's the barn dance that happens that night where the teenagers kick up their heels and kick up the sawdust.

We've had outbreaks of E.coli 0157 in all of these settings related to consumption of foods or beverages in these settings, and then there was a large E.coli 0157 outbreak that occurred at a University of Wisconsin facility last year where 34 cases occurred after a breakfast was prepared, served and eaten in the stock pavilion, where the day before all the cow manure had been sort of brought out with a frontloader and the sawdust had been wetted down to keep it from being dusty.

There's food prepared with contaminated water. Rodents, insects, and other vermin may obviously cross-contaminate food in the kitchen as well as earlier in the food chain.

Now, let's talk about a few prevention strategies that would seem to be very helpful to reduce contamination in the kitchen. Obviously basic food safety education is a good idea in avoiding risky food practices. One we're focusing a little bit on is this idea of separating the handling of raw meat from infant care and that's actually not -- those are two roles that are often combined in our culture and it may be helpful to separate them, and to purchase foods processed for safety, pasteurized milk and juice obviously but also pasteurized shell eggs and irradiated ground beef.

Another thing the consumer can do is to ask the restaurants, the waiter if there is one or the person on the other end of the intercom, about their sick leave policies. Prevention strategies for food establishments to reduce contamination in the kitchen. Again, basic food safety training and certification seems like a really good idea to me. So does paid sick leave, making handwashing easy and frequent and reducing contact of bare hands with ready-to-eat food seem like good ideas.

So, to me, does including pathogen reduction standards in purchase contracts. I know some restaurant chains do that. It seems to me like it

would be a good idea if all of them did.

For institutional kitchens serving very high-risk populations, foods processed additionally for safety are available now. Nursing homes, hospitals, elder care kitchens. These are serving high-risk populations. Pasteurized shell eggs and liquid eggs to avoid Salmonella enteritidis infections are on the market now. Irradiated ground beef to avoid E.coli 0157 and Salmonella infections is on the market now, and frozen chicken and turkey, freezing chicken and turkey is not -- it doesn't reduce Salmonella at all, but it does actually diminish campylobacter by two to three logs and would reduce the risk of campylobacter infections.

Now, I think food safety education is important but not sufficient to protect public health, and there are a number of reasons why. This is a common discussion point and a common argument. You will hear, well, if only the consumer prepared the food properly, our problems would be over, and the trouble -- there's several problems with that, and let's discuss them.

First of all, of course, raw foods of animal origin are often contaminated in the first place with pathogens that cause serious infections may be

difficult or not treatable with grave complications.

Problem Number 1 is that traditional recipes call for limited cooking. I mentioned raw oysters. Let's talk about rare ground beef, and there are cookbooks full of rare ground beef recipes still. There are cookbooks full of egg recipes that leave them uncooked or undercooked or soft boiled. The eggnog served at the White House in the 1999 Christmas was made with raw egg. There is a lot of raw egg that is consumed, prepared and consumed by chefs who supposedly know what they're doing in this country and are following traditional recipes. That's a problem. That's not, you know, food mishandling so much as that's following tradition instead of changing cuisine radically.

It's hard to tell. Problem Number 2 is it's hard to tell when food is thoroughly cooked. Boiled eggs. How long do you have to boil an egg before it's done? You can't really stick the thermometer in it. Baked lasagna is something people don't think about core temperatures in, but if it's got raw egg in it, they should. A browned burger, is that safe or not? There's actually some discussion that maybe it isn't.

A third major problem is that the raw meat, poultry and eggs in the kitchen are handled by someone

who is often handling other foods that might be fresh produce that's going to be rinsed and eaten without cooking. So, those are all reasons, I think, why it's fine if the consumer does cook things properly, adequately and thoroughly, but it's not enough.

Now, if the chain of production is from farm to table, then contamination can also occur from farm to table. We've been talking about the potential for temperature abuse, cross-contamination, worker health and hygiene issues during final preparation and cooking.

I think to turn a little bit now and try to focus on some of the pathogens that we're really dealing with here in this conference, the principle points of entry for campylobacter, E.coli 0157, Salmonella and Yersinia start at the production level, and there's further potential contamination that can occur after that but those start really at the production level.

Listeria monocytogenes, predominantly a problem in ready-to-eat meats, typically enters those meats after they've been processed, so that's at the processing level. For the Norwalk-like viruses and hepatitis C with human reservoirs, it's typically at the production and preparation level.

Now, I wish we could get very quantitative about this and really describe, well, what proportion of all of these enter at which level and what proportion are related to meat and poultry versus fruit and vegetable and nuts, but this is not the time or place to do that, and I'm not even going to attempt it. But I am going to try to divide the meat stream into the land animal stream, producing meat, poultry, dairy and eggs, the plant stream producing fruits, nuts and vegetables, and the fish and shellfish stream, all of which cross from production processing and final preparation and give just a sketch of how some of our favorite pathogens flow through this particular landscape.

Vibrio parahaemolyticus zoonosis. It starts with healthy normal-looking shellfish in their healthy normal-looking beds, and they harbor Vibrio parahaemolyticus. That can then pass right down through to the shellfish as consumed, along the way contaminating any other fish or shellfish that might be in the same bucket at processing or final preparation levels.

This is sort of an image of Norwalk-like viruses, and we think mostly of ill humans contaminating meat and poultry as they prepare it or

salads and other vegetables as they prepare that, but also the line that goes up to the fish and shellfish reflects the fact that the oysterman who goes out and harvest the oysters may in fact contaminate the oysters right at the point of production.

I remember vividly an oysterman who, as we were investigating an outbreak of oyster-related Norwalk virus, said, "Well, it couldn't be them oysters at all because he'd been sick before the oysters were even harvested" and had vomited over the side directly into the six-foot deep very shallow oyster bed. So, it couldn't be the oysters.

And for many of the pathogens that we're looking at, such as the zoonotic Salmonella, the carrier food animals begin contamination during production with further contamination, cross-contamination being possible either as manure leaks over into the plants, the plant fields or during processing, ordering, final preparation and cooking with, as I said, the occasional helpful contribution of the ill foodhandler.

Now, prevention, of course, is possible at many points, and we've been talking about the final bottom chunk there where foodhandler training, handwashing, sick leave, restaurant inspection,

consumer education, is sort of a package deal, but there are a number of points possible all along the chain that are going to be discussed in detail.

I would like to focus just on this same matrix now and just focus on a few of the boxes. Here in 1996, when HACCP was introduced in the processing of meats and with this dotted red line being the monitoring samples, we have a unique opportunity to see what happens when we introduce a new system into -- a new food safety system into this whole matrix. Someone else is going to review this in detail. So, I shan't spend much time on this, but this is the results of HACCP monitoring samples for Salmonella testing in ground beef, and I've separated out. This is percent positive along here with the baseline at 7.5 percent by year, separated out by large, small and very small plants, and the basic trend after an initial perhaps disappointing increase is a general downward trend in all sizes of plants.

That's the FSIS data on monitoring of ground beef samples, all winding up in areas that are substantially below the initial baseline, and I'm going to skip then forward to the human illness data as measured through FoodNet at CDC, and there, here is a graph showing the changes in incidents of several

foodborne infections relative to 1996. So, 1996, they're all relatively -- they're all normalized at one, and then you can see that for each of these, Salmonella, campylobacter, Listeria and Yersinia, there is a decrease. Salmonella is in fact the least of the decreases, 15 percent, campylobacter 25 percent, Listeria 31 percent, and Yersinia 49 percent decreases, all in the same time frame as HACCP, although perhaps a number of other factors like food safety education could play a role.

Now, I would like to suggest that similarly, we could move vertically up and down this column adding education, handwashing and sick leave at the preparation level and perhaps quality assurance programs, an expanded quality assurance program at the production level, and that additional monitoring points for microbial monitoring may be very helpful in assessing the individual impact of those. Similarly, we could hope in the future to have a broadening of this approach across food types, again with monitoring to verify the effectiveness of the programs.

I'll summarize then by saying that foodborne pathogens can enter the food chain at multiple points. Pathogen reduction approaches can reduce the risk, as I think is illustrated by HACCP and the monitoring, the

microbial monitoring that verified its effect. In the kitchen, specifically, educating the food preparers is important and so is promoting handwashing, keeping ill workers out of the kitchen and decreasing, most importantly, I think, decreasing contamination of food coming into the kitchen.

Microbial standards and purchase contracts may be one way to achieve that, but for high-risk populations, using safer food products that are available and on the market now is an immediate strategy to protect them.

Thank you very much.

(Applause)

DR. DOYLE: All right. Well, the morning session is complete. I hope you've written down your questions and are prepared to ask those after lunch. We're going to take an extended lunch break and get back together at 12:30.

DR. HULEBAK: I just wanted to add one note, that as I was listening to Dr. Tauxe, rethought the wisdom of having the break before his talk. The way we've done it now, we're going out to brunch actually, having just heard from someone for whom vomitus is his bread and butter.

But thank you. Enjoy brunch, and we'll see

you back at 12:30.

(Whereupon, at 11:04 a.m., the meeting was recessed, to reconvene this same day, Monday, May 6th, 2002, at 12:30 p.m.)

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

12:37 p.m.

DR. HULEBAK: Good afternoon.

I'd like to begin the afternoon session which will actually complete the morning session with the moderated discussion for Panel 1.

Before we begin that discussion, I've a couple of announcements to make. There is a message at the registration desk for Jim Alstrom. Second news note, there are discount parking coupons available at the registration desk. For anyone who drove and parked in the parking lot, we'll get you a discount on the parking charge. So, please seek those out.

And also, we've only been able to sell one of these so far. So, maybe everyone's just very brave and has no problem with floor mikes, but remember these cards are at the front desk, at the registration desk. If you'd like to use them to submit a question, please do.

We're now ready to begin with the moderated discussion. Questions directed to the panel, by panel members to each other, however they come, and the discussion will be moderated by the panel chair, Dr. Michael Doyle.

DR. DOYLE: Well, welcome back. My colleagues have set the stage and now the stage is yours. So, I would hope that you will take advantage of this opportunity to ask your questions, make your comments, be sure to use the microphones because this session is being recorded and captured, but I would encourage you to keep this to the science. So, if you have points to make or if you have questions to be asked, remember that this session is to be focused on the science, and so I would encourage you to stay so focused.

Since I don't see an overwhelming number of you coming forward to the microphones, I'm going to start out with the first question, and that is, do we have the science and, if so, perhaps maybe we ought to better organize our thoughts as to where the most influential points of contamination are within the various points of the food continuum.

I know Dr. Tauxe had talked about specific pathogens of concern relative to the animals. Are those the only organisms that we should be concerned about? Have we identified perhaps in priority order those that are of highest important, and then do we know, based on science, based on risk factor studies or

whatever, what are the most influential factors that contribute to the contamination?

That same question goes to each and every one of you because there are different points in the continuum at which contamination occurs.

DR. HULEBAK: Dr. Doyle, I'd like to add an addendum to that question because Dr. Acuff pointed out that in swine slaughter, the bunge isn't bagged, and you did point out -- not typically, and you did point out that that is a potential point of contamination. So, there's a situation where at least there's an opportunity to be addressed that hasn't been addressed.

My question is very much along the lines of Dr. Doyle's question. Why do you think that is?

DR. ACUFF: I don't know why they don't. I think probably volume is one of the reasons, just because it's, you know, -- I'm sure it would be more difficult to apply that technique, but in terms of why it's not done on a regular basis, I don't know. I'm sure there's probably somebody here, though, that could answer that more clearly.

DR. DOYLE: Well, let's --

DR. ACUFF: It's an unknown. It's an unknown quantity. I don't know. There must be some reason.

DR. DOYLE: Well, maybe we can start with Dr.

Dargatz, and can you help us? I know you're -- oh, I'm sorry. Go ahead.

MS. MUCKLOW: I got a real question, please. Not being a scientist, I'm going to try to ask a science-based question, and you can throw me out if you will.

I wondered if Dr. Tauxe could tell us what data the CDC has that relate serotypes from human illnesses to serotypes in products. That's my first question. You know, is there some data that gives us some clear direction on the relationships of those serotypes since there's so much more serotyping being done today?

All of the Salmonella performance-based testing that is done, if it's a positive, it goes to the serotype, isn't that correct, Karen?

DR. HULEBAK: We do have data on the serotype, yes.

MS. MUCKLOW: Yes, and so, has there been any kind of effort by CDC to tie those to the specific illnesses?

DR. TAUXE: That's a great question. We have not systematically put together all of the serotype information that we have from humans with what is just now coming out of the FSIS performance standard

testing, but that is an interesting and important thing to do.

I know that that is -- and then, behind that is a question about, well, what about what's found on the farms, and how does what's found on the farms relate to what's finally found in the meat, and then going forward, how does what's found in the meat relate to what's found in the final product or in the consumer?

Serotype is one good way to start approaching that. Unfortunately, some of our serotypes, like Typhinurium, are so common that they may be in many different foods, and they may be -- the same serotype may be in many different foods, and so that strategy doesn't work too well, and that's where we've been using a molecular, we call it, fingerprinting technique to subdivide the common serotypes out, and I think the real tremendous comparisons that can be made when we take the common serotypes and do the subtyping with this fingerprinting, which is something that FSIS also can do and other parts of USDA can also do, and then we can see where does the -- where do the Typhinuriums sort out. We think that's a very powerful tool.

We would expect to find a number of serotypes common on the farm and common in meat which don't

appear to be common in humans. That would not surprise us at all, and so the point would be to go in the other direction and find the serotypes that are common in humans. Where do those sort out among different animal groups? Some of them we know, for instance, are common in pet reptiles but not in foods at all, and so a small but important fraction of Salmonella is associated with pet reptiles, and the serotype is part of how we can determine that.

So, I think this is something we think is important and can be done in the future. It'll be powerful when it's combined with another serotype -- another subtyping in addition to serotype. Denmark does that, for instance, and is able to sort out most of where their Salmonella comes from that way.

MS. MUCKLOW: How far in the future do we have to wait?

DR. TAUXE: That's a good question. We have the subtyping strategies now for most of the major serotypes worked out, and we hope to be able to -- and then, it's a question of doing the same with FSIS isolates and their capacity to do those and then can we assemble those data together?

MS. MUCKLOW: If public health protection is the goal, then that's an essential linkage that we

don't have at this point, and it might behoove you to look to see if we can accelerate that linkage a little faster, so we really know what we're looking for, what we're hunting for.

DR. TAUXE: Well, yes, I'm sure there are people in the audience or even on the podium who deal with FSIS laboratory capacity who are listening as well as I am.

MS. MUCKLOW: The second question I have, unless anybody else is crowding to the microphone, is that, when the mega reg was proposed and the millions of illnesses and so on were all recited and when it was finalized, there were similar numbers. I took great exception. I mean, I always want to know where the 5,000 people are buried, and I'd really like to know how we get to those numbers, and they do seem to keep changing and maybe change is good for us, but I'd really like to know very much, is there a paper somewhere that can somehow give me some rational extrapolation that explains to me how we get to -- I think it was 70,000 today, illnesses.

I'd really -- you know, that number gets floated around, and it's repeated often enough that a lot of people think it's the Holy Grail, and I'd just love to see where that number comes from.

Now, somebody else can have the microphone.

