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Symposium on Meat and Poultry Inspection:

What Do Recent Changes Mean for Food Safety?

1:30 p.m. to 5:00 p.m.
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C O N T E N T S

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P R O C E E D I N G S

MR. WALDROP: Good afternoon, everyone. Thank you very much for coming.

I notice, as per most meetings, that the majority of the folks are in the back. If you can't see the PowerPoint, I would encourage you to come up to the front, but I think you should be able to see it from way back there in the back seats.

Thank you all very much for coming here and attending our Symposium on Meat and Poultry Inspection. Today we are going to explore some of the recent changes at the Food Safety and Inspection Service and what those changes have been to their regulatory inspection programs and what those changes mean for food safety.

As you are all aware, food safety is a very important and increasing concern among both consumers and industry across the country. Foodborne illness, traced to both domestic and imported foods, has become an increasingly serious problem in the U.S.

Food safety is also a hot topic here in Washington. In March, the President established a White House Food Safety Working Group to examine the need to

upgrade our food safety laws. Most of the recent action in Congress on food safety is focused on the Food and Drug Administration and modernizing their statutory authority.

However, FDA, as we all know, isn't the only agency in charge of regulating the safety of the food supply. Over the past several years, the Food Safety and Inspection Service has invested substantial resources in trying to develop a more risk-based inspection program. The agency has proposed new data collection and analysis systems. The agency has also proposed changes to its regulatory policies that, if instituted, could result in significant changes in how the agency conducts its inspection activities.

Some of these changes were made in response to increased positive findings for pathogens or investigations following foodborne illness outbreaks, while other efforts were the result of changes in agency thinking or even the result of congressional mandates.

These new approaches being developed by FSIS could contribute to the dialogue on efforts to modernize food safety law. However, there has been little formal discussion of the merits and shortcomings of FSIS actions

and how those actions as a whole contribute to food safety.

Today we hope to help foster that discussion. We will first hear from Dan Engeljohn, Deputy Assistant Administrator of the Food Safety and Inspection Service. Dan will provide an overview of some of the recent changes at FSIS and provide us with a look at where the agency is headed in the future.

Following Dan's presentation, we will hear from stakeholders in the meat industry and then representatives from the National Academies of Science, consumer groups, and the meat and poultry inspectors.

We have asked these panelists to provide their perspectives on FSIS's efforts to improve its inspection programs and its data capacity and what more they think needs to be done. In addition, we have asked them to examine what is working and what needs to be improved or changed.

Following the two panels, we will then ask everyone to join us back up here at the front, and we will open up the discussion to questions from the audience.

I would like to thank, first of all, all the panelists for agreeing to participate in today's discussion.

We look forward to hearing your presentations. I would also like to thank those organizations that have helped make today's symposium possible, and there is a list of those folks in your packets.

So, without further ado, let me introduce Dan Engeljohn. Dan is Deputy Assistant Administrator at the Office of Policy and Program Development for FSIS, where he oversees the risk management activities associated with meat, poultry, and processed egg products and leads the strategic planning efforts involving the development of food safety regulations. Dan represents FSIS on the National Advisory Committee on Microbiological Criteria for Foods and also serves as an adjunct assistant professor of nutrition on the graduate faculty at Howard University.

Dan?

FSIS Presentation

MR. ENGELJOHN: Thank you. Well, thank you very much for the opportunity to be here and to provide you an overview about what we are doing at FSIS, what we are about, where we have been, and where we are going. I hope to do that in the few slides that I am going to present to you today, and I am happy to provide a perspective in part on

the agency's perspective and then, as I normally always do, give you my own opinion about where things stand. If, in fact, we are not prepared to give an agency position, I can certainly give you a policy perspective in terms of what our thinking might be on a particular issue.

For those of you not familiar with FSIS, our mission is different than FDA in that we are the public health regulatory agency at USDA. We were formed into one agency handling all food safety aspects at USDA through the 1994 Farm Bill Act, and as a consequence, any meat, poultry, or processed egg product falls under our purview in terms of ensuring that it is safe, wholesome, and properly labeled.

We have three primary statutes that we work within, which would be the Federal Meat Inspection Act, the Poultry Product Inspection Act, and the Egg Product Inspection Act. All three acts have very, very similar language, and to a great extent, the agency applies our inspection activities similarly across all three commodities. There are a few differences, and we will talk about them a bit.

There are some limitations I wanted to make sure that you also were aware in terms of our Federal Meat

Inspection Program, as compared to other countries. Our inspection authority starts at slaughter or for eggs in the egg plant when they are presented before they are either graded or sorted for further processing, and then, really, we have jurisdiction at all points thereafter when the product is labeled to ensure that the product is not adulterated as it gets to the consumer.

We have applied our inspection activity for the most part in the federally inspected slaughter and processing facilities. We have entered into retail, in particular, to address in the early years issues related to species substitution or issues relating to labeling that competitors would bring up, but, for the most part, in the more recent years, we focused either on sampling product at retail for E. coli O157:H7 as an activity.

We now have authority for catfish for which we are developing a regulation to implement this next year. It does provide new authority for the first time for the agency, which would be to have authority on farm, really meaning to oversee the ponds for which the catfish are raised and then the transportation of them to the processing facilities. So this is a new activity to help provide the

agency new focus and perhaps new perspective on what it is we could or should be doing with the other commodities that we regulate.

To be clear, the agency has tried in particular with the HACCP regulations in the mid 1990s to clarify who is responsible for what. We regulate an industry that applies for a grant of inspection to produce a meat, poultry, or egg product. As such, the agency provides inspection at those facilities, and it is the responsibility of the industry to prepare a safe product to put it into commerce. And it is the responsibility of the agency to ensure that the product is safe before it leaves that facility and then while it is in commerce.

A bit of perspective about the program that we operate, it is a resource-intense program with inspection in all facilities that we regulate. I have given you the poundage here for the products domestically that we inspect. Our program is also set up such that product coming into the United States must be from a country that is deemed to be equivalent as having an inspection system, at least that is equivalent to that of the United States, and then those countries are accepted for export to the United States and

then comes in and then is treated as domestic program.

We do have a mechanism today whereby we schedule inspection activity for our inspectors through our performance-based inspection system. It was developed in the mid 1980s, and we calculate that we perform roughly 8 million inspection procedures a year for which we have data on various aspects of the activities that our inspectors perform.

We do this with roughly 7,800 full-time inspectors, which would include food technologists, as well as veterinary medical officers, and this is in 6,200 facilities. It is also important to note that for every slaughter facility and an egg processing plant, there is continuous inspection, meaning that the inspector has to be present in order for the operation to proceed, and then, for the further processing operations, there is a daily inspection that occurs.

I did want to give a perspective that we are proud of the fact that we do conduct verification testing of product to give us some perspective about the products that we regulate. This gives you a bit of the information in terms of the microbiological tests that are performed each

year, roughly 88,000. Just under 89,000 microbiological tests are performed, for which the agency uses the data to make some assessment about the effectiveness of our program.

We do at FSIS adopt the goals that are set out for food safety from a national perspective, and we do look at E. coli O157, salmonella, and campylobacter, as well as listeria in terms of measuring whether or not our program is effective.

Over the years, attribution being what it is, getting better but still not as good as it could be, we are trying to make our best estimates as to what impact our regulatory program has on the food that Americans consume, and so, from that, the food safety goals that were set up were from the baseline year of 1997. The year 2010 is the year for which there is a purposeful intent of reducing by half the number of human infections from various pathogens, and these goals represent the goals set about for all foods, not just those regulated by FSIS.

I apologize for the small print at the bottom, but what we have tried to do through our best attribution estimates, working with CDC and expert elicitation, as well as other information to try to best estimate what the impact

of our program is, for ground beef from our 2007 data, we estimate that 0.34 cases per 100,000 are attributed to ground beef, and this would be in comparison to that 1.1 number that is up there for the year 2008, which is the latest information.

For listeria monocytogenes, we estimate that the contribution from the ready-to-eat meat and poultry products to listeria infections is 0.14 cases per 100,000.

For salmonella, broilers is the target commodity for which we measure whether or not we are making an impact on salmonellosis, and we estimate that 0.84 cases per 100,000 are attributable to broilers.

Each year we look at the information and modify these numbers. I will say that the numbers each year, we estimate have gone down from the estimates that we have for 2007. The prior year, 2006, was higher, and then we will have next-year information about this past calendar year's comparison.

I was asked to give a perspective about the major activities that the agency has pursued over the last 10 years, for which there has been a great deal of activity. That activity was really standard-setting rulemaking in that

we had a number of initiatives underway in which we issued Proposed and Final Rules.