DR. TAUXE: Yes, ma'am, that was published.

MS. MUCKLOW: Maybe you'll give me that paper at some point.

DR. TAUXE: You can download it from the web. It's published in a journal called Emerging Infectious Diseases in 1999. Give me your address, I'll send you a copy.

MS. MUCKLOW: That would be wonderful. How did we get that -- okay. All right. That's fine.

MS. ROACH: Hello. My name is Steve Roach. I'm with Food Animal Concerns Trust, and I have another way to kind of complicate looking at pathogens, besides just serotyping.

This question is mainly directed towards Dr. Dargatz but also Dr. Tauxe maybe can help answer it as well. I'm concerned. What I'm concerned about is antibiotic resistance, and I'm just curious with the -- okay. Let me get the acronyms right. With the NAHMS data, where you took the pathogens, I was just wondering, have you all done any antimicrobial susceptibility testing with those isolates that you took from the farm to look to see if whether you can find any relationship to on-farm management practices, because I know you all are taking a lot of data on

antibiotic use on farms.

So, it seemed like you have a research project there that would be -- we would probably expect that you would find resistance in where drugs have been used on the farm, but I was wondering if you'd looked at that at all, and again it's just a general question. How much, again with the FSIS samples that we take, are they tested for antimicrobial susceptibility? So, how much is NAHMS linked with NARMS, and how much are they actually looked at in terms of what happens on farms? That's my question.

DR. DARGATZ: I'll speak to the NAHMS part of that. All of the Salmonella isolates that we've collected from the NAHMS studies flow into the NARMS, the National Antimicrobial Resistance Monitoring System, for enteric bacteria. So, all of those Salmonella isolates go to the ARS lab in Athens and are tested for antimicrobial susceptibilities using that NARMS panels.

MR. ROACH: Okay. But then, do you go back and look at -- does the rest of the data go with them? So, can you say this is related to this type of on-farm practice or anything like that?

DR. DARGATZ: Actually, the resistance profiles then come back to us to match up with the farm

demographics and that type of information, and we do get to look at those. To date, we're in the process of publishing the results from the first feedlot study that I showed you, trying to catch up in that process, as we've backlogged some of those testing profiles.

As it stands right now, the look at the feedlot isolates, we were unable to demonstrate at the current feeding practices feeding antimicrobials and the resistance profiles that we saw among those Salmonella isolates that we tested.

MR. ROACH: Okay. So, you didn't see any relationship between the susceptibility and the feeding practice?

DR. DARGATZ: Right.

DR. ACUFF: Actually, we've done some similar work in our lab, and we have followed cattle on test farms through the university system where medical records are kept, and we know exactly what the cattle have been fed and what they've been treated for, and even in cattle that we have brought through the system without any exposure to antibiotics, we've been able to pick out resistant Salmonella from some of those animals. So, you know, don't know what that's good for, but it's an interesting situation. I wouldn't want to shoot any birds.

MR. ROACH: If I can comment further, I'm from the Agricultural Research Service, with the National Antimicrobial Resistance Monitoring Survey in Athens. We have an agreement with FSIS and also with NAHMS to take isolates and run them in the appropriate epidemiologic patterns. All of that data is on the website for you to view and then we go back, as Dave was saying, that if we have epidemiologic data on on-farm practices that we would publish papers on that data. So, certainly if there are further questions about that, we'd be happy to discuss them.

MS. DONLEY: Good afternoon. Great panel. I'm Nancy Donley with STOP, Safe Tables Our Priority, and we're a foodborne illness victims organization. I'd kind of like to answer part of that question that was addressed to Dr. Tauxe by Rosemary a few minutes ago.

I have way too many addresses of what I can give you and be happy to provide you a list where bodies are buried with some of our foodborne illness victims, and it is something that I think the CDC does a very, very, very particular job of -- it's a hard job to extrapolate numbers of foodborne illness in victims, but I don't think it should be treated so flip as to say that you'd just like to know where the bodies are

buried. I can help you with that information, however. If you'd like to give me a call, I'll be happy to tell you.

My question is that we've heard today a number of times from a couple of different commentators about the fact of education, and our organization is really very, very, very supportive of education in all -- from farm to table. My question is that you can educate, if you'll pardon the expression, till the cows come home, but how do you change behavior modification? Because until we get to that point and until we have some sort of feedback mechanism saying are these on-farm strategies being implemented, where we can then have some measurable results in how are these programs affecting all the way to the consumer, we're kind of left with not knowing how effective our educational programs are.

I guess my question is, do we have -- right now currently, from all of the farm to fork, do we have any feedback measurement programs going on where we know how effective we are? I can just say from personal experience with our membership and just talking with, you know, consumers on the street with our hotline, that many people, consumers, I can only speak about general consumers and who reach out to us,

they know what they should be doing.

It's like Dr. Tauxe said earlier, is that, they want to eat their meat less than fully cooked or they want the soft runny eggs. How do we get them educated to change their behavior?

DR. DOYLE: Dr. Tauxe, do you have any answers for that?

DR. TAUXE: Well, it's an important question that I think leaves a number of us scratching our heads. In public health, I think we often pursue multipronged strategies trying to make life safer, make the U.S. a healthier population, and changing behaviors is always a challenge. I mean, you think of the way we handle automobile safety in this country. We certainly provide driver education in the schools. We license people. We test them to see if they're good enough at driving, and then we put in a whole array of safety features and interlocks in all the cars, so that even if people choose not to do everything that they learned in driver's ed, there are still a number of safety features that kick in when they're in their crash.

It's been -- it's always long-term. It's always complicated, and I think we need to recognize that human behavior is, especially behavior around central core cultural features, like food, is just not

going to be very quick to change, and we can't just assume it will change overnight.

DR. ACUFF: I think Ms. Donley has an excellent point actually. In fact, we were discussing before we came up that applying rules, you know, and having a list of things that you're supposed to do or supposed to not to do as far as food education is concerned is one thing, but changing someone's frame of reference, providing an aseptic sense of things is probably more important in terms of education, teaching people to think in terms of what is acceptable behavior and what is not, instead of trying to follow a list of rules, and one of the examples that when we were talking that I was using was we were driving past the grocery store, and one of my kids said, "Hey, there's the guy that works in the meat market." I said, "Well, how do you know that? Where?" She said, "Oh, he's over there walking across the street", and so there he was in his frock walking across the street to the grocery store, and I said, "Well, how do you know he's going to work?" She said, "Because he has his gloves", and he had his disposable gloves in his hand, you know, walking across the street to the store.

So, the whole system of his outfit and gloves was to protect him, not to protect us, and it's a whole

frame of mind that we need to work on as far as education is concerned, I think.

DR. DOYLE: I'd like to follow up on Ms. Mucklow's question and be a little bit more specific than Dr. Tauxe.

Can the surveillance of human illness be improved to enable the identification of the impact of reducing specific hazards? So, if we implement a critical control point, such as reducing E.coli carriage in cattle or reducing E.coli 0157 in ground beef, if we implement these critical control points to reduce contamination, can our surveillance or will our surveillance ultimately be able to show what impact that has had on the number of cases of E.coli 0157 infection?

DR. TAUXE: Well, I think that -- we hope so in that surveillance, I think, such as we do in food, and that is two things, one is it's simply a count of the number of infections by something like E.coli 0157, and other things being equal, other things not changing, if one thing changes in the system and we think contamination rates drop, we would expect to see the ultimate number of illnesses that resulted also drop.

The trouble is that other things are never

equal, and there are lots of things happening at once, and it's very -- I mean, as sort of the final proof, the final test is the sum of everything that's happening before that, and it can be hard to sort out.

However, the second thing that our FoodNet studies are is a series of more detailed investigations of sporadic cases in our case control studies, and there, I think we can see specific risk factors drop-in/drop-out. We did a case control study of E.coli 0157 infections back in '91, and back then, a clear risk factor that emerged from the study was eating at a fast food -- eating hamburger at a fast food restaurant. When we repeated the study with FoodNet in 1996, that risk factor was gone and did not emerge, and that, I think, was a pretty clear indication to us that something had changed in the quick or the fast food industry between '91 and '95 which is not hard to imagine.

So, we can see specific risk factors, I think, can drop out when there are things that we can measure. As you illustrated, one of the risk factors that's really of concern right now is direct or indirect contact with animals, and this goes along with a string of outbreaks that we've had in county fairs, in other agricultural settings, that suggest to us that

actually the 0157 problem is expanding and increasing and is spreading throughout cattle populations that may not have been exposed before and is affecting kids and adults who haven't been exposed before.

So, I guess that if a major intervention occurs, and the surveillance numbers do not drop, I think that means that further interventions are required. If numbers do drop, I think that's a suggestion we're headed in the right direction.

DR. DOYLE: Okay. Here's a question from the audience for Larry Decker.

Why are the state inspection programs spending their resources testing product from stores that is produced in federal establishments? Shouldn't they be concentrating efforts on small state-inspected plants that need to be brought up to USDA standards?

DR. DECKER: That's a good question. I can only speak for New York, and we really are not spending much, if any, resources on sampling products that come out of federal facilities.

To my knowledge, the only time we do that is if it's associated with a complaint, whether it be illness or some other type, and then whatever the information that we receive from the laboratories is passed on to USDA, if it's appropriate.

Most of our efforts are spent on our New York State-regulated establishments as far as sampling and inspection activities.

DR. DOYLE: Thank you.

Another question. As we have heard so far, the problem starts on the farm. Why is that most emphasis on pathogen reduction in the plant and not enough on the farm? Why is so much emphasis being placed on the processing plant and not enough on the farms is the way I read the question.

DR. DARGATZ: Well, I guess, in terms of looking at the farm, one of the things from our studies, we've not seen any consistency and strong relationships between on-farm management and the presence or absence of some of these pathogens. We've been able to identify them. They're widely distributed, albeit at fairly low prevalence, on these farms and that doesn't mean that we shouldn't continue to look and that doesn't mean that we aren't continuing to generate hypotheses about how we might intervene in that production process on the farm. It's just to date, we haven't seen any strong consistently-present risk factors, and as you saw, we've got the results of another study, this most recent feedyard study, that we're looking at in terms of risk factor analysis as

well to see if we do find those consistent risk factors that make sense, that could be further tested under a more controlled application or controlled environment to see if those things can be applied and make a difference. But to date, I have trouble recommending exactly what those interventions might be.

DR. DOYLE: Well, isn't it in part that we don't have highly-effective interventions or treatments that could be used on the farm and be practical in their use?

DR. DARGATZ: I think what many people have looked at to date have been management of diet or management of animal factors, that sort of thing, that could be incorporated into the standard sort of protocols for how animals are managed or handled on the farms, and more and more, we're beginning to look at some of the more active systems to see if we might intervene in that, in the ways that we create niches for these organisms or the ways that these organisms persist and affecting the ecology of the organisms on the farm by intervening, say, in the form of vaccines or competitive exclusion or products that we might give to the animal to mitigate against the levels of those organisms that either colonize or are shed by the animals.

So, in terms of the early work looking at how do we tweak the system to change that, we haven't seen a lot of suggestions of ways to get that done. I think the work is on-going to look at some of the more active interventions.

DR. DOYLE: Rob?

DR. TAUXE: I think that there's an example of some on-farm interventions that gives me some hope that there may well be strategies that work, if you'll switch to the egg part of the issue, and there, the quality assurance program that was piloted in Pennsylvania developed a series of strategies that have certainly not put the Pennsylvania egg industry out of business but rather I believe it's now 80 percent of the producers are voluntarily part of and that at the same time has reduced the level of contamination -- of Salmonella enteritidis colonization in those farms substantially below what it used to be, and of course, there really isn't a slaughter process to talk about with eggs, but so, if we were going to do anything about what went on as far as contaminating the contents of eggs, it had to happen at the farm, but that work was done -- I mean, that was an industry and an academic and state and federal agriculture department collaborative effort to develop that and look at what

worked.

That's been reasonably successful and is now being emulated in a number of states. It wasn't obvious going in to that perhaps that it would be successful, but that's a model for what could be done. I would like to suggest that as practices within slaughter plants become optimal, I mean, that at some point, the rate-limiting step is going to be the introduction of pathogens on the animals themselves coming in and that it's a natural extension is going to be to go back to the farms and to consider points on the farm and between farm and slaughter that are ultimately affecting the contamination of the final product.

DR. DOYLE: And that leads me back to my original question. Do we have enough science behind us to say specifically where the hot spots are? Where is the E.coli 0157 or how is it getting into the cattle and being transmitted among the cattle?

Campylobacter. How is campylobacter getting into the poultry and being transmitted among poultry? Do we have enough scientific evidence to say this is where we ought to be focusing our efforts because these seem to be the hot spots? Do we need to do more work in that area?

DR. ACUFF: Well, I'm sure we have an incomplete picture. We have some. I mean, we have a picture, we just don't have all the details, but we never have had all the details, you know. We just have to do the best with what we have. But I think we have enough information to know that there are certain areas we need to emphasize, and in doing so, we will probably turn up additional information that will allow us to develop that further.

DR. DOYLE: Well, I saw Dr. Dargatz said that chlorination of drinking water for cattle didn't have any effect, but I've seen a lot of reports to suggest water may be an important vehicle for transmitting 0157 in cattle. So, how does that fit?

DR. DARGATZ: I think a couple of maybe comments on that. One is that the studies that we're talking about are large epidemiologic studies, and I think that sometimes we have difficulty measuring accurately what's going on.

In addition, I think as we begin to look across the sort of real world environment, we see a lot of other intervening factors that may come into play, and there's no single sort of controlled factor that we're measuring, and so I think that when we narrow things down and we look specifically at a particular

factor, we may be able to demonstrate that that has a role, but when we take it to the complexity of the real world environment, sometimes there are other things that contribute to that as well and remove our ability to look specifically at a particular practice.

I think we're learning more and more about the ecology of these organisms on the farm, and we're learning more and more about how these organisms move on to the farm, move around the farm, that sort of thing, and it keeps making things more and more complex, but we have to try to get a handle on the complexity of that system in order to be able to intervene along the major pathways, and I think we're still in the process of discovering exactly what those major pathways are.

PARTICIPANT: Yeah. I just have another example of an effective on-farm control program. In Denmark, they've had an -- and also pretty much all of Scandinavia, they have very good controls in Salmonella in poultry. So, poultry systems are much more simple than the cattle system that Dr. Dargatz worked with because it's pretty much all-in/all-out, and you can get a biosecurity, and if you control it at the breeders and you can pretty much control Salmonella pretty well in poultry, and they have much lower levels

than we have here because they've made the decision to do that. So, they have had a very effective Salmonella reduction program. Some of the other pathogens aren't as easy to deal with, but that's just another example.

DR. DOYLE: Anyone like to respond to that?

DR. ACUFF: Yeah. I would. You know, I mean, there are certainly things we can do on the farm to deal with some of the issues. The problem maybe with cattle is maybe the lack of vertical integration, and, you know, you can have somebody doing a really effective job of trying to control things at the farm and then just down the road, you have somebody with some cattle that are primarily grown for a tax deduction, and they can end up, you know, in the same plants. So, you know, it's hard to control when you don't have control of the whole system.

DR. DOYLE: Yes, sir?