I would characterize these rulemaking activities as preventive in their approach in that the HACCP regulations issued that applies to both not-ready-to-eat and ready-to-eat products, and they began full implementation between the years 1997 and 2000. As well with HACCP, there was a pathogen reduction component for certain classes of raw products.

The Rules of Practice issued, which was a means by which industry would be able to appeal the decisions that are made in terms of enforcement actions by the agency, and at the same time, the agency issued clarified sanitation performance standards and removed some of the activities that we did with regards to prior approval. We used to prior-approve all blueprints, as well as equipment that would be used in a meat or poultry operation. With the issuance of the HACCP regulations, that burden shifted to the industry to demonstrate that they were using appropriate and suitable materials.

We issued Lethality Performance Standards for ready-to-eat commodities, such as cooked poultry, cooked

roast beef, and cooked meat patties.

In terms of the more recent times in the past 5 years, we have not been in the mode of preventative regulations. I characterize them as failure-based rulemaking in that for listeria monocytogenes, we issued an Interim Final Rule that put in place controls for the control of listeria in exposed ready-to-eat meat products.

There was basically a 2-year cycle for large outbreaks associated with meat and poultry products prior to this time. There has not been any since associated with meat and poultry products, but, in any case, we issued that regulation in response to what we characterize as failure by industry to control that hazard.

Then the Specified Risk Materials issued as a form of an emergency regulation in terms of an overall government failure to prevent BSE from entering the U.S. and getting into the food supply.

So those were the two primary regulations that I would address in terms of being put forward. Clearly, the emphasis was away from rulemaking in the last 5 years. However, there have been significant changes in terms of our inspection verification. We believe that we have provided

some significant enhancements in terms of how we have dealt with salmonella in raw classes of poultry.

We identified and categorized using the existing performance standards that were put in place through the HACCP pathogen reduction regulation in the late '90s, driving industry to control the salmonella that would be in products and, in particular, for broilers, categorizing that in terms of meeting half the current standard versus being above half but not failing and then failing.

We believe that through our focused activity there that there has been a substantive change in the control for salmonella in broiler carcasses, as well as other commodities but broilers in particular. As well, we instituted a verification program for turkeys, which we had not done before.

For E. coli O157:H7, although a great deal of activity had been focused upon ground beef, the agency began taking enforcement actions, as well as verification testing, in trim and now its slaughter in terms of our focus there to prevent E. coli from going forward into the grinding operations.

Then, importantly, data quality and sufficiency

enhancements, I think, were a primary focus of more recent time in terms of better defining what our goals are with our verification testing program and ensuring that when we schedule samples that they get collected and that we are analyzing the data, and then, as well, ensuring that the inspection tasks that are performed are being assessed to see whether or not we can identify trends and whether or not we are, in fact, properly conducting our verification activities, which include on-site inspection, testing of product, and then reviews more thoroughly of the food safety systems, and then a very concerted effort with regards to attribution to relate progress in terms of the effectiveness of our program.

So all this at the bottom there really related to our efforts at better defining what we are doing in operations, as well as ensuring that we are reviewing the data that we are collecting to see whether or not we can identify trends that could identify a potential failure that might occur, and then ensure that we are aligning our resources, so that we are, in fact, properly getting into those operations, identifying what vulnerabilities are there, and ensuring that the industry is controlling them.

Where we are now, we have the Food Safety Working Group which has identified at least five goals that the Federal Government as a whole is intent upon addressing. These would relate to prevention, strengthening surveillance and risk analysis, expanding risk-based inspection and enforcement, rapidly responding to outbreaks and to facilitate recovery, and then targeting our resources effectively.

All of this would be what FDA, CDC, and FSIS, in particular, as well as industry, consumers, academia, will engage in, in order to better define what the food safety expectations are and what the measures of success should be. This is a work in progress in terms of defining where we are going, but I believe that it is going to set the standard for us in terms of defining how our program is going to be measured for effectiveness.

Then, finally, I just want to focus on the future actions in the most immediate, as well as in the long term, and where I see us going as an agency. Most particular right now is the focus, again, upon HACCP in that, from the agency's perspective, we believe that there is a need to refocus on not-ready-to-eat products.

We have had success with our ready-to-eat program, in particular on the listeria aspects, but we believe that there is a need to focus upon not-ready-to-eat products; in part, the increased presence of non-intact product, this would either be a mechanically tenderized or enhanced product, ground products, or further processed products that have been, in some fashion, manipulated, as well as the breaded and browned products that are also perhaps char-marked that appear to be ready to eat.

We believe that these products are going to present significant risk in part because of changes perhaps in consumer behavior and handling and how products are prepared; in any case, the decisions about what level of control is necessary for these products that are not represented as raw products. A raw meat product that you can look at is different than one that may appear to be ready to eat, and we think there is a need for significant focus there.

Validation is a particular issue for the agency in terms of ensuring that the interventions and treatments that are applied to food safety systems are, in fact, effective in what they are intended to accomplish. We think that

there is a problem there in terms of not necessarily having the right kind of data to demonstrate that the systems are working as intended, and so that will be a focus of the agency in particular.

The agency as well needs to better understand consumer handling and preparation practices, and I think this is an area where we really need to know what consumers understand in terms of the difference between a ready-to-eat and not-ready-to-eat product, how they handle that product and prepare it, and whether or not they are, in fact, capable of preparing that product safely.

From the perspective of food products, cross-contamination is an issue for which there is very little research to demonstrate what contribution that has. Our laws or at least the interpretation of our laws have been on the product itself, whether or not the product can be safely prepared, not necessarily the contribution to foodborne illness that that product might represent, simply because it is contaminated with pathogens.

In part, our pathogen reduction regulation was to get at the reduction of pathogens, but I think that we need to refocus on that particular issue.

We also need to be able to expand our capacity to be able to identify trends and to respond effectively through policy corrections. In part, it is my opinion that this is best done through ensuring that we have designed our verification activities in a manner to give us the type of robust data that would help us make these kind of determinations. It also involves inspection as a primary activity that can be used to inform whether or not we are, in fact, properly ensuring that the product is in compliance with the regulations. So this would, most importantly, be influenced by an inspection activity.

Then, finally, it is my opinion that we need to develop more and better performance standards to ensure continuous improvements in the operations that we regulate, so that, in fact, we can be improving public health through a constant and vigilant attention to whether or not we are, in fact, reducing pathogen exposure to the public in the right place, and that may not necessarily be in the Federal establishments.

Like I said before, we do have jurisdiction at retail and in distribution where there may be more appropriate places or necessary places for the agency to

focus on ensuring that the pathogens on the products we regulate are properly controlled.

With that, that is the overview that I have for our inspection program and the immediate future, and I am sure I will get questions to address later.

Thank you.

MR. WALDROP: Thank you very much, Dan.

I apologize. I realize I forgot to introduce myself at the beginning of all this. So I will do that now, and then we will move on to the next panel. My name is Chris Waldrop, and I am the Director of the Food Policy Institute at Consumer Federation of America. We are putting on this symposium.

I will ask our first panel to come up to the table here.

[Pause.]

MR. WALDROP: Our next panel is going to provide their perspective on some of the changes that Dan just talked about. I am going to introduce the panel, and then I will let them go one by one and provide their presentations.

So, first, we are going to hear from Mark Dopp. Mark is the General Counsel and Senior Vice President of

Regulatory Affairs at the American Meat Institute, where he oversees policy development and research and represents industry views to government officials on many regulatory initiatives and legal issues. Prior to joining AMI in 1999, Mark worked at Hogan and Hartson where he was active in areas of food and agricultural law on behalf of many clients, including domestic and foreign corporations.

Next to Mark is Bob Reinhard who is Director of Food Safety and Regulatory Affairs for the Sara Lee Corporation. Bob's responsibilities at Sara Lee include directing and overseeing all food safety and regulatory initiatives and providing scientific advice on legislative matters. Bob currently serves as chair of the Grocery Manufacturers Association Meat Poultry and Egg Products Committee and on the Scientific and Regulatory Affairs Council for GMA.

Then, finally, at the end, only because there is a big screen in between, we will hear from Bob Hibbert. Bob is a partner at the law firm of K&L Gates where he focuses upon Federal regulation of the food and agricultural industries with emphasis upon USDA. Particular areas of concentration include food safety, food security, animal

health, labeling, advertising, and new product development. Bob formerly served as a senior attorney with the U.S. Department of Agriculture and directed USDA's standards and labeling staff, formulating policy in areas including food safety, product standards, and nutrition labeling.

So I will turn it over to Mark.

Panel Presentations

MR. DOPP: Thank you, Chris. Chris, thanks for the opportunity to appear and talk to everybody. I really appreciate this. I was looking forward to it for quite sometime.