PARTICIPANT: Yeah. I had a question for Dr. Dargatz.

In the data that you've presented, you presented the beef and pork data for Salmonella as all Salmonella species, and you presented the poultry data only for Salmonella enteritidis. Why is that?

DR. DARGATZ: That's the only agent that we were interested in the layers. That was focused

specifically on the SE. In the cattle and the pork studies, we were interested in all of the Salmonella species, and as I said, we've gone on to serotype all of those isolates and in fact to go -- to do the antimicrobial susceptibility patterns on all of those as well.

PARTICIPANT: I have a second question there, too, about the E.coli 0157:H7.

Have you guys tested any of the found samples that you have to determine if there's Shiga toxin-producing bacteria? I guess, in a broader sense for the group, is that somewhere where we should focus more versus is it just H7 or is it Shiga toxin-producing H7?

Thank you.

DR. DARGATZ: All of our work on the farms has been first to identify the 0157 and then to probe those to see if they had the genes for either SLT1 or SLT2. So, we've focused specifically at 0157. We haven't looked at other veritoxin-producing E.coli.

DR. TAUXE: I think that's -- the other Shiga toxin-producing E.coli are out there, certainly described. They seem less likely to cause hemolytic uremic syndrome, but they seem just -- they do seem like -- as likely as 0157 to cause dysentery and bloody diarrhea, and we're expanding public health

surveillance for those as new diagnostic tools become available. Where they come from and what their associations are with food or with swimming or farm visits or whatever remains to -- really remains to be clarified, but that's an issue that's going to move forward in the next couple of years, I think.

I'd like to say, I think, Dr. Dargatz, you outlined studies that are cross-sectional and observational, and as you said, they provide excellent hypotheses for further work and further testing, and I'd like to underline how important I think basically intervention trials are going to be as the way to really show what can work and what cannot, and you don't have to know everything in order to begin intervention trials. You just have to have some reasonable hypotheses and the ability to measure the outcome and that's, I think, where we are with several of these pathogens and that's where we're going to -- once you have the hypotheses, you've got to test them.

Now, how that occurs and which consortia of industry, academic and regulators proceed is a good issue, but I -- I think intervention trials are critically needed for a number of these pathogens, on-farm intervention trials.

DR. DOYLE: Dr. Bailey?

DR. BAILEY: Hi. Stan Bailey from ARS in Athens. I did want to comment just briefly on the comment about poultry in Denmark.

There are some things that possibly we can learn from Denmark and Sweden, but it's important to understand that we grow more chickens in Athens, Georgia, than Denmark and Sweden do together, and basically they've tested for enteritidis and Typhinurium and depopulated their breeder stock, and they have because of the systems they grow much tighter biocontrol. So, it's not as simple as just saying throwing out something like why don't you do what they do in Denmark.

Now, clearly, we can learn things from those systems and we are working toward doing that. I am obviously fully supportive of taking things back to the farm and taking it through. We have to start there and work on other intervention programs and that's what we're doing, but just because that was brought out, I thought I should put that out for people to understand more clearly.

Thanks.

DR. DOYLE: Thank you for that.

Mr. Decker, we have another question for you, unless somebody -- go ahead, Rob. Did you have a

comment?

DR. TAUXE: Well, I wanted to actually raise a question that's kind of a fascinating issue that I've heard discussed about this transition between what's on the farm and what's in the slaughter plant, particularly the issue of the layerage or the receiving and holding pens at the slaughter plant, and this is work that Dennis Heard or Scott Heard has done looking at pigs, where pigs on farms have very low carriage rates of Salmonella, and if you slaughter them and necropsy them on farms, they have very low slaughter rates, very low positivity rates for Salmonella.

If you take those pigs and put them in a truck and take them to his pig pen, a clean pig pen at the university, and let them spend the night there and then necropsy them, slaughter them, they have very low rates of Salmonella. So, just riding in a truck didn't make that go up, a clean truck, and then they go to the layerage point, where they encounter a wall of Salmonella, and he was able to show that, of course, the pig at that point, rather hungry and thirsty, samples the environment and has a last supper of Salmonella, of a whole mix of different strains that are there in the layerage pen that may not have been cleaned in a long time, some of which are invasive,

some of which in just a few hours can actually produce in fact deep tissue infection in a normal-looking pig, and some of which are rather inert and just sit around in the GI tract of the pig.

But that means that you could have things very clean on the farm, you could have even things very clean during transport, but that if this is generalizable, that what happens at layerage may mean you actually have a bacterimic animal and positive deep tissue with certain strains of Salmonella, which might be different from the ones in the cut. He found particularly Typhinurium was good at that invasion thing and was showing up in funny places, like deep tissue nodes, and I wonder, could -- is that a point that needs some further exploration?

DR. DOYLE: As I recall, some of this occurred within two hours of exposure, too. It was very rapid.

DR. TAUXE: Very fast, right.

DR. DOYLE: All right. Any comments?

(No response)

DR. DOYLE: Well, let's move on to the next question then.

Larry Decker. Many in the meat industry complain that the Salmonella standard is excessive.

They assert that plate counts are sufficient as a way to measure plant sanitation. Supporters of the Salmonella standard claim that industry didn't clean up its act until that standard was imposed.

Where does the truth lie?

DR. DECKER: Good question. I'd like to defer if there's somebody that would like to comment on that. I really don't have the information on that.

DR. DOYLE: Dr. Acuff, if you'd like to make a stab at that one?

DR. ACUFF: Well, no. Aerobic plate counts, you know, I think, are an effective way to do some things, and, you know, I understand that Salmonella is something that, I don't know, maybe it sounds a lot more high-tech or something, you know, but you can do a lot with an aerobic plate count, and I don't know that they should be poo-poohed really. I mean, there are times when an APC is very effective and very helpful.

In terms of Salmonella causing -- what was the question? Salmonella causing a clean-up or causing the -- how was that stated?

DR. DOYLE: Supporters of the Salmonella standard claim that industry didn't clean up its act until that standard was imposed.

DR. ACUFF: Well, you know, and we'll be

talking about microbiological criteria tomorrow some, but one of the arguments has always been that a criterion makes a hammer, you know, that you can use to force people to do certain things that you want them to do, and so I guess in that sense, you might say, well, maybe it was the hammer that provided some additional clean-up.

But I'm not sure that you can effectively measure that with Salmonella. Maybe you could more effectively measure it with something else. You know, maybe it's not directly related and maybe it is. Maybe it's a disconnect but directly related. I don't know. That's a tough question. Who knows the answer to that?

But I think that it's going to be addressed tomorrow in pretty significant detail whenever we get to the criteria section.

DR. DOYLE: I guess based on the science, too, from what I've read and observed, is that you can't always directly relate plate counts to the incidence of Salmonella. So, if you really want to know what effect your sanitation program or whatever interventions you might have has had on reducing pathogen loads, you'd have to look directly for the target organism of concern.

DR. ACUFF: That's true, if you can find the target organism. A lot of times, you have to have an indicator that's a little easier to find.

DR. DOYLE: Any other questions before we move on?

DR. TAUXE: I might comment that the notion of having some level of verification, microbial verification built into the program, I think, is absolutely critical, and it either should reflect the pathogen of concern or clearly reflect the pathogen of concern, and this gets, I think, back to a couple of deeper issues, one of them being consumer confidence and what we all are about, and the consumer confidence is something that we take for granted in this country but no one takes for granted in Europe any more, and I think consumer confidence in the process is something that once lost will be extremely expensive to regain. That has happened in Europe. They lost all confidence in the meat supply of Europe after BSE and foot and mouth didn't help either, and so the important issues about making it crystal clear what the impact on pathogens of concern are is something that the egg industry has faced, and they have included microbial testing for Salmonella enteritidis as part of the quality control programs that they do, and it seems to

me that it's something that needs to be built into any of the control programs, if part of the argument is going to be making it clear to the public what the impact is.

DR. ACUFF: Well, I don't want to get off the subject because I know we're going to talk about it later, but I do believe that you have to have some connection back to the pathogen to be able to evaluate pathogen control, but if the pathogen that you're looking for is in such low levels that you can rarely detect it, when you do detect it, and when you advertise that you are sampling for that organism in this sampling program, that seems a little deceptive to me because if you have a pathogen that's very difficult to detect, and it's usually in low numbers, broadcasting that you have a lot of negative samples doesn't really do much for consumer confidence when all of a sudden there's an outbreak.

DR. TAUXE: Like 0157, you mean?

DR. ACUFF: Right.

DR. TAUXE: Yeah.

DR. ACUFF: So, if you have something that works well as an indicator, and you can explain to consumers that what you're doing is verifying process control that is designed to control the pathogen, then

I think you're going to be more effective and less deceptive about the whole thing.

DR. DOYLE: Yes, sir?

PARTICIPANT: This question isn't directed at anybody in particular, but could any of you speak on the effectiveness of activated lactoferin as an antimicrobial point along the process from farm to fork where it's applicable?

DR. DOYLE: Anyone on the panel familiar with activated lactoferin and its efficacy in reducing pathogens in meat, poultry or eggs?

(No response)

DR. DOYLE: Anyone in the audience want to comment on that?

(No response)

DR. DOYLE: I think some people know, but they're not talking.

Do we have any other questions or do you want to hear one from me again?

At least one or more of the panelists indicated that there are differences among processing plant facilities in where pathogens may occur, develop, be transmitted. That being the case, is it possible to establish uniform criteria for all processing plants? I'm thinking of Listeria as one example because

Listeria tends to be more of a processing plant issue than an animal issue.

Anyone care to respond to that? How about Dr. Acuff over here?

DR. ACUFF: Well, I think it's possible because, I mean, while there are differences in the plants, really what we're talking about is the difference in arrangements sometimes and a difference in age and sometimes the flow of the process is dictated by the way the plant was set up originally, and you know how many times the plants have to go through alterations to produce current products.

But the idea that you would have some goals set forth the end product, you know, would, I think, not be -- I think that the process can still be controlled regardless of the differences in the plants. It's just that each plant has to take an individual approach to the problem. You can't just have a generic across-the-board here's what you have to do to fix it. People have to use their heads in their specific situation.

DR. DOYLE: Dr. Tauxe, you didn't say anything about Cryptosporidia. Where does that fit in your -- from your perspective?

DR. TAUXE: I did not mention Cryptosporidia,

except to put it on the list, the big list at the beginning. We have been as part of FoodNet conducting a major case control study of Crypto that I hope will be cutting -- our parasitological colleagues will be cutting the analysis on this year.

Their lead hypothesis around Crypto are less associated with foods and more associated with drinking water and concern about it in municipal water supplies that are -- get their water from the surface, from rivers and streams that might be downstream of cattle farms actually. So, it's another indirect connection, but the biggest concerns that they have have to do with municipal water supplies and contamination of those supplies with Crypto which is not entirely dealt with by routine chlorination.

DR. DOYLE: Yes, Bill?

MR. MYER: Bill Myer from Seattle. A question about recalls.

When FSIS does a meat recall for hamburger, a PFGE pattern is made of the 0157, and I'm wondering, is there some communication between FSIS, this recall pattern, the PFGE, and ill people through CDC? If there is that communication, how is it disseminated to the public, and if there isn't a communication, why not?

DR. DOYLE: Dr. Tauxe, would you be interested in responding?

DR. TAUXE: With, say, E.coli 0157, we're in constant contact with state health departments. We're doing molecular subtyping of those strains, and if there is concern about one particular strain or one particular pattern, that can be posted to the entire network of state health departments, and they may then review and see whether they have similar patterns in their data banks and that sort of thing happens all the time from a pattern that one state may have a concern with will be shared with the others and that can be very productive.

There have been occasions when FSIS has communicated concern about a particular strain to us, not always with complete identification of what that strain might be but with concern about whether it might be being observed currently, and we share those with the states as well.

That question, the basic question about what about comparing strains in all recalls with what's going on in the human database is something we're actively exploring. It's not a routine at this point.

DR. ACUFF: I have a question for -- I know that we've spent several years now using PFGE for some

of our fingerprinting and tracing. Is that still state of the art? Is that -- do we have anything better coming along or --

DR. TAUXE: Yes and yes. Just last year, it's state of the art because just in December of last year, the last states in this country joined the PulseNet System. So, for them, it's the latest thing and that means now we have participation of all 50 states as well as FDA and USDA.

Also, it's expanding around the world. Just late last year, the European Community decided to adopt PulseNet as their standard for subtyping and so PulseNet Europe is now in formation. It's also in Canada and there are discussions with Latin America and Asian countries. So, it is the most widely-applied tool.

There is active interest and investigation now. We've -- in what the next generation will be, and the next generation will clearly be something that depends on actual genetic sequence. Gene sequencing is something that costs a lot of money but the price of gene sequencing is dropping rapidly, and it may be that because of the effort to equip state health departments to prepare for a potential bioterror attack, that they -- more and more of them will have gene sequencers

available, and so we now have an active program with three state health departments and several investigators testing out gene sequence-based strategies, and so perhaps within five years, a gene sequence-based system that would be backwards compatible with PFGE but also forward compatible may be available.

DR. DOYLE: We have time for one last question from the audience, and I think, Dr. Tauxe, this in part is for you, although anyone can answer.

With the data you have worked with over the past few years, would you be more or less likely to support the designation of any one pathogen or the addition of more pathogens to a list of adulterants?

DR. TAUXE: We have some problem pathogens out there. The one that would lead the list for me is something we haven't mentioned today and that's Salmonella of a particular serotype and then a strain within that and that is Salmonella Newport 9+. We call it 9+ because it's resistant to at least nine different antimicrobials. This one actually is harming cattle. It's spreading through dairy farms in the country. It makes them ill. It can kill even adult cattle occasionally, and it is rapidly increasing in humans as well, and we presume that there's a connection between

the animal illness and the human illness because humans are getting sick from consuming cheeses made from raw milk or from ground beef, and both of those may be related to the dairy source.

I'm very worried about that particular pathogen. I'm not sure it needs to be designated an adulterant. It's clearly designated a real serious animal health and human health problem because the only agent that really still works and is available to treat it is Fluoroquinalones and pediatricians don't like to use Fluoroquinalones. So, that makes it very problematic from the human point of view.

That would be my Number 1 organism of concern. I don't know if that reaches adulterant state, but it's a damn bad organism.

DR. DOYLE: Well, there's a second part to this question. Is there zero in pathogen tolerance?

DR. TAUXE: Is there zero in pathogen tolerance?

DR. DOYLE: That is, should there be zero tolerance for these pathogens?

DR. TAUXE: We have zero tolerance for botulism. We have zero tolerance -- we probably have serious tolerance for Salmonella typhi in milk. There are certain organisms that cause very severe illness

which we will not tolerate in our food supply. So, yes, there is room for zero tolerance.

DR. DOYLE: All right. Well, this brings to a close the first panel. So, I want to commend our four panelists and please join me in thanking these panelists for an excellent job.

(Applause)

DR. HULEBAK: Thank you very much, Dr. Doyle and panelists.

We'll now move, switch out this panel and move Panel 2 up.

(Pause)

DR. HULEBAK: Thank you.

We're now ready for Panel 2. These panelists and their able chair will look at the "Impacts of HACCP Systems and Approaches, Including Prerequisite and Good Manufacturing Programs".