I appreciated Dan's comments as well. He actually touched on a couple of things that, if I had known you were going to raise a couple of those things, Dan, I would have asked you for the slide because it is going to be spot on with what I was going to say.

Anyway, my name is Mark Dopp. I am the Senior Vice President and General Counsel at AMI. Let me give you just 30-seconds worth of who AMI is, for those of you not familiar with us. I hope most of you are, if not everybody.

AMI does not represent every federally inspected to State-inspected establishment in the country, but we

represent the vast majority of those, the larger companies. By the way, our smallest member company has three employees. So this perception that somehow AMI only represents the big guys is, frankly, not true. In fact, something like, I think, 75 or 80 percent of our membership has fewer than 100 employees. So we can hopefully dispel the myth that somehow we only represent the big guys.

Our members, however, do produce more than 90 percent of the beef, pork, veal, and lamb produced in the country. Dan talked about HACCP. Again, for the record, it was AMI that petitioned back in 1994 for mandatory HACCP, something that took a little longer than perhaps we had all hoped for, but it came about.

I have to tell you that I joined AMI 10 years ago, April of 1999, and one of the first things that the board did, in the wake of some unfortunate incidents, was to declare food safety to be our top priority.

Every year, AMI goes through what we call our "Top 10." We come up with our Top 10 Goals and Objectives, and I can tell you every year since I have been there, food safety has always been number one, and I suspect it always will be number one because it is good business to produce safe food.

About a year or so after I came to AMI, the other thing that took place was that the board declared, voted unanimously to declare, that food safety would be viewed as a noncompetitive issue. What that means for us is that -- Bob is up here, and you are going to hear from him next, and this has happened in just the last few days -- if a member company of ours or, for that matter, if a nonmember company of ours has a problem, they are dealing with listeria issue, E. coli issue -- let's face it. Some of the smaller operators don't have the resources that some of the bigger companies do.

If somebody has a problem, they are in a position to pick up the phone and call somebody like Bob, call somebody like Dr. John Butts, who spoke at the listeria meeting a couple days ago. Bob and John and people of like nature will help answer questions. They will help walk them through to find a solution to cure the problem. Now, that is what we mean when we say that food safety is a noncompetitive issue because, again, everybody recognizes it, and you will see some information from Bob a little later.

If something goes awry in the hot dog business or

the ground beef business, it affects everybody adversely. So it is in our collective best interest to try and address that, and that is what people like Bob do what they do.

Here is a refrain that we have been hearing, to my way of thinking, excessively over the past few weeks, if not the last few months: "The food safety system is broken." With all due respect, I would, respectfully, disagree with the people who assert that.

At least I am limiting my remarks today to meat and poultry products. I do not believe the food safety system is broken, and I will talk a little bit. It doesn't mean it can't be improved because it can, and I have got a few slides on incidence and prevalence, et cetera.

If you look at the prevalence of pathogens, they have declined in the last 10 years since HACCP went into place. Generally, with some exceptions, illnesses have also declined over the past 10 years. That is not a recipe for somebody being able to say, at least to my way of thinking, that the food safety system is broken.

Here is some data. This is sort of a more general graph of some data that I think is consistent with what Dan put up. In the last 8 years, there has been a decline, a

45-percent decline, in the prevalence of O157 in ground beef. Similarly, if you look at listeria monocytogenes in RTE products, we got a 74-percent reduction. Frankly, I think that especially when it comes to ready-to-eat products and especially when it comes to listeria, there is room for some debate, arguably. I would be the first to concede that with respect to ground beef, but, when you are talking about listeria in particular, frankly, I think that that is a success story. I think most people would probably agree with that.

I started my career 25 years ago. It is my 25-year anniversary from graduating from law school this year. My first year and a half, I was in the General Counsel's office at USDA, and my client agency was FSIS. They did not call themselves a "public health regulatory agency" at that time. It was just a regulatory agency.

In the past 8 to 10 years, roughly, Dan, I would say you started incorporating public health. That is fine. There is nothing wrong with that. I applaud that. That is the right way to go.

That said, if you are going to do that, we need to look at how what we have done affects illnesses, and, again,

if you look at the reduction in illnesses, again, this is not a recipe. This is evidence that the food safety system is not broken. Incidence of foodborne illness for E. coli, the incidence rate is down 40 percent in the last -- I'm sorry. I don't have the 2008 data. For listeria, you find not as big a reduction but a 10-percent reduction.

If you go back to the slide that Dan had, I wrote this down relatively quickly, Dan, but you have got in 1997, it was 2.1. Last year, it was 1.1, and the target is 1.0 for E. coli. For listeria in 1997, it was 0.5. The target right now, we are at 0.29, and the target is 0.24. That type of reduction tells us that we are doing a lot of things correctly. Again, it doesn't mean there is not room for improvement.

Here is a slide. This came out just in the last week or so. This is CDC data. The 829 is the average number of illnesses over that 3-year period. We are talking about almost a 60-percent reduction in that 6-year period. So, again, I think that this is evidence that the system is not broken, notwithstanding what you hear some of the politicians on Capitol Hill say.

I am not the only one that seems to think this.

At a hearing on April 23, Al Almanza, who is the Administrator of FSIS, testified before the Livestock Subcommittee, an Ag Committee subcommittee, and Mr. Scott, who is the chairman of that subcommittee, his final question was, "Well, Mr. Almanza, before you walk out the door, if you were going to grade how the inspection system is doing, what kind of a grade would you give it?" Well, Al said A-plus.

Now, you know what, he may have been a little generous. You can't debate that because he is your boss, Dan.

[Laughter.]

MR. DOPP: A-plus may be a little bit of an overreach. Okay? But the point is we have done a lot of good things over the past 10 years, and I think the industry is to be commended for that. I think the agency is to be commended for doing a lot of good things, but, like I said, whatever grade you want to assign the system, there is always room for improvement -- always.

So what will enhance the inspection system? I have got a couple of ideas or one particular tool that I want to suggest, but I also want to just touch base on

another topic: Are additional performance standards necessary? Dan says he thinks they are.

You know what, I think more or different performance standards can serve a useful purpose if they are properly constructed, if they are properly constructed to achieve a measurable, useful public health outcome. AMI will not oppose performance standards that are so designed.

The flip side is if it is based on some arbitrary measure that can't be tied to public health benefits, then I would argue there is no point in going through the exercise of developing a performance standard. In fact, it might even be counterproductive.

As an example, I think I would make the argument that the existing salmonella performance standard is an example of just that. Interestingly, we see a reduction in salmonella in chickens, a notable reduction in the past few years, a notable reduction in salmonella in pork, a notable reduction in salmonella in ground beef, and, interestingly, the incidence of foodborne illness with respect to salmonella has gone up.

Where is the link? It is a fair question to ask. If we are going to have a performance standard, let's make

sure that they actually measure something, that they are tied to something that we can wrap our hands around and say this is doing something constructive.

All right. So I said I was going to suggest a tool that is unrelated to performance standards. I just wanted to touch base on that for a second. A tool for improvement in our view and something that we asked for is what I would call "test and control."

Specifically, in 2005, AMI, National Meat Association, the Turkey Federation, the Chicken Council, NAMP, Southwest -- I don't want to leave anybody out -- then-FPA, now-GMA/FPA, put together about a 15- or 17-page document -- I just put the cover sheet here -- on best practices for holding product after it has been tested. We have made that available.

We sent that, along with this little cover letter, back in, I think it was, November of 2005. This was mailed, hard copy, to every single federally inspected establishment, regardless of size, every single State-inspected establishment, basically urging, if not begging, those companies, if you have product that has been tested, we are pressing you, don't let the product enter

commerce.

Well, you know what, unfortunately, it didn't work out as well as we had hoped. This is a chart that we put together looking at the recalls for E. coli since 2003, and if you look at the number of recalls -- I don't have 2009 data up there, but, over that 6-year period, there were 65 recalls associated with E. coli. Of those, 29 were related to illnesses. That is why we don't get an A-plus. We still have illnesses. We still have outbreaks. We have work to do there. I am the first to admit it. But that means that 36 of those recalls could have been avoided if the company had held the product.

Similarly -- and this is, frankly, why I think we have a success story -- in that 6-year period, we have 80 recalls associated with listeria. Not a single one is associated with an outbreak or an illness -- not a single one. You can go back and go through the recall website for FSIS. Go through the archives. In every single one of these, you will find that it says -- I am paraphrasing -- the recall is taking place because of FSIS microbiological sampling.

What that is code for is they shipped product

after it had tested. After it had been sampled, they shipped it, and they didn't hold it until they knew what the result was.

I would argue that this is something that can be done. In fact, AMI submitted a letter to then-Under Secretary for Food Safety, Dr. Richard Raymond, in May of 2008 advocating that the agency policy change to require companies to hold their controlled product, tested by FSIS, and until the test results are known. That is something we have asked for; it still hasn't happened.

It is a good idea for two reasons. One, it keeps potentially problematic product out of the market. It is that simple. Second, if the agency and the industry didn't have to deal with the 80 recalls over that 6-year period and the 36 recalls that are affiliated with not holding tested product for E. coli, there's a lot of resources that get wasted or were wasted. It would not have been wasted had the product been held properly. That is why we think this is a good policy.

Bob made me put this up there, and it is a good point. This does not mean that we are advocating that there be increased finished-product testing. Simply put, you

can't test your way to food safety. However, again, it would be a very useful tool, and at least at AMI, we would adamantly and actively support a change in agency policy such that if FSIS tests the product, it should be held.

So what else is there that can be done to enhance the inspection system? Here is a word that is on everybody's lips: transparency, transparency, transparency. You can't walk around town today without hearing somebody talk about transparency.

Well, I am not going to talk about transparency. I am going to talk about something else that was also incorporated into the very same memo that President Obama issued on January 21. My other suggestion -- and there are other things we can do -- my other suggestion for improving or enhancing the food safety system, the third bullet point in the memorandum entitled "Transparency and Open Government" talked about collaboration.

What am I getting at here? Simply put, I have talked to people at the agency. I have talked to the Administrator. I have talked to the Under Secretary when Dr. Raymond was still in office. In the last, oh, I'd say probably since the 1994 lawsuit involving O157:H7, FSIS has

increasingly moved to regulation through notice and directive, and I would argue that that is counterproductive.

I would argue that there are a lot of smart people in the industry that are willing to work with the agency to help develop better regulatory policies that will not only enhance food safety but will also make the inspection system more efficient and will not waste agency resources.

This is a direct quote from the memorandum: "The government should be collaborative. Executive departments and agencies should use innovative tools, methods, and systems to cooperate among themselves" -- and I didn't underscore it, and I should have -- "and with non-profit organizations, businesses, and individuals in the private sector."

What I am asking for is we want to be in the room talking to the agency when they are thinking about developing new policies. Dan referenced some future activities. We would like to be able to participate.

For those of you who follow college football, I will just say this because it comes to mind. For those of you who follow college football, there is a school, Fresno State. It is out in California, obviously. The coach out

there is a guy named Pat Hill. Fresno State plays in either the WAC or one of the B's, not one of the big conferences. But his view is, you know what, for Fresno State to make its mark in college football, they will play anybody, anywhere, anytime, you name the place.

So I guess my closing comment will be we will meet with the agency and anybody else who wants to try and find a way to enhance food safety anytime, anywhere, anyplace.

With that, thanks for listening.

MR. REINHARD: Thank you, Mark, and I appreciate being here. My name is Bob Reinhard, with Sara Lee Corporation.

I will quickly tell you about Sara Lee Corporation. I didn't put it in the slides. We are a consumer products company in which, probably, most people understand. We are approximately 50-percent regulated by FSIS. The other 50 percent of our corporation is regulated by FDA. So we have experiences on both sides, under both jurisdictions.

The other thing we do is we do quite a bit of consumer products, especially internationally, Kiwi Shoe Polish, lots of lotions, shampoos, air fresheners, those

type things. So we have another part of our business, probably, that people are a little bit less familiar with that plays a big part, our coffee and tea part of our business, which they always don't think of as food.

But to go ahead and get started, I was asked to give a company perspective versus really what Mark gave, an industry perspective. So what I am going to put up is really a perspective from one company, one regulated entity that has an idea of what FSIS and what industry does together. I believe in what my title says that this is really a partnership in public health and food safety that the industry and FSIS have worked on or Sara Lee and FSIS, then, have worked on, for that matter, if we take it to a different level.

I am going to talk about company views and expectations. They won't surprise anyone on what they are. I am going to talk about common industry and regulatory objectives.

Data is a big thing for me. I am a data person. I believe it is necessary. I remember when we wouldn't collect data in the days based of what we thought regulators would do. So I think anything that gets in the way of data

is a real mistake, and so I will talk a bunch about data. I will show a lot of data, some FSIS data that maybe everyone hasn't seen. Maybe you all have. I don't know, but I will point it out. I think it shows where data can be used, how data then supports what happens.

I will focus on some major events related to ready-to-eat. Generally speaking, all of our products are ready-to-eat, except for some breakfast sausage.

Then I will talk about the future and what I think some opportunities are for everyone together to work on.

We have a mission statement. I am in the Food Safety and Scientific Affairs Department. It is like any other mission statement, but it is important that everybody understand what we do and what we try to do, and we do look for value-based food safety solutions. It is not just about throwing a lot of resources at a problem and hoping then that it goes away because you did that. It is about making sure you put the resources to the things that matter, where the value is to drive safe products.

So what is important to a company? What is important to Sara Lee? At one point in time, Sara Lee did a risk assessment on enterprise threats, what would affect

Sara Lee Corporation the most, what could potentially put Sara Lee Corporation out of business. We looked at all kinds of different things in this risk assessment: what are the international implications of Federal trade restrictions, what is the likelihood of another competitor beating us and putting us out of business, what is the possibility of a hostile takeover.

Actually, the largest threat through our risk assessment to our enterprise would be a food safety event. So it is known by Corporate America that food safety is very important. We offer safe and wholesome products, and we want our consumers to know that. So protecting our consumers and maintaining our brand value is the number-one thing of what we want to do every day. It absolutely comes first, from the board room the shop floor.

We have to meet our customer expectations -- our customers being not the consumers, but those, then, that go forward and run their business and sell our products, they have high expectations for food safety -- and mitigate or eliminate risk to ongoing business operations.

One thing that FSIS is very successful in -- and sometimes we get caught up in talking about what I will

describe as the lowest common denominator and making policy to the lowest common denominator in the industry -- in actuality, FSIS has the ability to suspend operations to withhold the mark of inspection. That is why they are all in business. That is why they all do what they do.

Dan mentioned the Rules of Practice, which I didn't put in my list for the past 15 years, the big things, but it is a big thing. FSIS using that tool effectively in the field when they need to is pretty important, and that threat of business and ongoing business is probably one of the largest tools they have to get accomplished what they need if companies aren't meeting the food safety expectations that everyone else would expect a prudent company to meet.

We have a lot of global influences, and I don't want to underestimate the global influences that we have. We are greatly affected by the World Health Organization and Codex. We do things internationally. We do things internationally as a company.

As we go forward, as a rule, Sara Lee tends to model our systems worldwide off of USDA FSIS expectations. So our food safety systems to model off of that, but, when

you go international and you go and put things in, Codex, World Health Organization, all of those things, their systems, their HACCP-based processes, we use in addition.

Our trade associations have a great influence on us, both domestically and internationally, non-government organizations, which a lot of people in this room are a part of, and then, finally, our customers and consumer wishes -- and this is not in any particular order of what is first because I would probably say the last two rise to the top a lot of the time.

On the regulatory side, we obviously have FSIS and U.S. Department of Agriculture and FDA and HHS. There are a couple more, CDC, which was already talked about, so I think everybody is familiar with. The Consumer Product Safety Commission regulates the safety of toys, coupon inserts, those type things that we may do. So we have quite a bit of interaction with them on different times, depending on what we are doing, and FTC obviously in regulating advertising and what kind of claims you make about your products.

So this is my first slide about really the topic today. I really feel that FSIS and industry have a common goal, and all I did on this slide was go down through -- and

I will talk to it -- the different things that we want. First and foremost, which everybody will mention every time, is to protect public health, but, secondly, the industry and FSIS are both required to maintain consumer confidence.

Consumers having confidence in the products that are offered domestically -- meat products, even FDA-regulated products, whatever they are -- both the company being their brand, their product category, or their industry and then the regulatory agency being their industry and how their regulatory process works, it is pretty important. It ranks up there as one of the things we all try to do all the time.

We both engage employees in the process. This goes both ways. I have been in a lot of plants. I spend the vast majority of my time in plants, even though some people feel like they see me here a lot in the last few months in Washington, D.C.

Employees as general -- or I will say even as a rule -- employees in plants, inspectors for FSIS in plants want to know and assure they are making a safe food product. There are not any of them that want to take shortcuts and not do that basic fundamental thing as a rule. So, when you

go out and you engage those employees, when you meet with inspectors in plants and you go over what expectations you believe there are for FSIS, what expectations there are on your establishment, depending on what you are talking about, the synergies that they have, the things they have in common, the working together, go a long way in assuring a safe food product.