Panel 2 is chaired by Dr. Susan Sumner, who's the head of the Department of Food Science and Technology at the Virginia Polytechnic Institute and State University.

Dr. Sumner received her B.S. in Food Science from North Carolina State University and her Master's and Ph.D. in Food Science and Food Safety from the University of Wisconsin. Her research interests are

into edible films as microbial barriers and decontamination of pathogenic microorganisms on fresh produce and on poultry. She also focuses on food safety education for the food industry and maintains, from what I can see, an active teaching schedule.

I introduce to you Dr. Sumner, chair of Panel 2.

Panel 2: Impacts of HACCP Systems and Approaches, Including Prerequisite and Good Manufacturing Programs

DR. SUMNER: Thank you.

I'd like to make a couple of thank yous. One, thank you for being here today to listen to the panel talk about HACCP and its impacts, and also a thank you to the first panel who did a great job at bringing up and introducing the hazards which we all know are the first principle when we start looking at HACCP.

I do want to make a couple of introductory comments to start us off and to get us going. HACCP is a term that each one of us brings to it our own connotation of what we think it is. Each of you, many of you live with it every day in your facilities and how do you make it work and how do you measure those impacts.

I want to throw out a couple of things that

I'm interested in and hopefully the panel will follow up with that. We will have two presentations, then a short break, our final presentation before we open it up to our panel dialogue and our panel discussions with you today.

When we look at HACCP or Hazard Analysis Critical Control Points, we know it's a systematic approach to food safety. We know it's built on prevention, but how do we go about implementing it and putting it into place? Many people would argue that it was because it became regulated, that's why many of us put it into place, to make it into practice and to put it together and what we want to do with it.

I think there are a couple of things that we do know about HACCP, and how do we measure whether it's successful or not. Again, each one of you, like HACCP plans are designed to be individual, you have your own idea of how it's been successful in your facility and how you measure that success, but for me, when I look toward HACCP and what it has to do, it has to build on the standard operating standard sanitation procedures that we already have in place. Good manufacturing practices, all of those types of things we have to build on with HACCP or it's not going to really do anything for us to go into do that.

We also have to bring in the aspect of management. We have to make HACCP a company culture. We got into some good discussion there originally. How do we change behavior? How do we change practices? Again, many of us as we go to try to implement HACCP have had to do that very thing. We've had to change a culture with employees to come about to understand the hazard and what they could do to measure and to change with that.

How do we put HACCP into place? For different audiences, besides just meat and poultry processors, but how do we get individual families to look at HACCP, and how do we change that behavior?

Having two children, I'm convinced that before we're going to see a decrease in anybody's change in behavior, it's going to start out with inundating them with washing their hands and what they need to do. They get inundated in school with don't do drugs, don't smoke and all those types of things, and I think it's time for us really to bring the food safety part back to them in an early age, too, to start their thinking about effect.

My children know when they go anywhere, they don't eat undercooked ground beef, and they don't eat sprouts, even if it's offered to them at someone's home

to do that, but if we look at the impacts of HACCP, how do we look at and how do we measure an impact? Is it just the decrease in pathogen contamination that we find? Is that how we're going to measure our impact? Can we get to that elusive public health aspect and see that it's a decrease in foodborne illness outbreaks? Can we use HACCP to help guide us there? Has it helped improve our operations in our facilities? Is that another measure of an impact or success for HACCP? Does it help us? Do we work towards validation and verification programs to do that? But each one of us have a measure right now, I'm sure, in place that you look for to guide you in your HACCP program to do that.

Today with the presentations and building up to the dialogue section, we're going to talk about what are the impacts and approaches to HACCP. We're going to talk about that impact on public health. Is that something that we can measure? Is that attainable? Is that something that we can do? Then we're also going to look at the experiences worldwide with HACCP to carry us forward as we do that.

I would like to introduce our first speaker today. Dr. Delila Parham is currently the Chief of the Zoonoses Branch of the Food and Animal Sciences Division for the Office of Public Health and Science

for the Food Safety and Inspection Service.

She's been with the Food Safety and Inspection Service for over 15 years and has worked in various program areas within the agency. She earned her veterinarian degree from the Ohio State University in Columbus, Ohio.

Dr. Parham?

DR. PARHAM: As you can see, this isn't my strong suit here in terms of getting it on the screen. So, as soon as we get it on the screen, we'll be ready to go.

(Pause)

DR. PARHAM: I must tell you, we don't quite know how to get the presentation on the screens here. So, if you'll just bear with us.

For most of you, though, I believe you have a handout, "HACCP Impacts on Contamination Levels in Meat and Poultry Products". Do most of you have it? Is that yes? Okay. Something so simple, I should have had my children here. Thank you.

Thank you, Dr. Sumner. I am very pleased to serve on the panel today, and this afternoon, I would like to talk briefly about HACCP impacts on contamination levels in meat and poultry products, and then, as Dr. Sumner said, I am an employee of the Food

Safety and Inspection Service, so I am more than happy to give you an FSIS perspective. I'm sure there are more than one, so an FSIS perspective.

The information I will be sharing with you this afternoon is not new, but it is important that it be presented in a scientific dialogue, a forum, such as this, so that it can undergo the close scrutiny that's necessary to ensure that FSIS continues to build on a sound scientific foundation.

This discussion will be centered around the pathogen reduction in HACCP rule. We'll be looking at those things that we use to measure impact. That's the E.coli performance criteria, Salmonella performance standards, and then we'll look at somewhat how we assess impact and that's Salmonella compliance sampling results and other measures of impact.

The daily mission of the Food Safety and Inspection Service is to protect the public's health through ensuring to the greatest extent possible the safety of meat, poultry and egg products, both domestic and imported, and you know, we do this through the HACCP rule, enforcement of the pathogen reduction and HACCP rule.

If you will remember, and most of you do, I'm sure, FSIS issued the pathogen reduction HACCP rule

July of 1996, and while the agency has always realized the need to update its HACCP -- I mean, to update its inspection system, it was in late 1992, you know, early 1993, you know, that we recognized -- I'm off one. I apologize. We're off by one slide. But we recognized at that time that we needed to change our inspection system, okay, and we thought we would do that -- let me back up. We're here, please.

In 1993, the outbreak of Escherichia coli 0151:H7 made us more acutely aware of the need to modernize our inspection system. Again, the system of inspection was just not adequate, as you well know, primarily because it did not detect pathogenic microorganisms, the major cause of foodborne illness.

Now, our objective of the pathogen reduction and HACCP rule was to build effective measures for reducing and controlling pathogenic microorganisms into food production processes, and when we looked at our pathogen reduction and HACCP rule, how were we going to do this? So, we built in, if you will, three elements of the pathogen reduction and HACCP rule, and we'll talk about that because some of you may remember and some of us say four, so we'll talk about that.

But the first one, sanitation standard operating procedures, and this is where, of course,

that plants are required to develop complete sanitation programs and operate a complete sanitation program, and then we had our HACCP system which requires that plants address hazards in their operations and establish a means of controlling them, and then, of course, the fourth one being microbiological testing, and we've used this, I think it was stated in our last question and answer session, if you will, the microbiological testing, this is an important verification tool for the HACCP system.

As I stated, microbiological testing as part of the pathogen reduction and HACCP rule will be our main focus, if you will, for our discussion this afternoon. All federally-inspected meat and poultry plants must test carcasses for generic E.coli. This is generic E.coli Biotype 1, and this is used to verify that their processes are under control for preventing and removing fecal contamination. In addition, FSIS is testing raw ground product for Salmonella to verify that the pathogen reduction performance standards are being met.

I want to look briefly at the E.coli performance criteria. The testing requirements went into effect, if you'll remember, in January 1997, and this was for cattle, swine, chickens and turkeys, and

the frequency of testing is based on the production volume, but all of the plants with established criteria test a minimum of one sample each week of operation. Now, there is an exception, and the exception is for very small plants and that frequency is much reduced.

The performance criteria are provided in three categories, acceptable, marginal and unacceptable, and this is determined by our baseline survey which were conducted by FSIS for each slaughter class during its development.

The upper limits for the acceptable and marginal ranges are denoted by little m and big M, respectively. Anything greater than little m but less than big M is considered marginal. The results are unacceptable if they're greater than big M.

If you'll look at the table here, and if you will allow me to give you an example, and we'll just look at broilers or chickens, the chickens have a lower limit of the margin of range and that's referred to as little m, remember, of 100 colony-forming units per milliliter of fluid, and then they have this upper limit of marginal range referred to as big M of 1,000 colony-forming units per milliliter of fluid.

Now, all the samples below the 100, if you will, the 100 colony-forming units per milliliter and

that's in pink, if you will, the broiler line, okay, all of those samples are considered acceptable. So, of 13 samples, only three are permitted to fall in the marginal range of 100 to 1,000 colony-forming units per milliliter.

Now, data from our E.coli analysis are reported on the process control chart, our table showing the most recent 13 tests, and this we consider a moving window, if you will, of results which provides a continuous picture of a plant's performance in controlling E.coli. FSIS personnel verify that the slaughter plants test for generic E.coli.

Now, if we look at our Salmonella performance standards, the pathogen reduction performance standards for Salmonella were established to determine prevalence of the organism in raw products. Like E.coli performance standards, performance criteria, the performance standard, excuse me, for Salmonella are based on baseline surveys conducted by FSIS during development of the pathogen and reduction HACCP rule. Excuse me, please.

(Pause)

DR. PARHAM: Thank you.

If you'll just allow me to start that one again. The pathogen reduction performance standards

for Salmonella were established to determine prevalence of the organism in raw products. Like the E.coli performance standards, the performance standards for Salmonella are based on our baseline survey conducted when we were developing our pathogen reduction and HACCP rule.

Now, to ensure the success of the HACCP program and to provide the smaller plant additional time to prepare for implementation, we followed a schedule to introduce the plants to HACCP, if you will. Okay. Now, the schedule for large plants, January, we implemented large plants January of 1998, and this was for greater than or equal to 500 employees, a plant that was the size that employed more than 500 employees, and then at our small plants, we implemented HACCP in January 1999, and this was done for size, if you will, for small plants, being a plant that employed 10 to 499 employees, and then our first small plants, okay, and very small as you can see, plants that employed less than 10 employee and this was implemented in January of 2000.

In the rule, FSIS gave four reasons that it considered Salmonella to be the appropriate organism to use as the measure of performance in pathogen reduction. Okay. I think this question was alluded to

perhaps earlier in our question and answer session in terms of an indicator of an organism or what is the best organism to use, but at the time we implemented our rule, okay, or we published our rule, we considered these things about Salmonella, and there were four of them, as I said. Salmonella is among the most common cause of foodborne illness associated with meat and poultry products. That was our first -- the first thing we looked at, and then we looked at the second thing, which is that Salmonella is relatively easy to find.

Our current testing methods or through our current testing methods, we can recover Salmonella fairly easily from a variety of our meat and poultry products. And then for our third thing we looked at, Salmonella is a useful indicator of the interventions aimed at reducing Salmonella, we think, are likely to be beneficial in reducing contamination by other enteric pathogens, and then finally, Salmonella occurs on meat and poultry products at frequencies that permit it to be detected and monitored.

So, this is, if you will, the Salmonella performance standards as we have outlined them, and we published them in the Federal Register. Salmonella performance standards have been established for all the

classes in ground products, those are steers and heifers, cows and bulls, hogs, broilers, ground beef, ground chicken, and ground turkey.

The Salmonella performance standard provides an approximately 80 percent probability of passing when the establishment is operating at what was set or we established as our national baseline prevalence for Salmonella, and if you'll allow me to give you an example, again if you look in the pink, for some reason I seem to like using chickens, okay, but let's look first, if you will, at the performance standard for young cattle, steers and heifers. You notice that is one percent, and of 82 samples tested, which is considered one sample set, so it would take 82 samples before we'd have one sample set. So, of 82 samples tested, okay, not more than one sample can be positive to achieve the standard, and plants are expected to meet the standards consistently over time to reflect the process control system.

Now, the Salmonella performance standard is not used to determine product disposition, and luckily, I don't have to talk very much more about our standards here because Loren Lange, okay, will be discussing FSIS and the performance standard and how we set those standards for Salmonella. So, that is our discussion

for tomorrow.

FSIS has provided several progress reports. All of that, if you will, was our build-up, how we established our E.coli criteria and then how we set our performance standard for Salmonella to lead us into our progress report or our results that we have obtained over the years in testing for Salmonella.

We provided several progress reports on our -- for Salmonella testing of raw meat and poultry since implementation of HACCP, and the first one was done in March 1999, and then the most recent progress report was given in April of this year, April 2002, and as Secretary Veneman said, the report indicates that prevalence of Salmonella has declined in all classes of products to levels below what we established as our baseline prevalence. Okay. We determined those things, you know, prior to setting -- prior to the HACCP rule.

I would like to just let you know briefly, though, how we get our data. Okay. First of all, the samples are collected and analyzed through a computer-generated sample request. That's the way we start, okay, and then the samples are collected daily by FSIS inspector according to protocol for specific product classes, and then it is sent to our FSIS laboratories

and is reported as positive or negative, and I think someone else asked this question, also.

Yes, the positive isolates are sent to our National Veterinary Services Laboratory to identify serotypes, and then those serotypes, that information is then -- those isolates are tested, if you will, by our -- by the Agricultural Research Service for antimicrobial resistance.

As I said, the samples were collected, and this is our 1998 through 2001 data. Samples were collected and analyzed according to the protocol we just discussed, and it was established to determine compliance with regulatory standards. For compliance testing, FSIS personnel, as I said, collect the samples and all of that, and now these are the results for 1998 through 2001.

So, from 1998 to 2001, for all plants, if we look at our carcass data first, that's steers and heifers, the steers and heifers, if you notice, the standard is one percent, and in 19 -- and we'll just go through the last column which is 2001, if you will, for steers and heifers, which averaged a 0.4 percent, if you will, under HACCP compared to one percent prior -- let me see -- prior to HACCP, cows and bulls averaged 2.2 percent compared to 2.7 percent which is -- I'm

sorry. I'm giving you the 2000 data.

For 2001, my apologies, the cows -- the steers and heifers averaged 0.6 percent, okay, compared to our one performance standard, one percent performance standard, and then for cows and bulls, the 2001 data show the 2.4 percent as the average as compared to our 2.7 percent as a performance standard. For hogs, we have a 3.8 percent standard -- excuse me -- average, okay, 3.8 percent for all plants in 2001 compared to our 8.7, and then in -- for broilers, we see that in 2001, broilers averaged 11.9 percent compared to our standard of 20 percent, and this was for 2001.

When we look at ground products, we see that for ground beef, in 2001, we see 2.8 percent as an average and the standard was 7.5 percent. For ground chicken, we had 19.5 percent as an average, okay, compared to 44.6 percent and then for ground turkey, 26.2 percent compared to our standard of 49.9 percent.

If you just look briefly here, our annual data show that in some products, and we go back to broilers, such as broilers, the prevalence increased by a slight percentage, and this is on calendar year, from 2000, if you will, to 2001. Okay. But it declined in other products, and if I go back to our other table, if

you will, you see that in ground beef, -- excuse me -- that such -- if you see -- you notice that it's decreased -- I've gotten that mixed up. I'm sorry.

Despite the -- but it declined in other products, such as ground beef. The 2.8 percent, if you notice, it was a decline from our 2000 data of 3.3 percent in 2000, a decline from 1999 of 4.3 percent, okay, and then, of course, you can see its highest in 1998 at 6.4 percent.

Now, of course, we do notice, too, that our sample sizes have increased over the years, okay, but we do notice, too, that our performance -- our percent have decreased. Annual data show that these -- that we believe, okay, that we have decreased to levels below the baseline prevalence estimates determined prior to HACCP, as you can see in the table.

Okay. This one, I have to ask you to add a couple things, and the Y axis, that's percent, and we are going to discuss, if you will, you're looking basically at broilers. Okay. And here, we can see that there are differences by plant size with some product classes exceeding the standard for 2001. In 2001, cows and bulls averaged zero percent, this is not on your chart, in large plants, 1.3 percent in small plants, and 3.7 percent in very small plants, which

exceeded the baseline standard of 2.7 percent.

If you will go back to your tables, you will see that, but in this one, just for broilers, in 2001, broilers averaged 9.7 percent in large plants, 13 percent in small plants, and 37.2 percent in very small plants, exceeding the standard of 20 percent.

FSIS does have a concern, if you will, about our very small plant statistics, and we will be investigating that further.

Now, you can see this full report, and I apologize because I did stumble through a couple of things. I apologize for that, but I would advise you, please, to look at our full report at our website, http://www.fsis.usda.

I want to mention, though, that there are limitations to our FSIS Salmonella data that we believe does impact on the numbers that we get, okay, on the data that we have, and those limitations include, first of all, this is a regulatory testing program, and it's probably best to track and print performance, not estimating prevalence.

Now, all size plants are represented each year. You'll remember that we said that small plants did not come -- only large plants came on board initially. That was 1998. Then we had our small

plants to come on in 1999, and then, of course, our very small plants did not come on until 2000. So, we recognized that not all sizes of plants are represented each year.

Then when we think about, you know, the testing and how we've set up our computer-generated testing scheme, the plant testing is randomly scheduled and is not based on production volume, and then, finally, we look at one more thing that we don't -- other factors that we don't consider, and one being seasonality. The way our test scheme is set up now, we do not consider factors like seasonality. The bulk of our FSIS testing occurs in the first half of the calendar year for all three years of HACCP implementation, and because we know that Salmonella is seasonally sensitive, if you will, this may further limit somewhat our interpretation of our results.

FSIS recognizes that Salmonella performance standards, if you will, established in the 1996 pathogen reduction and HACCP rule were not based on a risk assessment or a scientifically-established public health outcome. Yet, despite this and the limitations in its data, FSIS believes that the data as analyzed show that the contamination levels on raw meat and poultry products have been reduced as a result of the

HACCP rule.

We believe the data show that strict adherence to good HACCP and sanitation programs can make the difference in food safety, and then as confident as FSIS is that its data show a real reduction in the prevalence of Salmonella in raw meat and poultry, our confidence is increased when FSIS data is coupled with FoodNet data, which indicates a decline in the incidence of Salmonella during 1996 to 2001.

A report issued in April of 2000 by the Centers for Disease Control that Dr. Tauxe mentioned earlier in its morbidity and mortality report provided preliminary FoodNet data on the incidence of foodborne illnesses for selected sites in the United States, and as you remember, Foodnet is CDC's emerging infections program, foodborne active surveillance network, and this collected data at 10 foodborne -- of about 10 foodborne diseases in nine U.S. sites to quantify and monitor the foodborne illness.

The data show a decrease in the major bacteria of foodborne illnesses and although the data do not show a sustained decline in some infections, the report does indicate that during 1996 to 2001, Salmonella decreased by 15 percent, as Dr. Tauxe reported, and of course, you can see the full report at

the Centers for Disease Control website.

I would like to mention, though, that like FSIS data, there are limitations to FoodNet data as well, and among those things, the variations in testing for pathogen may account for variations in incident. This is in the report. Some illnesses may be acquired through non-foodborne sources, and the data may not be reflective of the entire United States population.

FSIS is determined to reduce the incidence of foodborne illness due to meat, poultry and egg products, and while CDC credits the pathogen reduction and HACCP rule with contributing to this decline, there always will remain some uncertainty in coupling HACCP impacts, if you will, on contamination levels in meat and poultry products with the reduction in foodborne illness.

I think this came up and we thank the panel because they took some tough questions about some of this, but this leaves us with the question, though, would we or would FSIS and can we be as confident that HACCP has had a beneficial impact on contamination levels in meat and poultry products if foodborne illness had increased? This, like so many other questions we'll entertain, is one of many, I think, we'll probably think more about in our session this

afternoon.

Thank you for your attention.

(Applause)

DR. SUMNER: I think she left us with a very good question that we'll probably come back to with the panel.

Our next speaker is Jack Guzewich. Jack is the Director of the Emergency Coordination and Response at CFSPAN, and I asked him about being the Director of the Emergency Coordination and Response. That sounds like a very, very time-consuming and hot topic job to do. Had the opportunity to work with Jack quite a bit through the International Association for Food Protection, bringing back some of those issues with that.

He's been with the CFSPAN Group for five years, and prior to that, he was with the State of New York for 27 years. I do think it's very nice of FSIS to invite him to come over from CFSPAN to part of our presentations today.

Jack?

MR. GUZEWICH: Thank you, Susan, and thank you, Karen, for inviting me for this presentation. I suspect they invited someone from FDA, so that they could blame me for giving the bad news or something,

but we'll see.

This is a challenging topic we have to speak on. I'm very pleased to be here to speak about it. It's one that I spend a lot of time thinking about. How can we measure the impact of our regulations, whether they're done at the federal, state or local levels, on public health? Are we really making a difference?

So, how do we go about doing this? How do we decide whether or not activities that we implement in government, and, of course, really it's industry that are implementing these things based on regulations, policies, interpretations? How do we decide if we're making a difference?

Well, we can look at disease trends obviously. We can look at microbial and other testing of food or the food environment, look for levels of organisms, whichever ones you want to pick. We can look at inspectional or compliance findings and try to judge based on regulatory compliance if we have improved public health.

We can look at enforcement actions and the number of actions taken. We can look at consumer behaviors and attitudes and try to reflect upon those and whether consumers are reacting positively to

actions that we've taken in government.

Let's look at those ideas in a little more detail for a minute. First, disease trends. Sporadic cases. As Dr. Tauxe described earlier today, sporadic cases are one of the methods that public health agencies have classically used to try to monitor the occurrence of disease in a community, however big a community you want to describe. There are many inherent problems with sporadic disease which some of you probably are well aware of. It's the old tip of the iceberg kind of problem, and one of the things that epidemiologists are often involved in is trying to come up with multiplier factors to determine how many times more than the number they actually see do they feel really occurs in the community when they monitor sporadic diseases. So, sporadic diseases are one of our anchors for this, but they're problematic because of all the inherent problems about reporting diseases.

We can look at outbreaks, and we can see usually in much more detail what actually caused people to become ill from outbreaks. One of the problems with sporadic cases is a person has a certain disease, you've confirmed that from a laboratory specimen, but you really don't know why the person came down with that disease. What were his or her exposure? What

were his or her risk factors?

In an outbreak, oftentimes if intensive investigation is done, the epidemiologists can make a pretty convincing statistical association risk factor for some particular occurrence, not case of foodborne diseases, for consumption of a particular kind of food and becoming ill and that's pretty good evidence that that food caused people to be ill, and so they can get the cause and effect that we're all looking for in outbreak investigations.

The question becomes, how reflective are outbreaks of the universe as a whole? If we're seeing outbreaks in something, does that mean that this condition only occurs in the outbreak setting or is it also causing sporadic disease? How reflective are outbreaks of the world as a whole? Maybe they're different. Maybe outbreaks that occur in restaurants occur there because things are done differently than are done in homes, and so extrapolating from a restaurant environment to a home environment may not be an appropriate leap to make.

We can get involved in special studies, and we've already heard a lot of talk today about FoodNet, and during Dr. Tauxe's tenure at CDC, he's been involved in an awful lot of innovations, including

FoodNet, that have given us much, much better insight into the causes of foodborne disease and the vehicles and like that than we had prior to that time. He's made a great contribution there and certainly FoodNet is one of those examples. We have a lot better understanding of the foodborne disease because of FoodNet. So, there's lots to be gained there.

We have age and risk factor studies. You've heard some of us those talked about today. They can do -- epidemiologists can do studies to say, for instance, people who have a particular kind of disease are more frequently eaten food outside the home as one of the conclusions FoodNet has come up with. So, when we can identify these kind of risk factors or Salmonella risk factors or campylobacter risk factors, we can get inferences about interventions that might help us prevent these diseases in the future.

Then we get to those infamous numbers that have already been talked about earlier today, and Dr. Tauxe and actually the lead author of that paper was Dr. Paul Meade in Dr. Tauxe's unit at CDC are often cited for their number 76 million cases of projected or estimated cases of disease in the U.S. every year and the 325,000 hospitalizations and the 5,000 deaths. These are estimates that evolve out of the above kind

of data sets.

Well, how does CDC go about determining the burden of disease? This is a pyramid stolen right from CDC's data, but basically as most of us are aware, exposure in the general population is the first step to coming down with these infectious diseases, and some number of people become ill with outright symptoms and signs of the disease, and some of those people seek care but only some of them seek care. So, right off the bat, there's a percentage of people in the population who become ill with this disease that, either because it's not severe enough or they choose not to, don't seek care. There's a big loss of cases right there.

Those people who seek care and FoodNet has generated a lot of data on this, some of them will have specimens collected by the physician or the health care provider, many of them will not, and so although the diagnosis may be made of a diarrheal disease, perhaps even speculation about the cause, without a specimen to the laboratory, we don't really know for sure what was the agent that caused that person's disease. There's varying numbers as to how often physicians order specimens collected from such patients.

Lab tests for the organism, if done in a

laboratory that uses the proper methods, we'll find the organism, although as FoodNet has shown, that organisms like 0157:H7, there are so many clinical laboratories that don't routinely test for that organism. So, therefore, even though the specimen's collected, it doesn't mean you're going to confirm that the patient really suffered from that disease.

Then you have a culture-confirmed case. Hopefully the physician and clinical laboratory report that to their local or state health agency and eventually those agencies, through cooperation with CDC, forwards that information on to CDC for national statistics. Well, there's losses of data all the way through this system. So that, what CDC gets in the end is only a shadow of what actually is occurring in the community. That's one of our problems in trying to measure the impact of our interventions.

Let's look at FoodNet just for a second to remember what the stated goals are from CDC for the FoodNet Program. What you'll notice here is that there's nothing on here about measuring the impacts of HACCP, not any of these goals. This comes right off of their web page. What they do do is they measure the -- they describe the epidemiology of the new diseases. They've done a great job in FoodNet with that. We have

a much better understanding of some of the underlying factors involved in the agents being studied in FoodNet through those efforts.

We estimate the frequency and severity of diseases and those estimates come up in those numbers that we talked about earlier, the 76 million, etc. Those come out of those kind of studies, and we estimate the attributable risk for different foods and that's one of the big projects FoodNet and CDC is working on right now, is trying to refine a new paper of estimates of how much foodborne disease is associated with the various vehicles and that'll be an interesting thing that we'll all look forward to. I call it Meade 2 myself. I'm really looking forward to that paper when it comes out. We'll all spend a lot of time talking about it, I'm sure. But measuring HACCP wasn't in there.

Now, let's go to those 76 million numbers just for a minute, so we can understand what does this really say to us. According to that same paper, of those 76 million cases of illness, 81 percent of them are from unknown agents. 81 percent are from unknown agents. Of the known agents, 67 percent are Norwalk-like agents. Now, Dr. Tauxe referred to those a little bit this morning, but most of the efforts that FSIS

undertakes by the nature of the food that they oversee will spend little time on Norwalk-like agents and yet 67 percent of them are Norwalk-like agents that are the known causes.

Campylobacter, 14 percent. Salmonella, 9.7 percent. Listeria was so low, it doesn't even come up as a decimal point up to the first point, and E.coli 0157, .5 percent of cases. So, in a sense, the agents that we're focusing on so much today are a small percentage of the overall burden of foodborne illness that we deal with in the country. So, how do we measure the impact of HACCP on foodborne illness?

Of the 5,000 deaths we have, 64 percent of those, according to that same paper, are from unknown agents. Of the known agents, Norwalk is 7 percent, campylobacter 5, Salmonella 30 percent, that seems pretty important, I can see we're talking about Salmonella, Listeria 27 percent, and E.coli 0157 2.9 percent. So, you can see when you put these things in perspective that we're only looking at a percentage of the overall burden when we focus on some of the agents we do here today, not that they're not important and we shouldn't be focusing on them, but putting some perspective on measuring the impact of our programs on public health.

Microtesting, a standard technique that we use across government and industry and academia to get a handle on a situation and try to add some denominators and numerators to it. So, we can do raw material testing, extensively used, a useful tool for improving the quality of food and food safety. In-line sampling, processing plant environment sampling, end product testing and, of course, Salmonella testing for meat and poultry done by FSIS are examples of that kind of product testing, and then we try to draw inferences from those results as to the impact they're having on public health. We'll come back to these in a minute.

We have inspectional findings, a classical way of trying to have some idea of the impact of regulatory programs on public health. So, if we have fewer violations of some sort, then maybe we can say that because of HACCP, we have a fewer frequency of occurrences of something, cross-contamination, temperature abuse, whatever the factor is you want to measure.

We have to have regular inspections all the time and a baseline of data to do this. FSIS, I think, is in pretty good shape in that regard. They've had some baseline data from which they can draw some of these inferences. We can have pathogens or other

indicators set by regulatory agencies. We can monitor those kind of things. We get into all the debates that you've all entered into about Salmonella in that regard, and we can have surveys of end product, retail products to see what the impacts are.

One of the problems we have there, of course, is that some of these agents, as has been discussed earlier, are in fairly low frequency in the food supply. So, when you don't find them, what does a negative test tell you? And in the enforcement area, we can look at seizure actions, recalls, injunctions, prosecutions. Some people infer from the frequency of these kind of things levels of public health protection or levels of compliance in the food supply. Whether they actually tell us the level of public health protection or not probably is more debatable.

Consumer behavior and attitudes. We would like to think if we had good effective HACCP programs, that consumers would respond positively to that with higher confidence in the food supply. They would have an understanding of HACCP. They'd have an understanding of what it's doing for the safety of the food that they purchase and consume, and they would have a recognition of food safety and although I don't have a bullet for it up here, perhaps some of those

concepts would even carry over into consumers and their own practices at home or other places they prepare food.

Now, we get into all the problems with all these standard methods that we use. To begin with, we have little or no baseline data for a lot of these areas that we measure or else, if we have a baseline, the baseline is changed over time. The way we measure today is different from the way we measured in the past, and so we're trying to figure out, well, what do the numbers today mean with relation to the numbers that we collected in the past? Can we really compare these things or are we comparing apples and oranges?

There's been inconsistent data collection over time. Funding varies over time. Maybe the level of number of samples collected has increased over time or the training of the staff has changed over time or the laboratory methods have changed over time. So, again, comparing one data set with other data sets is problematic because we're not comparing like things.