But going just down through, assure processes are validated to produce safe products for the company, for FSIS to verify that processes in Federal establishments are producing safe products. For a company, you have to establish a system to monitor and maintain control in that process, and then, for FSIS, they have to verify that you are maintaining control of your process.

So this is almost like, without me reading the whole slide, a hand in glove. It goes together very, very easily. The company, the establishment is held responsible for their food safety systems. The regulatory agency, FSIS, verifies those food safety systems are working and all the different steps and processes.

It is about data and understanding what that data says and that that data states that you have what you need,

whether it be individual data from an establishment or total industry data, some of which I am going to show here in a minute.

Risk-based sampling with public health outcomes. I am going to now switch, and I am going to talk a little bit more about ready-to-eat products, specifically listeria monocytogenes, an example to me of how FSIS and how the industry work together.

The timeline of major events for a listeria monocytogenes, I have another presentation where I go through each one, almost as a line item. I think it is like 16 slides, and you go through every event. But this is a general idea of what happened going back to 1985, as on this end of the chart, followed all the way up to 2008 when people started to focus on listeria monocytogenes and what happened.

There were some big events. The science changed, and we went to PFGE patterns, and we were able to understand common sources. I think that is pretty important but, also, the things that USDA and the industry did then to mitigate it.

Here is the business case for food safety, and

this is just an example of a product which is going across in the blue lines. In the food industry, growth in the industry is small. It is relatively small, anywhere from 1 to 2 percent in any product category. It doesn't matter what there is. It may follow population growth, but otherwise consumers aren't going out next week and eating twice as much food. They will eat the same amount of foods. They will just trade in between the different categories of what they want.

When there is a food safety incident in an area, in a product area -- as you see right here, this is sliced lunch meat category. This is a recall in December of 1998 and January of 1999. The entire category drops. The entire category can drop in this example from 1.5 to 2 percent over the 2 months to 3, 4, 5 percent. If you hear the peanut and those issues that have gone on, it has even been more than this.

When consumers lose confidence in the category, the entire industry loses. The entire industry falls and has trouble, and, obviously, we are in the business to, one, make a profit for our stockholders, to make sure that we are there for our employees who want to go to work and continue

to make our products. So there is a big business case here, and, actually, this is an old data. If you look at more recent data, some of the more recent recalls, industries are devastated now by recalls. Consumers have really gotten into their habits of if there is a problem, avoid it, and when they do that, the entire industry fails.

So what does that mean? Well, it means everything needs to be focused on preventive. There is a part of reactive that I am not going to get into that needs to happen if there is an event, and I will talk about it maybe a little bit when I talk at the end, but being preventive is where all the reward is. It is where all the resource needs to go, those type of things.

So some major events, Dan already talked about them. So I am not going to go through them all. There's five or six here. Dan talked about all of these. So I don't think there is anything new.

I did want to talk about there was an AMI listeria training course that started in 2000. I believe we have done 22 of these at this time now all over the country. A couple thousand different establishments have attended, employees, and in October 2001, food safety being a

noncompetitive issue, it was really a watershed mark. It is where the industry said it is time to step up, step forward, and for everybody to work together to solve their problems.

This changed what I did for a living. It really changed where I spend most of my time. I spend quite a bit of my time on non-Sara-Lee-related issues but industry issues trying to help make sure that the industry is driving food safety and that we don't have a problem.

So what is necessary for FSIS to be successful? I have seven things listed up here. Three of them are the same, but I think it starts in the beginning, and sometimes steps are skipped, especially when you try to skip down to six, which is appropriate policy, before you do the other five. I believe collaboration in the first step, communication with stakeholders is critical, and then it is about going out and collecting data. You have to have data at this point in time, whatever you are looking at, so you can then communicate the results of that data again with stakeholders and understand how it was collected and then do your risk assessment and your risk management.

I believe FSIS, and not FDA, is required to do a risk assessment with all rulemaking. I know it is

burdensome. Rulemaking is burdensome to the agency. I know a lot of people wish it could be much more streamlined, but the reality of rulemaking and the reality of the way things work, it is pretty important to make sure you get the right information based off of what you are trying to do.

Mark showed some information on salmonella. I don't know why -- if I did, we would certainly try to tell you and go address it -- that you can have such a reduction in an industry but then increase in illnesses, but it has occurred. So we have to go try to figure that out.

Then, after the risk assessment, I think it is important again to communicate with stakeholders. Then appropriate policies and expectations can be laid out. Everyone can quickly buy into them because they have been included through the process. I believe this speeds up rulemaking, then, as they then go to the next step, and you can then put the expectations out for your inspection resources and be able to answer all those hard questions that sometime then come from the field and training and outreach for those that aren't able to participate in all the parts.

Well, it starts with data. I think FSIS, as Dan

mentioned this -- I am going to show you a little bit different numbers than he did because I actually think they collect more samples than he showed. OPHS has projects to collect data on the industry. I think it is very important when you go to set a policy that you understand what the data is and what is needed.

First of all, you can verify that the industry is meeting regulatory expectation. This is for those organisms that have zero tolerance or nondeductible limits as far as regulatory requirements, but understanding trends and doing the risk of what is of value is very important, and it is often overlooked because it is boring when you go sit in these risk assessment meetings or you work on a risk assessment process. It is very number crunch-oriented, and it is very hard for people to stay awake for so long to get through that entire process, but it is very important.

FSIS has four project codes now for ready-to-eat products. I am not going to go through these all, but, anyhow, the first one is RTE001, and that has to do with sampling for those products most likely to contain listeria monocytogenes. They do about 10,400 samples a year here. Then they have ALLRTE where they do another 4,420 samples

per year. This is just all ready-to-eat products regulated by FSIS. They used to have some exclusions. They took the exclusions out, and so this is all products samples by FSIS. They do IBTs where they go in when there is a cause for verification, the establishment is meeting the requirements, and then they do a routine LM, routine listeria monocytogenes sampling, where they sample product, food contact services, and non-contact services.

This data, this information gives FSIS an idea of how they are doing. To me, this is their scorecard. This is where they say we know where we were, we know where we went, how are we doing.

So I have a slide that shows how they have done, going back to 1990. I know sometimes there have been differing opinions on whether or not this data directly relates to public health or any of these type arguments. The reality of it is this is thousands of data points each year, going back for the past 19 years, and there is no question that the slope shows a reduction. So whatever the exposure was in 1990, the reduction to 2008 is tremendous. This is really a success story.

The thing that goes along with this data, Mark

already showed this, the 74-percent reduction, but these are the recalls. Mark brought this up for a different reason than I am going to bring this up. These are the recalls since 2003 due to illness investigation. The second line up there is zero. In listeria monocytogenes, there hasn't been a recall due to an outbreak since 2002. There have been two investigations, potentially, dealing with FSIS-regulated products on LM, 2005; a single death last year, 2008, which I don't know if it was ever called an outbreak or not, but I know there was a single death. Those are the only two events since 2002.

If you looked at this slide prior to 2002, the volume of product that was being recalled, the major outbreaks that were going on approximately every two years with these huge volume recalls in between, it was unbelievable. We have really changed how things work with listeria. The industry, the agency worked pretty hard on this. There were some watershed things that happened here.

FSIS, to support this early in 2003 and 2004, came out with their Interim Final Rule on listeria monocytogenes. It did encourage testing. It did, to some extent, give reward for testing and for going forward and finding

problems and eliminating them before they occur. So this is the one thing you can see.

Now, there is some new data out that I will mention very briefly. There are still positives for LM in ready-to-eat product. I showed you. 0.43, I believe, was '07 or '08, 1.43, 1.42. FSIS started to do most probable numbers, which is actually count how many organisms there are in the product and what is likely to cause illness.

If you look at calendar year 2007, all of them are less than 50 CFUs per gram or MPNs per gram, which is an estimate of CFUs, but the vast majority, 71 of the samples, are less than 0.3.

In 2008, they changed. The test level of detection went from 0.3 to 0.03. This is just straight numbers, the samples, as 23 are less than 0.03, the vast majority less than 3. There are two, one that says greater than 30 down there. There were five samples. Actually, I know that four of those samples were taken from a single establishment on a single day. Two of them had MPNs, I believe, of 93 or 98 -- I can't remember which one the MPN calculates to -- and two of them had 42 MPN per gram, but, other than that, of all the positives FSIS had, this really

supports why we are not seeing the outbreaks in the field.

Why aren't they linking meat and poultry products to outbreaks? It is because the industry has reduced the incidence to a very low level with FSIS, and the levels in which finished products then test that are positive are very low, potentially below the levels needed to become infected or to have illness. Now, I am not going to say that is always the case, but a lot of times, that is the case, based off of these numbers.