Epidemiological and laboratory methods have been inconsistent. In the laboratory area, the technology that's happened in laboratories in the last 10 years and 15 years is incredible, and so can you compare 20-year old data with today's data and say

you're comparing like situations?

Outcome data were not collected with the idea of answering this question. One of the problems we have is that an awful lot of the data that we're using to make this conclusion was collected for legitimate purposes and may provide useful insights but it wasn't collected to answer this question. So, it's problematic sometimes whether we can extrapolate data used for one purpose to answer a different question.

Surveillance has changed over time. As Dr. Tauxe mentioned this morning, recently public health agencies have received a huge influx of money to respond to bioterrorism. As this money works its way into the public health system, if they can find enough epidemiologists with the money they have to hire them with, you will see surveillance go up. You could easily see an increase in foodborne disease in the next three years, folks, simply because there's going to be more resource out there and laboratories and more epidemiologists looking at these diseases and concurrently diseases that were being missed in the past may suddenly be picked up and reported. So, don't be surprised if you see that happen.

No one contributing factor causes all illness. This is one of the toughest thing we have to

do, is that there are multiple factors from the multiple times a contamination can occur, the multiple places where organisms can survive different steps, the different ways they can be treated or not treated properly all the way through to the time of service means that there's no one thing you can pick out of that whole stream and say this was the cause. There were a lot of things. A whole chain of infections, one of the terms they used in epidemiology, that leads to disease, and so picking up the one step and attributing everything in the world to that step is really a questionable practice to do.

Many interventions were being implemented at the same time as HACCP. An awful lot has happened in the last 10 years and sometimes we fail to reflect upon this. All the things that have happened in the area of food safety, in education, in the increased sampling activities, in the inspectional activities and the number of technological improvements that have occurred in the last 10 years. So, all these things are happening at the same time. So, how do we pick one out and say aha, this is what caused the change?

I set as an example a situation I was dealing with when I was in New York before I came to FDA. We were early on in the process of dealing with a problem

of Salmonella enteritidis in eggs, and I spent a lot of time with Dr. Tauxe on that issue, many hours wrestling with that one, and in the early to mid-'80s, you can see we had a few outbreaks. The solid line here is outbreaks and the bars are Salmonella enteritidis cases being seen by our clinical laboratory in the New York State Health Department.

You can see that the number of outbreaks increased at about the same rate as the cases being seen in the laboratory. Well, if they're coming from the same source, if contaminated eggs are really a primary source of Salmonella enteritidis, then you'd expect the number of outbreaks to go up concurrent with the number of cases being seen in the laboratory. That makes sense. Interventions went into the place, the SE quality assurance in egg programs that Dr. Tauxe referred to this morning, and we hope that those interventions, programs like that, along with education of consumers, requirements that eggs be refrigerated properly and encouraging people to cook eggs in all their various foods, that the combination of those things would result in a reduction of disease. That's what we're all about in the public health agency.

Well, the number of outbreaks, you can see by the middle '90s was coming down drastically, and if

you'd see the years since then, it would continue down in this direction, but look at the cases. At the same time the outbreaks were going down, the cases weren't going down. Well, if the interventions were -- you know, the epidemiologists -- the classic thing the epidemiologist wants to do in an outbreak, he wants to arrive here because it's going to go down from here, and you can take credit for that, you see, and you can say what a good job have I done, you know. I mean, I personally stopped all that disease. How do you account for the fact that the number of outbreaks are going down but the number of cases don't go down at the same time? Can't explain it. Couldn't explain it then.

Eventually, eventually, the number of cases tailed off, but you'd like to think that the same thing was happening, you'd get parallel lines on the way down. These are the kind of things that confound our ability to explain the impact we have when we have interventions in place.

Now, HACCP in the U.S. is being used in a lot of different places. This is another confounder. We can't just attribute it to one section of the food system because it's being used in a lot of places. It's being used voluntarily by many processors as well

as those that do it under regulation. It's used in seafood and fishery products and meat and poultry obviously and juice products. Voluntary programs exist in the retail food industry and milk shippers. Some local governments require it to be used by food and different parts of the food system, and some state governments do as well.

So, it's being used in a lot of different places which makes it confounding for us to try to figure out which piece of HACCP is accounting for this reduction in foodborne disease.

I want to take a minute and explain this. We're going to step out of the box here and get away from food safety for a second, but believe it or not, there's going to be a parallel here at the end. This is a system that was put in place by the New York City Police Department in the mid-1990s. The New York City Police Department was measuring the effectiveness of their activities based on things the police officers did every day, the speed with which they responded to reports, to calls, and the number of arrests they performed, the number of tickets that they issued.

This was the way they measured their activity, not unlike the way we do in regulatory agencies. We measure our activity based on the number

of inspections we do, the number of samples we collect, things like that. Okay. And the outcome that they were looking for, the output was convictions.

Well, the problem was that the people in the City of New York did not really feel that the city was getting any safer. They weren't really having a safe city. The crime rates were not going down, and so their approach of just measuring this activity and trying to base their whole activity on this was not resulting in this down here, and so what they did is they went in a whole different approach, and in the police world, a precinct, part of the city, is covered by a person of the rank of captain, and they decided that they would make captains individually responsible for the crime rate in their precincts.

Rather than looking at the citywide crime rate, they would look at the precinct-wide crime rate, and they would generate statistics on a daily basis for the crime rates in the city for the -- in the precincts for the number of crimes reported in the last 24 hours in that precinct, etc. They made a series of -- it's all electronic now. They have maps that show the zones where different kinds of crimes occur and so on.

On a monthly basis, the captain meets with the Commissioner of Police and reports on the different

rates or the different kinds of, you know, larcenies and murders and carjackings, etc., that go on in their area, and what impact they're having and what interventions they're having within their individual precincts to impact upon the incidence of that kind of activity in their precinct.

Can you imagine a person responsible for a food safety program who is suddenly told that we're going to measure your effectiveness no longer on the number of inspections you performed or the number of samples you collected, but by the rate of foodborne disease in the area that you cover? That would be kind of a novel thing.

Now, it's a little easier here. Rob's making notes on that one, I can see Rob likes that. It's a little different here because most of the things that happen to a captain in the precinct occur in his or her area or maybe adjoining areas, other than the fact that they might do a murder and move the body over and drop it in their area. It's harder if you're responsible for food safety in a given geographic area if the food that made people sick has come from across the country or across the globe.

In our food system these days, it's a little harder for that supervisor locally to have an impact on

the food that's come hundreds or thousands of miles, but it's an interesting concept to think about.

If we go on to this next slide and look at it in terms of food safety, where instead of having the police analogy now, we have some contaminated food in the food system, and our activities that we do to try to impact on the food safety are inspections and HACCP and education and sampling and new technologies and multiple different things. Our output hopefully is less contaminated food out of these kind of systems, and therefore we'd have less foodborne disease. We'd have improved public health.

Well, where do we measure these things the best these days? Well, we measure them the best up in this area here. We measure these things fairly well. We can tell you how many of these things we've done. We've got units of measurements. We've got rates. We've got all kinds of good stuff, and to some extent, we can measure this pretty well, too. We can tell you how much contaminated food there is out in the distribution system.

What we don't measure is, well, is whether this is impacting on the foodborne disease really. We have a hard time making this link. We don't really have a system that is designed to work on that

direction, and so how do we know if we have improved public health? That's the question. That was the talk I was asked to give. FSIS wants an FDA person to talk about this. Karen doesn't say anything. She just sort of nods.

So, has it had an impact on public health? Actually, I think it has but not for the reasons that we can measure. It will be very difficult for us to demonstrate that any one intervention has resulted in a specific percentage reduction in foodborne disease in general or any one agent or vehicle.

HACCP has changed the focus of government, industry, academia and consumers. HACCP has prompted us to improve surveillance of disease and of agents in foods. The dialogue HACCP has prompted has had a major impact on the changes in how food safety has been addressed in all types of interventions compared to 10 years or so ago, and those of you who have been around for a long time reflect upon how we did food safety 10 or 15 years ago and things have changed a tremendous amount over that period of time.

We will continue to try to link measurements of foodborne disease with interventions, sometimes with more success than others. I think Salmonella enteritidis in eggs because it was -- so much of it was

associated with one vehicle, was he case where it's a little easier to see the impacts we've had.

But finally, we can say that FoodNet data show a decrease in some major pathogens at the same time as HACCP and a number of interventions have been implemented and there's got to be some linkage there, although we can't show it statistically.

Thank you.

(Applause)

DR. SUMNER: Like to thank our first two speakers for getting us on our way.

We now have a scheduled break, and they need to be back when? 3:00. Come back at 3. Shortly before 3:00.

Thank you.

(Whereupon, a recess was taken.)

DR. SUMNER: We do have one more presentation before we open it up for your comments and discussions with the panel to round out our topics for today.

Our next presenter is Dr. Alex Castillo, and Alex just recently moved to Texas A&M University because he really wanted to be close to Gary Acuff and to move up there to do that. He was formerly a professor with the University of Guadalajara for 22 years before he joined Texas A&M University just about

a month ago to do that.

His research focus is on pathogen interventions in fresh produce and the ecology of foodborne bacterial pathogens in foods of animal and plant origin, and he's going to round out our panel for today.

DR. CASTILLO: Thank you.

Well, I appreciate very much this opportunity to be with you and share some of our views that we have gathered on HACCP around some activities, training activities that we have been developing and some implementation basically across Latin America.

Even though the title of the topic says, "HACCP Experiences Worldwide", my experience is limited to the Americas and the Caribbean. So, I will unfortunately not know anything that is happening in Asia or something like that.

But I think from what we have collected in our experiences, we can set some points. First of all, some of you may be thinking what is going on or what does HACCP in, say, Uruguay have to do with the United States, all right, or with food safety in the United States? Well, a lot because and especially now that we have global trade, it is amazing seeing how much especially fruits and vegetables that are not grown in

the United States enter the United States. Okay. So, it is very good for the public health in the United States having a strong -- that other countries have strong food safety programs. So, that is why it is of very much relevance to the United States what we have to say about it.

Now, let me, first of all, let me tell you the current stage of HACCP in basically Latin America, Mexico, for example, HACCP has regulations for seafood. It's required by law for either product that is for export and product that is for domestic consumption. However, we normally handle and we are in the process of reducing those double standards, but we feel we are using the two standards. One standard for the seafood that goes, you know, for export, that is strictly HACCP is enforced, and the HACCP that is applied for domestic product that probably -- oh, well, let's let it go. Okay.

We're in the process of improving hopefully soon. Okay. Now, in Central America, we have the example of Costa Rica. Costa Rica's an interesting country. First of all, they don't have an army, and they don't need it, and second of all, they want to make HACCP mandatory for everything, every single food product. So, I hope that they will have an army and

also they will not have this type of regulation without reviewing very well that, but that's what they want to do, and I hope they will not have an army. I was just kidding.

And HACCP regulations in Central America, we have not seen except in Nicaragua where they are trying to make HACCP mandatory for export of seafood, and they applied anyway and South America's interesting. Let's talk about the mercosur countries which is basically essentially Argentina, Uruguay, Brazil and basically. HACCP is widely used in those countries, but it is not required for any product that is sold in the country. It is only required and enforced its application for export of meat and fish products.

So, we know that basically we have here two years of HACCP in Latin America. One is HACCP for the product that I sell, but I want to compete with the domestic products in Europe and the United States, and therefore I apply -- I have agreed in some programs and my production is we have state of the art technology and all these stuff for some products, and the other is the HACCP that is applied or we want to apply it for domestic products. So, we are in that stage and we need to improve that. I agree.

Now, another thing that is interesting is the

view that, I mean, the real HACCP by some food processors in Latin America, most of them see HACCP and food safety as a means to stay in business because even though HACCP is not mandatory by law, but many times, they are required by their purchasers. They say okay, I'm going to buy you this product, but you have to make it under HACCP, and if you don't make it under HACCP, then I will not be buying it to you -- from you.

So, that is the most important incentive that we have seen among the agricultural product processors and producers as far as food safety in general, not only HACCP.

Now, there are some companies, normally large companies, that have, you know, those young, energetic personnel that they are hiring, and those have new ideas and they're trying to implement it. Essentially, there's very few of those people will really say okay, we want to do this, make this product and very strong food safety standards because we love people being healthier or something like that, just a few of them, if any.

Okay. Well, what do we need? We have also identified some needs for HACCP, and basically we found out that we still need to do a long way. We have done a lot of training, but there's a problem with training.

I'm going to be there in a few minutes. Implementation, especially as far as developing and validating control measures. Okay. Basically food processors, they say, well, just for lactic acid for the carcasses or dip it in chlorine, you will be there, and they just do it without even measuring or doing any bacterium count and out for its verification.

As far as training, we have a problem. Let's make it like the agricultural report, offer high, demand moderate. All right. Many times, the industry people, they refrain from getting HACCP instruction because it is very expensive. There are many people that they say okay, I know HACCP because they went and they took a three-day HACCP workshop with the former Professor Murano, and even though it was three days, it doesn't make you an expert. Okay.

And they don't see any difference in -- industry people don't see any difference from somebody else who has a strong -- is an expert and a strong background in HACCP implementation and training. He knows a lot. He can train them well, but he will charge them about $800 a day, they say forget it, I'm not taking it. Okay. And there's -- I mean, the difference cannot be seen.

So, basically, they are concerned about the

quality of the course, and one of the ways that they use to see if the course is of high quality is asking, is the course accredited? So, who accredits, who approves or who certifies or -- well, let's not say who certifies. Who accredits HACCP training programs? Well, the association or organization that is most commonly sought in the -- I would say in different countries is International HACCP Alliance. They endorse training programs and Latin American trainers, they basically -- those that are successful, they have sent their programs for review to the International HACCP Alliance.

The problem is we have right now the problem of a guy from Uruguay who sent his papers about nine months ago, and he has not gotten an answer yet, and then we found out that those documents were misplaced for six months or something.

Now, why is that happening? Because there's just few people in the alliance that are really, really taking care of that. They need to expand. Well, I know that you are not really alliance. Okay. Is there somebody with the alliance that read my lips and create an office in Latin America that will help you, okay, but this is what happens.

So, therefore, the training which is still

very necessary in Latin America is slow. It is not accessible to many people, and there's another problem that we have there. Well, not a problem. Most of the food industry are not large companies. They are medium size or small or very small, which is called in Latin -- in those countries is called the micro industry. It's very small, very small and small, and those guys don't have as much money to pay for that, but they don't realize that they can do it without spending too much money.

All right. As far as implementation, the industry, of course, are eager to start with HACCP programs, but they have little information on, you know, how to develop or apply control measures. Okay. Therefore, we still have some areas of the industry that they have not been able to figure a HACCP plan properly because they don't know where can they be -- I mean, can critical control point be inserted there. Okay.

So, one of the things, as I told you before, is that they just, you know, spray lactic acid because somebody read a paper published by somebody and say okay, apply lactic acid. They don't take control of the temperature. They don't take control of some things like that.

On the other side, we have large companies that they do a very good job at that. Okay. But that's probably the biggest problem in Latin America, is variety, you know. We're going to address that later.

These are some examples from our research experience on treatment validation. Okay. We developed the treatments. This is for beef carcasses from my former experience when I was studying in Texas A&M University, and we developed the treatment that basically you combine hot water and lactic acid treatment and you have, you know, good reductions of E.coli and Salmonella. I know that some people have also published that lactic acid treatments are not good at reducing E.coli 0157:H7, but it is just how you apply it and how you play with the treatments, and you need to adjust your treatments. It does work really.

Okay. And I'm not going to bore you with this slide. This is what makes us really proud. Okay. Gary Acuff and I, we developed a lactic acid treatment for chilled carcasses which was a challenge. All those sprays were applied only in hot carcasses, and somebody saw the need for a treatment for decontaminated chilled carcasses before fabrication, and we needed to adjust the system, and we were able to reduce that. So, even

another -- one more critical control point, if we validate and develop and validate a control measure, okay. So, that is it. You can see, for example, the control carcasses. This is the in-plant treatment.

As far as APCs, there's a huge difference and the same for coliforms and some for E.coli. What people call generic E.coli, we did not do pathogens there. Now, if we go back to Latin America, they don't really need our experiences on meats because they basically don't -- are not as strong meat producers as the United States, for example, for, you know, international trade. So, we needed to see where it was the most important area that needed HACCP implementation, talking specifically about critical control points or control measures, essentially.

Well, Mexico and Central America, basically they are in need for food safety of fruits and vegetables to improve that. Okay. And here, we have Jack Guzewich to tell us about it. In South America, they also produce some produce. They also export some meat, both to the U.S. and to the Economic -- the European Community. So, you can see, for example, from this chart, you can easily see where do they need HACCP the most. This is Mexico, Central America, and South America, and South America includes Argentina, Brazil,

Uruguay, Central America includes all these countries, Belize and so on, basically all of them, and this is the exports taken from the ARS data, exports for 2001 red meats, basically close to zero, fruits and vegetables, Mexico sends a lot of product.

It will be amazing for some of you to learn that at least in the southern region of the United States or at least in Texas, most of the produce that are consumed there, is consumed there, was not grown in the United States. Okay. This is consumed annually in Texas. 4.1 billions of pounds compared to .1 -- .5 billion pounds grown domestically. This information was personal communication from a broker in Houston.

So, this is data that -- this table was -- forgive me for that, Jack. I stole it from Jack Guzewich. Okay. And you can see in yellow color that one-third of the outbreaks associated with produce were related to imported produce. Okay. Cantaloupe, mango, parsley, raspberries, at least. Okay. Some others, we don't really know for some of them. Okay.

So, we know that we are importing product. We need to import that. I mean, I'm not saying, guys, don't buy produce from Mexico, now that I live in the United States. Okay. No, no, no. You guys need our products and we need you guys as clients. So, we need

to improve our food safety area at that point.

So, I go back to Mexico and happy trying to apply lactic acid sprays on carcasses and no carcasses to spray. Okay. So, we tried lactic acid. Our experience in lactic acid, on cantaloupes, as you can see, this is lactic acid compared to calcium hydroxide and then compared to chlorine treatment, and these three were applied by spraying and by dipping. This is wax. The controls, wax and water. You can see that lactic acid can be again an agent to disinfect at least melons, and now we know that we have had several outbreaks of Salmonella associated with melons probably that would be a good way to go, of course, after we solve the GMP problem at the packing shed. Okay.

Well, I'm not going to bore you with this information. Well, this is the in-plant comparison of lactic acid and the normal chlorine treatment that was applied in a packing shed. You can see this is the -- I think -- well, you can see this is chlorine. This is APC and coliforms, and this chlorine treatment and this is lactic acid. We were able to reduce a lot of the APCs.

Then we gave some recommendations, came back in the Summer, well, in the Spring, and they had reduced some of their counts, but still we were again

able to reduce, considerably reduce by applying lactic acid. So, that can have some future. Well, this is lactic acid on bell peppers, and the lactic acid also can take care of, as you can see here. This is in tomatoes. These are microorganisms that were internalized in tomatoes. We did that because we couldn't internalize any pathogens in melons, okay, and we had a good internalization in tomatoes, and after we applied -- we surface inoculated the tomatoes, we dipped them or sprayed them with cold and hot lactic acid or chlorine or just water, and we saw that we were not able to isolate -- to recover any of the pathogens. This is Salmonella and this is E.coli 0157:H7 internalized because we knew that they had been internalized because these are the other treatments, and we found some microorganisms in the interior, and we were able to -- were not able to recover the pathogens, except for one single sample. So, lactic acid can be good.

Well, just to finish HACCP auditing or verification. We have the same problem as training. We have a variety. We have people who do state of the art meat technology or fruit and vegetable technology and other plants where you can just find about anything, just anything, okay, and on the other side,

it is very difficult to assess effectiveness because we still have in the process of -- well, the industry people are in the process of learning how to, you know, evaluate, verify and validate. So, this is effectiveness.

Now, another thing is who is an expert? Who knows HACCP and who does not? Okay. And how many food-processing service establishments have embraced HACCP or how many plants have voluntarily embraced HACCP? These data come from Brazil. Okay. Really quick. This is one single survey. This is data that I was able to find over there. 23 percent -- this is for food service. It has nothing to do with fresh meats or poultry or eggs. But, you know, they serve that.

23 percent in that experience have adopted GMPs after they were interviewed, and out of them, 18 percent of them, in addition to GMPs, adopted HACCP. So, these guys are running. These guys are flying. Now, 59 percent of the interviewed establishments did not adopt HACCP and half of those establishments have not adopted HACCP because they just didn't know that there was HACCP around in 1998. Okay. So, we still have a long way to go, I'm afraid to say that.

Okay. As a conclusion, we have variety. Large companies apply HACCP, no problems, just like a

level of efficacy comparable to the United States, and some other plants, they do not know anything about HACCP. Okay. We still need some training and we still need to implement more HACCP.

So, we -- but we are trying because we already realize that if we want to sell our products to other countries that pay good dollars for them, they need to be comparable to what is produced in those countries.

Okay. I think that's it. Thank you very much.

(Applause)

Discussion on Impacts of HACCP Systems and Approaches

DR. SUMNER: We now come to the fun part of the panel. Hopefully, we challenged you to think of some nice questions to ask us. I also do know, having spent six years, a couple of years here in Washington, D.C., with National Food Processors Association, that I'll gauge the audience. We want to answer your questions, but I know a lot of you are going to start looking at your watches because it's D.C. and travel time and those types of things, but hopefully with what we've done, we've given you a reason and some questions to ask.

I do have a couple up here, but I encourage

you, if anyone has a burning question. Okay.

DR. ANDERSON: I have a question. I'm Don Anderson from RTI International. I have a question for Jack or maybe for Dr. Tauxe. I'd like to know a little bit more about these unknown agents. I mean, are these -- the significant percentage apparently of illnesses and even, I think it was, over 50 percent of deaths are from unknown agents.

Now, I guess what I'm wondering is, are these -- I'm not the scientist, but I'll use the best -- are these pathogens that have been isolated in these cases but they're unknown to science or are these pathogens and illnesses and deaths that we know are caused by foodborne causes but we're not able to isolate them? I mean, what are these unknown agents?

MR. GUZEWICH: I'll defer to Rob on that, if he wants to try it, because he's one of the authors on that paper.

DR. TAUXE: It's a good question. It's one we grappled with for some time as we were producing our estimates. Basically, what we did was, first of all, decide what is the -- how much -- how much diarrheal illness is there in the country and that was fairly straight -- there are several data sources that let us estimate that, and then we said now how -- what do we

know about the known causes of diarrheal infections and took them, and we know that we only hear about a small fraction of those that actually occur, and so we multiplied that up, estimated how many there might really be, and tried -- and added up all those estimates for all of the known pathogens, and basically we're left with a gap, that there's a lot of diarrheal illness in this country that is just not explainable by known pathogens and that to us means that there are more out there to be discovered, that these are people who are ill, a culture is done, nothing is noticed, nothing -- no results obtained, and we then -- and so, it's just -- it's unexplained illness is what it is.

Then the question of how much of that is foodborne came up, and in a nutshell, what we did was we made estimates for all of the known causes of diarrheal, and when we added it all up, we decided about a third of known diarrheal illness is foodborne, and now here's the great leap, you see. What's -- how do you estimate all that unknown?

First of all, you don't know what caused it, and now how much of that is foodborne, and the way we approached that was to say we have no better estimate than to assume that it's going to be like the sum of all the known ones, and so we said, well, a third of it

and that's how we arrived at it, but those are -- I think there's work left for the scientists in defining pathogens we simply don't know today, just like 30 years ago, we had no idea what campylobacter was. It was there, we just didn't know it.

DR. SUMNER: As a quick follow-up to that before the next question, one that was also turned in, that if we believe that HACCP is reducing illness from known agents, shouldn't we also believe that it has a similar effect on illness from unknown agents or would we expect that HACCP is too targeted toward known agents?

MR. GUZEWICH: Well, to the extent that HACCP tries to focus on causes of foodborne illness, underlying contributing factors, contamination, cooking, cross-contamination, refrigeration, etc., to the extent the unknown agents are affected by those interventions and that's conjecture, but to the extent that they're affected by those interventions, you would assume you're having an impact on those as well.

There are some efforts, I thought Rob might mention some of the activities in FoodNet, are to try to intensively investigate some diseases of unknown etiology, and this goes for the whole emerging infectious diseases program, not just the foodborne

ones, to go in and intensively sample patient specimens and investigate the underlying disease that people had for some of these kind of things, get them to laboratories that are really research laboratories, not routine production laboratories, and try to identify agents of some of these things.

So, there are organized efforts to try to better define these agents, whether they be bacterial, viral, parasitic or whatever else the causes are, chemical, etc. So, there are some efforts to try to answer that question.

MS. KOSTY: Hi. I'm Lynn Kosty with the American Meat Institute. I just had a follow-up question for Dr. Tauxe, and that is, my understanding was that when someone passes away on the death certificate, there is always a cause of death, and I was wondering what the circumstances in this particular case for the estimation for foodborne illness. Is there just a blank space left there? How do you determine exactly how many of those are attributed to foodborne illness, if you can't determine what the cause is?

And in addition to that, how many overall deaths in the United States, not related to foodborne illness or not believed to be related to foodborne

illness, are from unknown causes? Is it a similar rate? 64 percent, I believe, is what you said or does anyone know?

MR. GUZEWICH: We have a chair right here, Rob, if you want to join us.

DR. TAUXE: I'm going to have to have a taxi waiting here soon, I think.

We estimated death using -- not using death certificate data particularly, although one can get some information from death certificates, but I think we estimated deaths using death -- rates of death that we obtained again pathogen-by-pathogen and estimated from there.

We all wish that death certificate data were really accurate, but having been the intern on the ward called at 2:00 in the morning because someone has died that I had never seen before and being told I had to fill out the death certificate on the spot, I know that often what gets put down is cardiorespiratory arrest because the heart has stopped and the person is no longer breathing. That's why heart disease is the leading cause of death in this country. It's true. It's true. So, I don't -- and anything that might be found at autopsy, anything that might have grown from the culture obtained two hours before doesn't change

that. It's whatever the intern puts on the form at 2:00 in the morning, and it's very often cardiorespiratory arrest.

PARTICIPANT: This is for Alejandro Castillo. You spoke a great deal about many of the countries in Latin America but not Chile from which we get an enormous amount of produce. What is the situation there?

DR. CASTILLO: Well, I happened to be talking to somebody who was living in Chile for long years, and then he went to visit Texas A&M, and I asked him this question. After the cyanide in grapes scare, they have developed a very, very efficient system for covering the security of their foods and also the safety.

I'd say the Chilean food supply or produce supply would be good, but again every country that exports to the United States many times, they know what they have to accomplish in order to sell their products, but what I can tell you is that Chilean exporters, they take a very, very close care of the quality and safety of their products.

However, and here, we have a problem here, is that many of those types of operations do not include any real control measures. So, that is why at this time, HACCP really cannot be applied to an agricultural

-- well, to fruits and vegetables, fresh fruits and vegetables. What they do is they just harvest, wash. Some of them disinfect or think that they disinfect because they don't validate, and they pack. Okay. So, there's not really something that you are making sure that you're having a pathogen reduction step, okay, and therefore some product may be contaminated from the source, and even if you have a very good food safety program, if you just contaminate it, I don't see in the whole technology anything that will -- unless you implement that, will take care of that contamination.

That is why we're promoting so much these treatments to see if we can work that out, especially Chileans, if they do a good job at hygiene in packing. Okay. Now that they do a good job, probably they can implement something, a really effective treatment and then a formal HACCP plan could be developed for at least one product. Okay.

MS. MUCKLOW: I was going to rain on Dr. Tauxe's parade again, but Dr. Hulebak suggested we have little informal discussions, and so I had an informal discussion and the news was so good, that I thought you'd all like to hear it.

He said -- I asked him how CDC used to publish a list of outbreak information. By outbreak,

how many people got sick, what the vector was, what the location was, and we haven't seen that for several years. Like a really good bureaucrat, he told me that that was because the funds had run out. He tells me that the good news is that they're working on filling that information in. 1997 is up. They're working on the other intermediate years. So, we will soon have that for the vacant years, and I always found that information tremendously valuable. So, the sooner you go back and get that done, Bob, the better. Okay? We'd appreciate it.

I have a couple of other things, if I may. The International HACCP Alliance is alive and well. It has a global HACCP conference in Chicago next week. I am the vice president of the International HACCP Alliance. It was formed in 1994, before the mega reg was even proposed. It does some really good work, as you said, and one of the things that we have that I think will be useful knowledge to the people in this room is that we are working on developing some training materials appropriate for line supervisors to give to line workers that explains HACCP and explains what their part in the process is, and our hope is that that will then radiate out into their communities and their homes and so on. That material will be ready -- it

won't be ready next week, but it's coming along.

So, indeed, I'm sorry they lost Uruguay's paper or Uruguay didn't put enough stamps on it or whatever it was, but I hope it's been fixed.

Dr. Parham, you mentioned, and we didn't talk about this when we had our informal discussion in the ladies room, and I'm sorry, I should have thought about it, you presented us with a lot of data, and I have a problem and maybe you could explain to us why the agency, I think, measures their data by the results of sample sets rather than by the data points of individual samples, because as you well know, the passing grade for sample set varies very substantially by species, and I think we would be a lot ahead if you were measuring it by individual sample data points.

That may be a high higher grade than you get paid at the department; if so, you can turn it over to Dr. Hulebak.

But I think it's sort of interesting, and I think the data you gave us was by set, not by individual data points. I've got two more questions, but let's deal with that one.

DR. PARHAM: Okay. The data that I gave was by individual samples, okay, even though we've talked about the sample sets because we do use sample sets,

okay, but in terms of why we do that, and Loren Lange is scheduled to give that presentation tomorrow. He is here today, and so we'll ask him, okay, to come forward and talk a little bit about that.

Loren?

MS. MUCKLOW: He can put a wet cloth around his head and tell us that tomorrow then.