That is the same thing. Other examples of success, just real quickly, salmonella, I do want to mention that in 1997, because we do do poultry, we do do turkey slaughter, FSIS set guidance at 13 positives for 56 as a performance standard. This performance standard was set just because this is often debated.

The number 13 came from what would -- if FSIS were to take a sample of 56 samples, 80 percent of the time if a company is meeting the performance standard, based off of the number 13, they would pass; 20 percent of the time, even if you were meeting the performance standard, statistically you may fail, the performance standard being 13.6, I believe was the number at that time. So this was really set up,

instead of a 95.5 percent, which normally would be set up, it was set up aggressively that even if you were on the border of the performance standard, 20 percent of the time you would fail when FSIS has set.

There are 36 establishments currently. Actually, I think that is 35 because I believe one closed. In turkey, of those 35 establishments, 34 are now Category 1, which means they have less than 6 positives. So, if you go from 1997 all the way to current date, 34 of the 35 establishments that slaughter turkey have controlled salmonella to the point where they are Alternative 1, which is something the agency asked for a little over a year ago.

There is a new baseline study going on now. I know we expect data in July or they will finish in July. We will get data eventually, and if we speed that up, that would be great.

Here is just an example of the data. When FSIS talked in 2006 about addressing this, you can see where the industry dropped the numbers. One of the things that went on here was the agency potentially talked about food safety incentives, meaning if you could control salmonella, you could potentially run your line speeds a little faster.

Those things do work. I don't want us to lose sight of those. If there is a risk-reward scenario that can be put together, I think people should pay attention to it.

FSIS has done a pretty good job in outreach in a few of these key areas, but I am going to skip over them fairly quickly because I want to talk about the future.

The generic HACCP models, the programs, you know, I mentioned data. These are the risk assessments that FSIS has done in the past few years. There have been some big ones, BSE, avian influenza, E. coli O157:H7, poultry slaughter which is the salmonella, LM, risk-based sampling, and shell eggs, they did a risk assessment, but focusing on the future, I think it is important for the first point that I put up is that we look at attribution data, if we really want to protect public health.

Now, unfortunately, this is very easy to say, and it is very hard to do. There are two things that make this difficult. One, for all those people who would have to come together to do it across jurisdictions and different agencies, including State and local who carry a lot of the data needed, what do the questionnaires look like, what are the results of the food history, those type things, it is

hard to do.

Secondly, from a government agency standpoint, attribution data or collecting and understanding attribution data doesn't make probably the top 50 things on their list to do related to what their agency is responsible for, but I think as we go forward, as a group of stakeholders, as a group that wants to collaborate, coming up with the way to do attribution is important, not to say that expert elicitation to estimate attribution or any of those other things aren't acceptable. They are what we do now because sometimes you need to make decisions quickly based off of needs for policy, but attribution is there.

Using the data and utilizing results to really go after the things that have public health outcomes is important. I think that there are places where there is obviously some waste in resources, whether that be industry waste or regulatory waste. I think breaking away from some of the old things that we used to do that really don't have a public health outcome is needed, that really have a place to leave that responsibility possibly to somebody else.

I put it up: Establish risk-based inspection system. I almost did not put the word "risk-based

inspection," but based off of FDA and all the times we have used the word "risk-based inspection," I think the term is okay again to talk about risk-based inspection.

But where does this matter? Risk-based inspection to me is not about reducing inspection. It is not about reducing workforce. It is not about any of those things that people tend to throw up with risk-based inspection because, to me, risk-based inspection is taking these critical resources that you have, doing the same number of inspections with the same number of people, and putting them where they can have the greatest effect on public health outcomes.

So, if you need to move someone around, if they need to go do a different task, that is where risk-based inspection is a value, and I think sometimes we get caught up in that. I know this term, a year ago, I probably would not have put it in presentation. I am putting it back in the presentation because I think we can discuss it at least. It is something that we really need to look at because there is value here. There is a lot of good things that can be done, and so risk-based inspection is something in the future we need to look at.

We always have to remember the small and very small. I know sometimes they get left out. I think it is important to Sara Lee Corporation that they remain a part of our industry, that they remain our suppliers, that they remain involved. They offer great products and services to the industry, to consumers, and so sometimes, when conversations go on, they are forgot, and I think we need to always remember them.

And food safety incentives work. Food safety incentives are those things that give a risk and a reward when it comes to implementing and executing. Please remember food safety is the reward in and of itself. I believe that.

I also believe that when you get to utilizing data and results up above, which is my second point, and you then tie that down to, okay, how can we do incentives around that data and results, were there tasks being performed that aren't necessary if A, B, C are done, it really needs to be looked at. I think it is something that offers great potential for everyone.

Protecting health requires commitment of all stakeholders. I am one of those people that believes in

transparency. I believe everybody should be together in the room. We are open as an organization in what we think, what we think always isn't right, especially if it comes from me and it is my opinion, but we are open to at least talk about it and try to come up with the best way to do it.

We all have common goals in protecting public health, and data, data is one of those things that tells us how we are doing. It is the result in the end that matters.

Mark did put up that product testing isn't the result because product testing doesn't ever lead me to a place where I can comfortably sleep at night and feel like I tested enough to know a product is safe or I sorted enough to know a product that wasn't safe isn't in the product I said was safe.

Data on how your processes run, how you control, how you validate your food safety systems, this is where all the reward comes from, where you find out what is going on.

With that, I am going to turn it over to Bob, and I will answer questions later.

MR. HIBBERT: Thank you, Bob, and thanks. It is nice to be here. I appreciate the invitation.

I have been asked to give sort of a small business

perspective, which Bob reminded us we shouldn't forget, but as Mark indicated, AMI has that covered anyway. So I probably should just sit down and shut up, but that wouldn't be any fun. I used to use that line myself a little while ago.

The existential threat that Bob talked about that would face a big company with a food safety concern, in some ways, from a smaller company perspective is greater because the smaller company, by definition, doesn't have the larger corporate treasury to drop on and where they might weather such a storm. The smaller company is not a multi-plant operation that can readily move production around, should one facility be closed. So, to the extent that that smaller company is living closer to the bone, closer to the edge, its ability to remain in compliance, to turn out a safe product, to avoid regulatory incidents of any sort is, in some respects, even greater.

It is fair to say when HACCP and that whole structure was being rolled out, there was a fair amount of anxiety within the community of smaller establishments that this was going to be very damaging, and there is truth to that in the sense that whenever you increase sort of a

regulatory burden, particularly one that involves innovations and more science and more equipment and so on, that that is threatening from a small business perspective, where you don't have the possibilities, the economies of scale, and so on.

In fact, it is probably fair to say that the changes that FSIS brought on probably accelerated some trends, particularly that were rapidly moving along anyway; for example, in the slaughter industry. There are exceptions but to not be a small player and to also not be a smaller company that is trying to be all things to all people.

I think on the whole, where small businesses have adjusted and thrived and prospered under this system is by getting more focused on what they do and doing that, doing that with, in many instances, an improved level of control, and then they have been able to take advantage of some of the inherent advantages that small businesses have in most market places, being, in some cases, closer to the customer, being able to adjust more quickly, be more nimble, those kinds of things.

So I think on balance, most small businesses have

made that adjustment and have moved on and done all right within the system.

In terms of FSIS, generally where it is and where it has been, I mean, I find it gratifying, having worked there a long time ago. I have some alumni loyalty still to see what is happening, and some of it is sort of a backhanded outgrowth of the focus on FDA and the problems there, but people are sort of saying, "Hey, gee, what these other guys are doing over there is pretty good," and they are right.

In fact, I may be the only person who is sufficiently aged to have worked for FSIS when it was FSQS. Extra points for anybody here who knows what the "Q" versus the "I" meant. We will cover that later.

But why? First of all, obviously, the HACCP model itself makes sense. It makes fundamental sense to say to the regulated industry, "You take responsibility for what you are doing. Look at it in a systematic way. Set up controls. Set up measurements systems, and focus on continuous improvement." That system doesn't mean everything has been perfect, but the fundamental logic of that approach is there.

The other basic distinction here is, obviously, FSIS has the luxury, relative to FDA, that it has quite a bit of resources. It has more bodies that it can put on the field to deal with this issue than some of its colleagues.

Beyond that, I think it is fair to say that over the past several decades, what you have had is you have had a well-managed organization with lots of talented, capable people doing their jobs, and what you have also had that has been touched upon earlier is I think there have certainly been many bumps on the road, but I think what has evolved is something of a virtuous cycle between the private sector and government where there has been a collaborative effort to enhance food safety.