All right. Dr. Guzewich recognized, I think, one of the most important contributions to the reduction in pathogens in the 1990s, and it was the first time that that was recognized here today. I would remind everybody in this room and some will be too young to remember the history, but FSIS literally forbid the removal of any contaminants from surfaces of carcasses by any kind of washing or rinsing technology. Everything was required to be removed with a knife before 1993, and there are a few people with gray hair in this room that earned it along with me working on the agency to persuade them that indeed there were technologies that would help us to reduce pathogens.

The pasteurization, steam, hot water, all of those kinds of things that came in, beginning -- steam vacuum was the first in '94-95 and onwards, and I'm very appreciative that Dr. Guzewich mentioned that, and the final point I'd make for the Latin American

countries is that USDA has a lot of material from small firms. Much of that material was developed by the HACCP Alliance, and it's a very useful effort and might give them a spring start. I don't know if it's available in Spanish or not, but it certainly would be a big step forward for many of them.

Thank you.

DR. SUMNER: Questions that have been turned in. Why is it considered acceptable for ground chicken to have six times the occurrence rate for Salmonella than ground beef?

DR. PARHAM: Our standard, our Salmonella standard is based on our baseline survey. Okay. So, when we were implementing the HACCP rule, we went out and we collected data at all of the plants, okay, to set our baseline, and for chicken, if you will, ground chicken, that baseline, the performance standard was set at 44.6 percent.

If you will notice now, it is not that they are allowed, okay, to have much higher rates. They are well below, if you will, the baseline, and yes, we'd like to see them come, you know, down even more, but certainly they are meeting our standard, our performance standard.

DR. SUMNER: Please explain the seemingly

inverse correlation between the rise in Salmonella positives from 1998 to 2001 in steer/heifer slaughter plants while there was a decrease in ground beef during the same time.

DR. PARHAM: Please explain the seemingly increased correlation between the rise in Salmonella positives from 1998 to 2001 at steer/heifer slaughter plants while there was a decrease in ground beef during the same time.

There are a lot of things going on that are different, if you will, if you're talking steer/heifers, okay. Steer/heifers, of course, being our -- being the young animals, okay, and definitely with the lowest performance standard, okay, in Salmonella, okay, positives. Ground beef, on the other hand, that's a different product, okay, and if you notice, the performance standard is higher, if you will, for ground beef. I think it says while there was a decrease, I'm sorry, in ground beef during the same time.

I don't know that we can -- we have statistics, if you will, to show that this is -- this can be correlated. In fact, I would say that we can't at this time. I think perhaps to talk further on this, Walt Hill -- are you in the audience with us? Okay.

DR. HILL: I don't mean to beg the question, but let me first state that the Salmonella HACCP compliance data is not a statistical survey of what the prevalence of Salmonella is based on a nationwide prevalence or to what the public is exposed to. It's merely the results of our verification program, and as such, it does not represent the population of Salmonella that is present in those products.

With that said, everyone likes to compare these results from year-to-year. So, you take a non-statistically-designed statistic, if you will, and apply an eyeball test from year-to-year and come up with a conclusion, and so, I would like to say that it's encouraging that everyone likes to look at our data very carefully, but I'd say it's discouraging to read too much into it, and what Delila was just mentioning about the steer and heifer data, if you look at the slide that she showed, the fact that there's a slight increase in the contamination of steers and heifers.

In the year 2000, for example, the .4 percent represents a whole four samples that are positive for Salmonella, while in the year 2001, that rockets up to a whole 10 samples nationwide that are positive for Salmonella. I'm not a statistician, but I would say

that you would be hard-pressed to show that there's a statistically-significant increase between those numbers, and once again, I'd like to emphasize it's tempting to put these data into a time course and perhaps you can do that, if you're very careful in the conclusions you draw, and it might be good for some policy decisions, but as far as statistical rigor is concerned, it's inappropriate.

Thank you.

DR. SUMNER: One other thing you have in your data, you show with the broiler plants, the really small facilities had really gone up in their percentage, and I was just wondering how we compare that data when we start looking to worldwide experiences to see that they have smaller facilities over there and they're really having better results. Why do you think that might be with the small facilities?

DR. PARHAM: I would like to go back to the small facilities just a little bit, and if you look at our data for small facilities, certainly, let's say for 2000, of course, we did not have very large samples for '98, okay, for very small -- we had none, okay, for '98 and none for '99, and then when we looked at 2000, we have a very small number, 61, and then, of course, it

increases to 392 in 2001, okay. So, we had many more samples, of course, in 2001 than we did prior to, and we anticipated to some degree that very small plants would have a bit more of a problem, okay, getting, if you will, meeting the Salmonella performance standards.

We've done some things, but it's still positive in that we think that if you look at the small -- the large and the small plants, you see that when they came on board, some of their numbers were higher, also. So, we believe that those numbers are going to go down for very small plants as they continue to work through HACCP, okay, and get familiar with what is expected for them to do.

Compared to other countries, I don't have an exact answer for you. Certainly in terms of speculating, though, I think someone mentioned the size of the industry in the other countries compared to even for our very small plants in this country, the size of the industry, they're much larger here, okay, than, you know, in some of the other countries, and so that could be that we are looking at it as a matter of a smaller -- smaller numbers in other countries and better able to control to some degree.

Perhaps, Dr. Castillo, you want to talk on that a little bit, too? Okay. So, that's what I think

we would be seeing in the next few years, is that very small plants, those numbers will be coming down accordingly, okay, just as we've seen those numbers for beginning in '98 for the large plants, you know, start to come down for most of them in that situation.

PARTICIPANT: Dr. Parham, I have a question for you. With the E.coli criteria that have been established, I noticed for swine, it's about a hundredfold higher than what the upper limit would be for cattle.

What is the scientific basis for that?

DR. PARHAM: Okay. Again, and I'm going to ask you to think back on Dr. Hill's comments earlier, Walt Hill's comments, but when we did our sampling and establishing our standard, if you will, this was what we measured at the time, okay, and so we set our standards accordingly.

I don't know that we have any more data for you than that, you know, to say that that's what we were seeing at the time we set our criteria.

PARTICIPANT: So, it's not based on public health?

DR. PARHAM: No, it is not a public health outcome. No, sir. It is not based on a public health outcome.

PARTICIPANT: All right. Thank you.

DR. SUMNER: How often will a plant undergo an FSIS Salmonella sampling regime? Once a year? Once every two years? Five years? Ten years?

DR. PARHAM: If you will remember, we do have Salmonella sets, okay, if you will. 82, I think, you know, we are doing steers and heifers. So we could get a complete set, you would have 82 samples, you know, that kind of thing, but the samples may not be taken, if you will, on consecutive days. So, it will take us, if you will, a little longer maybe to complete some sets. We aren't taking consecutive days. If something comes up and we're not able to take that sample, so it could take us a little bit of time to complete it, okay, more than the 82 days.

Now, in terms of once a company, if you will, passes, you know, its Salmonella set, okay, we don't have, I must tell you, written rules here. We do this, if there's a computer-generated random sampling scheme, okay. So, and we have specifically that will not sample again for another year or any of those kinds of things, but certainly we don't target a plant immediately. We don't anticipate sampling them immediately upon finishing, you know, a set, and it was -- and they met the sample set, okay, but we don't have

numbers, if you will, to say we will not sample again for the next six months to a year to whatever, even though in reality, yes, we are looking at those things. Okay. It is something that we need to consider because some have said, of course, that we target the better plants, and we sample them more often, you know, that kind of thing, but, so this is something that we are looking at, but there is no time table, if you will. It is a computer-generated sampling scheme.

DR. SUMNER: If we take a look at HACCP and how it's evolved and the time frame really since it's been evolved in the regulation and everything, where do we see it going in the future from a science standpoint if it's a science-based arm? Where do we see it headed?

MR. GUZEWICH: Interesting question. I think we've seen HACCP implemented with some success in the food-processing industry, and I imagine that the science there will continue to improve, and it'll be refined in the food-processing industry, be it meat and poultry or other kinds of products.

I am concerned that we still struggle with getting the concepts applied at the retail level, and I don't know if that's a science issue or if that's a policy issue or a programmatic issue or a training

issue or whatever you want to call it, but implementing HACCP in small business, which is a problem even in the food-processing industry, at the retail level is still a struggle, and I guess if I were looking at the future, I would still be looking at how do we succeed in doing that.

DR. PARHAM: I think that we've seen that -- we believe that certainly HACCP works and the companies have taken control of their own process. I think that we will continue to see that. I think what we'll be wrestling with in the future certainly will be how we measure things, performance standards and what those types of things mean.

As you've seen today, what kind of impact. So, those are the issues, I think, that will be coming forward, not so much the process control. I think certainly everyone is taking and handling the process control part of it, but what does it all mean? Okay. That's what we'll be looking at, I believe.

DR. HULEBAK: I'd like to add one point in answer to that last question that Dr. Sumner posed.

By saying that I think as -- from a regulatory agency's perspective, as we look at the further evolution of HACCP, we'll be looking to clearly, first off, refine and further develop the data

that we use as we've used baselines in the past, look to develop much more complete and nuanced data sets, and I think that will take us in the direction of being able to meet another goal, which is to use risk assessment to help point our attention in more finely-targeted ways and to help us develop measures of effectiveness, HACCP's effectiveness and intervention effective, that are more intelligent, more finely-tuned and able to give us better answers about how good a job we're doing and how good a job the food industry is doing.

MR. ROACH: Yes, this is Steve Roach from Food Animal Concerns.

Just on hearing his response to the question about the sampling that FSIS is doing, my question to the panel is: is there any -- is the Federal Government doing any statistical sampling where we're trying to get a good sample of all the meat products or maybe, you know, you look at the top 50 producers of meat, and are we actually -- is anyone taking a statistical sample, accurate sample, to look at how much pathogens actually are on the food? Are we just kind of using measures that weren't designed to do that and then trying to get the data from that?

DR. PARHAM: Right now, we're using, if you

will, our Salmonella prevalence data, okay, but we've gone beyond that, okay, to some degree. We recognize that there are limitations there. Okay. So, right now, we are asking our National Microbiological Committee and the National -- NAS to help us in terms of the performance standards and things of that sort, so that we can go back and be able to actually have better statistics, if you will, how we should measure, what we should be looking at, those kinds of things.

We don't have anything right now today in that regard to tell you that we're going to program, you know, like tomorrow or anything like that certainly, but certainly we are considering those things, yes.

MR. ROACH: Do you have a time table for that? When there would be some type of national standard statistically-accurate sampling?

DR. PARHAM: I don't, no.

DR. HULEBAK: Let me also suggest that Loren Lange is going to address your question maybe now. I was going to give you a reason to stick around till tomorrow.

DR. LANGE: Yes. Let me add just -- to say one thing, that right now, there is a statistical baseline being conducted on egg products, liquid egg

products, prior to pasteurization, and we are actively involved with people I see in this room from the Agricultural Research Service where we are in the process of designing a nationwide baseline study of the whole microbial profile for beef trimmings. So, those things are under consideration right now.

Our best-laid plans, I guess, is to sort of, by the end of this year, actually, you know, initiate that beef trimming baseline study, and I think by the end of this year, the egg products study should be completed, at least the data collection phase of that baseline. So, the answer right now is we are internally really sort of weighing, you know, the allocation of resources between, you know, baseline studies that are statistically designed and HACCP verification, and we've got some options on the table right now.

I hope that doesn't say a lot but it should answer some. You know, redoing and conducting baseline studies are still part of our on-going microbial program.

DR. SUMNER: Jack, do you have any other suggestions? Karen's mentioned a couple dealing with the micro issues that we can better incorporate into HACCP, to help us measure the impact on public health.

MR. GUZEWICH: Well, in terms of being able to actually measure cause and effect, the problem with HACCP is it's too big a thing. It means too many things. It's a whole universe of interventions, and so when you're describing it, you're not describing one thing, you're describing a host of interventions done in a variety of different facilities, in a variety of different industries, and so to take this whole massive program and then try to en masse say this has made an impact on public health is really tough.

I do think a person could systematically take some -- one or two of the interventions out of HACCP and try to gauge the impact they have on public health but realize at the food-processing end that once a meat or poultry product leaves an FSIS-regulated facility and moves downstream through the distribution and into retail and into the household or preparation there, other things can happen that impact the outcome as well.

So, when you're measuring down at that end of the stream, you've still got to do a lot of interpolation to say how much impact was happening at the food-processing plant as opposed to what happened along the way.

Having said that, it would seem to me that

the closest we're going to get to that is down the road, but Dr. Tauxe has left here, but Rob works in the Center for Infectious Diseases at CDC. One of his counterpart centers is the Center for Environmental Health, and people in the Center for Environmental Health down there are beginning this process now to look at in a much more systematic way the contributing factors that lead to foodborne illness at the retail level and restaurants specifically, and they're going to be able to make comparisons between restaurants that have had outbreaks and restaurants that have not had outbreaks and compare the practices in those two kind of settings.

I think similar kinds of activity in any industry, meat-processing or whatever you want to say, might be more effective in showing relationships. Why does this kind of establishment have more problems than this kind of an establishment? I think going at it that way, you could interpolate back to cause and effect on human disease, but to be able to say that because we put in Step Number 2 in a meat-processing plant, that we've therefore reduced foodborne illness in the country by some incremental factor, there are too many things in between to ever be able to say that, I believe.

DR. SUMNER: Any other questions that you have?

(No response)

DR. SUMNER: If not, I don't want you to jump up out of your seats yet. Two things. Karen is going to wrap up a little bit for us, but I would like you to join me in thanking this afternoon's panel along again with our morning panel and the excellent job that they've done today.

(Applause)

Recap of Day 1

DR. HULEBAK: I want to thank you all very much for being here today. I look forward to seeing all of you here tomorrow. Virtually all of you stayed the whole day and that's commendable and really encouraging.

I think we've had a really -- we've had a series of really excellent scientific presentations today that have raised a number of really excellent scientific questions, many of which had no clear answers, and one or two of which had no answers. This is a good thing, if you're a scientist. It's always good to know that there is a -- there are plenty of important hypotheses out there that remain to be tested.

Some areas have come up in discussion today. For example, Scott Heard's data referred to by Rob Tauxe could present important continuing food safety research for ARS, and other work, for example, the data on Salmonella Newport in swine may present new opportunities for collaborative work among agencies, APHIS, ARS, and FSIS, together on that one issue. Opportunity for collaboration in food safety, I think, is a very good thing, and we ought to take advantage of it.

We talked about HACCP, whether it's been successful. We talked about how to measure whether interventions are successful. We talked about associations or the possibility of describing causal relationships between implementation of HACCP and effect on the public's health. Can we demonstrate causality? Well, no, but that is very, very hard to do using epidemiology, but we do see associations between the implementation of HACCP and declines in disease incidence.

We're inclined to say that's an association worth noting, and I daresay that if we weren't seeing declines in disease incidence, that strong arguments would be being made to make the opposite point.

I also want to note as a final note that

Rosemary Mucklow complimented FSIS for learning and flexible thinking, and I know that many of us will cherish that moment, and I just want to give Rosemary an opportunity for learning as well this afternoon. It's pronounced Guzewich.

So, thank you all very much for coming. Thanks for your attention, your good questions. Have a good evening, and we'll see you here tomorrow.

(Whereupon, at 4:10 p.m., the meeting was adjourned, to reconvene tomorrow morning, Tuesday, May 7th, 2002, at 8:30 a.m.)