I think there is data to back that up. There is anecdotal information to back that up. Again, that doesn't minimize bumps on the road that I am familiar with or have been involved in and others have as well, but I think that is a fair general statement of the reality and how it has evolved.

Let's turn that around and talk about the future and what might be done better. One that has been touched upon is the question of resources, the question of a better

allocation, more logical allocation of resources. Again, it just makes basic sense that if my job is to oversee the meat, poultry, and egg products industry and somebody gives me a budget of a billion dollars a year, give or take, and gives me lots of employees to get that job done, that I am going to do a better job if I have some flexibility in terms of deploying those resources and not be locked into making sure that everybody in this room has one of my people in their facility every single day.

The history of that issue has demonstrated this is one of these areas where the perfect has always been the enemy of the good on this issue.

Another piece of historical trivia, there was something called the Process Product Inspection Improvement Act of 1986 which gave FSIS, by statute, clear authority to do this. It also, for better, for worse, had a 5-year sunset provision attached to that law, and the sun set before it ever rose. It was never implemented, and they said the heck with it. A variety of factors killed that off, including lots of external opposition and internal confusion as well, but it never got done.

Obviously, in the past administration, that was a

priority. It was something specifically near and dear to the heart of the former Under Secretary, Dr. Raymond, to get somewhere on that. He wasn't able to get where he wanted to go, but the seeds were planted in terms of the data enhancements that the agency is working on, and one would hope that those data enhancements and the models that they are presumably going to generate some months hence, they are going to get it perhaps to very, very good.

It is going to still be not that difficult to say it is not perfect, I got a problem with this formula, I have got to worry about this data or the other. The forces could well coalesce to kill this thing once again, but I hope that doesn't happen because it shouldn't happen.

If you believe, as has been a strand of this discussion, that the agency in the broad sense knows what it is doing, you ought to be willing to give those people some leeway and some authority to move their people around in a more sensible way.

I think another area where we could see improvement is in the broader area of traceability. This spills into some other issues that extend beyond the agency's jurisdiction. For example, animal identification,

which is not in FSIS's hands, it is basically in its sister agency, Animal and Plant Health Inspection Service, because of the animal disease component of that issue, that surfaced pretty dramatically with the BSE issue a couple of years ago, at which time the agency and the Department committed unambiguously to a mandatory meaningful identification system.

It has not happened. APHIS has now embarked on a series of what they are terming "listening sessions" to go talk to folks about that. I would suggest those are really procrastinating sessions.

Everyone knows that there is an element of the producer community that is adamantly opposed to that. That is fine. That is their prerogative, but all the listening sessions in the world aren't going to change that dynamic, if the Department wants to do this -- and to tie this back to FSIS -- the collateral benefits as they attach to food safety, be it tracing illegal residues, possibly even tracing sources of pathogen are there, but that has got to get done.

This is an area where I think the public interest community could play an effective role because of this

impasse I talked about. We have this long-standing impasse where the political dynamic is the producers are going to get victimized by the packers and food processors, and we can't let that happen. I think the public interest, you might want to take a harder look at that issue and decide that it might want to weigh in a little bit more heavily.

Two other points I would make in terms of what could get better, I think the general issue of clearer and more coherent enforcement is important. Put yourself in the shoes of the hypothetical company. Let's say for my purposes it is a smaller company. They have their HACCP plan in order. They have an inspector coming in every day. Everything seems to be going fine. The mark of inspection is being put on that product every day. The records are in order, et cetera, et cetera. Then, one day, a food safety team comes in, spends a month in the plant, and all of a sudden, there's lots of terrible things wrong at that establishment.

Now, the food safety assessment team may well make some very valid points. They may find some just flat-out mistakes in the system, but you inevitably get into an area of subjective judgment, and FSIS says, "Oh, no, no, no. We

are scientific." Of course, this is subjective; these are judgments.

In some of those contexts, some of the better review types -- and the reviewers tend to be dedicated, capable people -- have acknowledged that they see this, that, yes, this is kind of on two tiers. Some of what we are doing is really suggesting enhancements, sort of best practices or whatnot, but it is more up to you if you want to do them or not. God bless those folks, but not everyone delineates things quite that clearly.

I will use the sports analogy too. It is kind of like what baseball players always say, "I can adjust to a high strike zone, a low strike zone, or whatever else, but I got to know from the umpire what the strike zone is." Hopefully, this will shake out over time.

You can almost hope for -- and this would require FSIS to sort of organize things a little better -- sort of a common law of environment almost to evolve where it is sort of pinned down a bit better, okay, based upon the 20 intensive reviews of this type of operation we have done, these are what we consider to be practices you should be doing. The agency is reluctant, I think, to pint itself

down that way, but, if it is going to be drawing those enforcement distinctions in the plan, I think some of that over time is necessary and would be helpful.

The last point I would make, it sort of ties into this and ties into Mark's final point, which I would agree with and expand upon. It is the question of sort of greater transparency and collaboration on policy-making.

I would even take it a couple steps further. I don't think it is simply a question of sitting down with people. I think in many instances, it is a question of actually the agency being more willing to engage in the discipline that is required by informal notice and comment rulemaking.

Mark mentioned this evolving in part from the E. coli notice. I would also point to the HACCP and pathogen reduction regulation itself. There is a certain mind-set within FSIS that sort of thinks in terms of the HACCP regulation being done, that is the only regulation we ever have to do; that everything we now do can be characterized as an interpretation of said regulation. So we never have to deal with all of this nonsense of drafting documents and notice of comment ever again, and that gets, in my mind,

stretched up to and, in some cases, past the breaking point.

Part of that is a pure legal issue, which I won't bore you with, but setting the pure legal issue aside, it is also a common-sense, good government issue. If you look back at the logic of what is in the Administrative Procedures Act with regard to informal rulemaking, it is a pretty simple logical -- what it basically says is if the government is going to impose some new obligation on someone, what it is supposed to do is think about it, write it down, publish it, say why it thinks what it thinks, get back responses from people who are going to be affected or are concerned, take those responses into account, and then make up its mind and explain its final decision. Look before you leap, and do it in a structured way.

I am not suggesting that the agency needs to be tied down with everything it does with this, but that process makes basic sense, and if it were engaged in more often, we could avoid some of the stuff that we see with, oh, there is a notice that came, how about this, well, yeah, maybe we can do some Q&A's and clear that up and so on and so on, and on and on we go.

I think if the agency could get pulled back in

selected circumstances to that type of discipline, I think it would be to everyone's advantage.

With that, I thank you for your attention. I think it is time for the break, and then we will start with the next panel later on.

Thank you.

[Applause.]

MR. WALDROP: Thank you very much, gentlemen.

Let's take a 10-minute break, and we will meet back here at 10 after 3:00, and then we will go to the next panel. So thank you very much.

[Break.]

MR. WALDROP: If everyone could please take your seats, we are going to get started again.

Thank you very much. I hope everyone had a chance to stretch your legs and get something to drink. We are going to move to the next panel. So, if the panelists could please come up here to the front.

I am going to introduce the next panelists and then let them come up one by one to give their presentations.

We are first going to hear from Maria Oria. Maria

is a Senior Program Officer at the Food and Nutrition Board at the National Academies of Science. She is the study director for food safety-related studies at the Food and Nutrition Board and recently coordinated the work of the Committee on Review of the Use of Process Control Indicators in FSIS Public Health Risk-Based Inspection System, and she is going to tell us a little bit about what came out of that committee. She is also currently directing a study to review the role of FDA in ensuring safe food. So she is covering both sides of the food regulatory system.

Following Maria will be Barbara Kowalcyk who is the Director of Food Safety for the Center for Foodborne Illness Research and Prevention, an organization she founded. Barbara became involved in foodborne illness prevention in 2001, following the death of her two-and-a-half-year-old son, Kevin, from complications due to an E. coli O157:H7 infection. Barbara has extensive experience in food safety advocacy and has served on USDA's National Advisory Committee on Microbiological Criteria for Foods since 2005 and currently serves on two National Academies of Science committees.

Finally, we will hear from Stan Painter, who is

the Chairman of the National Joint Council of Food Inspection Local Unions that is affiliated with the American Federation of Government Employees, AFL-CIO. The National Joint Council represents some 6,000 non-supervisory inspectors who work for FSIS. Stan has been an FSIS inspector for nearly 23 years and has served as the Chairman of the National Joint Council for nearly 5 years.

So I will turn the program over to Maria.

MS. ORIA: Thanks, Chris, very much, and good afternoon, everybody. I am very happy to be here and have a chance to present to you some of the recommendations the National Academies committee came up with in March.

For those of you that don't know what the National Academies is or does, I don't have any slides on it, but, basically, we are a non-profit organization, and we give advice to the government. And as part of that advice, of course, food and nutrition is a big part of that.

Last November, FSIS contracted with the National Academies to put together a standing committee on the use of public health data. So this committee had as a task to identify issues where the National Academies could provide recommendations, and as part of the work of this committee,

since November we have been conducting three different studies in parallel.

These are the two topics that were really the focus of the three studies. You can the see the word "risk-based" appears in all of the titles. I know that this is a hard term, but I am going to be using it over and over again because it was really the focus of these committees.

The first committee did a review of the methodology for risk-based surveillance of incomers activities of FSIS, and incomers include, for those of you that don't know, activities that FSIS does after poultry has been processed and before it is consumed. So it includes restaurants, institutions, warehouses, transporters, et cetera.

A second set of studies were done on the proposed risk-based inspection system by FSIS, and this topic was divided into two different areas. You will see what the rationale behind that was.

One of the areas of committee review was on the use of process control indicators, and the second area was review on the use of public health attribution data.

I am going to be talking mostly about the use of

process control indicators because that is the committee that I was involved with, but I was just going to say a few words about the other two committees and what they came up with.

So, just to put this in perspective, when it was mentioned earlier, the number of establishments that FSIS regulates, I think it is like 6,000 or 7,000, a number like that, and the number of inspectors that they have in order to inspect these establishments, which is somewhere around 7,000 also. To compare it with these activities of FSIS, we are talking here about more than 700,000 establishments and only 10.8 full-time employees. So the level of activity is a lot less, but, nevertheless, they wanted to have a system that is also based on risk and asked the Academies to review it.

So what FSIS was proposing was to first divide all the businesses in certain different types, and this was based on what kind of products they deal with, if they only involve storing them or if they also transport them and things of that type.

Then the FSIS proposed to use five different factors in order to kind of categorize these establishments

into a higher risk or a lower risk, and based on this categorization, they could survey them more often or less often. So the risk factors are there, inherent hazard, food defense, vulnerability of the establishments, the volume that they produce, then the consumers' susceptibility to foodborne disease, and then surveillance by other authorities.

To me, one of the key recommendations that the committee came up with was that last month the surveillance by other authorities really needed to be a major factor in inspecting these establishments more or less. What came through after the committee was doing their deliberations was really FSIS doesn't have a good grasp of what other State, local, and Federal authorities are doing in establishments. So, in order to really target their few resources that they have, the first thing that they need to do is to see if they are being inspected by another authority, so they don't duplicate the efforts to begin with.

So this was the suggestion of the committee. It was that instead of putting all the factors and giving all of them the same weight, the factor that really needs to

have the most weight is the surveillance or inspection by other authorities, and then, once you figure out which ones are not inspected by other authorities, then you start putting in the rest of the factors and categorizing the establishments in that way.

It is a very short summary, and I am sorry I have to keep going because I have just been given 15 minutes. If you have more questions, I will be happy to answer them later.

So I am going to, like I said, focus more on the committee that was doing a review of the use of process indicators in the FSIS Public Health Risk-Based Inspection System.

This is a little background for you. I am sure you all are familiar with this because FSIS has been working on this for a long time already, and they actually have gone to the public for feedback, and they have been improving their proposal time and again. So it is nothing new, but just to give you a little background, what FSIS is proposing to do is to take the inspection resources and allocate them based on risk to the public.

In order to do this, they have proposed a number

of indicators of process control that basically measure the performance of those establishments. Further on, you will see that they are also proposing to use two metrics for public health impact also.

We are meeting to do this in a very, to use the same word, transparent manner. They wanted to make this proposal to really have a very good basis and clearly dealing, like it says there in the slide.

So I took this figure from the proposal itself, and it really depicts what FSIS was trying to do. They identified two sets of different criteria, and like I said, a first set of criteria are indicators of process control. The committee thought that it was unfortunate that they used this term because indicators of process control are applied usually to statistical process controls. One could misinterpret this term, and you will see some of the recommendations referred to the use of terms. What these criteria could do would be to rate the establishments in terms of how well they are performing.

The other set of criteria relate more directly to public health impact. So they identified two of them. One could be volume. Of course, the more volume of product you

produce, if there is a problem, the more people you are going to affect, and then the public health attribution, which is based on the committee's comments, they thought it is a great idea but maybe not ready for prime time yet. I will just give you more details.

To go on, how is FSIS proposing to inspect these establishments in a different way? The idea is to characterize the establishments according to level of inspections. So there could be a LOI(1), LOI(2), and LOI(3), according to how well they are performing. LOI(1) are the establishments that are doing the best, and then LOI(3) are the establishments that are either not compliant with some of the regulations or doing worse than their peers. According to that categorization, they would be inspected more in depth or more often.

So the committee's charge was really to take a look at the indicators of process control that FSIS had proposed and evaluate if they are really appropriate for the purpose and also evaluate if the data that FSIS had used was appropriate and if the analysis of the data is appropriate.

So I will let you read them a little bit, but you can see that some of them relate to finding pathogens in the

product. They relate to the rate of noncompliance reports that an inspector has written for an establishment, enforcement actions, public health-related recalls, and patterns of salmonella virus that are related to public health, and then whether or not the establishment has been put in what is called "STEPS," which is a database for tracking E. coli O157:H7 positive suppliers of ground meat.

What I have seen is that this list was actually bigger, like say a few months ago, and then because of public comments and others in the food sector that have commented on this proposal, some of the indicators have actually dropped. So I have to say that by the time we actually looked at this proposal, it had already been reviewed by others. One could see the selection of process control indicators was actually justified at least -- that it wasn't proven, that is what I meant, the proposal.

Okay. So some general findings that the committee commented on its report, in general, there were very encouraging to the agency. The praised the work of the agency. They recognized that to actually develop a risk-based inspection system, it is a tremendous task. It is very difficult to collect data. It is very difficult to

actually make sense of what kind of process indicators one can use and which ones of them predict that something is going to go wrong in the future because this is really what you are trying to do.

They also were encouraging the agency to continue having a dialogue with the public and the sectors that are involved with the industry, with consumer groups, and it was also very pleased to have had the opportunity to do this review. So there were very positive comments in general to the agency for having engaged in this kind of public dialogue and in the process itself.

Also, they thought that in general the use of process control indicators wasn't a good idea. Now, the details of it, of course, is where the devil is.

Also, in very general terms, the committee, not only for this report but also for the other two reports that had to do with risk-based inspection systems, found that the proposed system lacked some clarity in the writing. So FSIS had not articulated very well the purpose, had not articulated very well the basis of selection of the process control indicators, and, also, they hadn't articulated very well the analysis of the data and what it meant. So there

were a few things that really require a lot of dialogue with FSIS for those reasons, because of lack of clarity. So that is something that really the committee encouraged the FSIS to continue improving it.

I am going to talk a little bit about some of them. In terms of the description of what they call the "algorithm" on the scientific basis, the committee found some problems in understanding that terminology that FSIS is using, and an example of it is the use of, like I mentioned, process control indicator," which is a term that is used mainly for statistic process control and in this context really makes a little bit less sense. So it would have been great to explain really what they meant by "process control indicator."

Then the committee also found that there was the same weight being given to all process control indicators. It may be a good consideration for the future to be looking at those and see if really all of them do have the same weight, or some of them might be more significant than others, might have more public impact than others.

Okay. A few other comments, they would like to see some improvement on the level of inspections and how the

agency is meaning to use them. They felt that the level of inspections weren't really well described in the report, in the proposal that we saw, that there wasn't really any explanation for how or when an establishment that is put in a Level of Inspection 3 goes to a Level of Inspection 2 and then to a Level of Inspection 1. So all of these details that I would say they are very important for an industry to know how they are going to be looked at were lacking. So the committee was asking for those details also.

Okay. Then, on the analysis of data that FSIS has used, this was a problem because -- in the last panel, we heard a lot about the need for data, and so this becomes a problem when you are trying to devise a risk-based inspection system, especially if you wanted to be data driven like FSIS wanted it to be. The lack of data was really a problem.

You can think of it from a different perspective, which it can be very good that you don't find any pathogens in your product, so what really is an improvement for food safety, and it is a great thing that we don't have as many salmonella levels, for instance, or that we don't find E. coli, and these trends that we see there, they are

decreasing in the detection of pathogens, but when you are talking about process control indicators, you actually want to have that data. So the key is to find an indicator that would work for them. So that was a problem that was found in basically all of the process control indicators that they proposed, except for two of them.

So, to compensate for the lack of data, they use a data analyses that is called "Lift Analysis," which is very crude, and it can actually give you relationships, even though the frequency of data or the frequency of events is very low. The committee thought this was a good idea because, if you are using more complex data analyses, you don't find relationships, then you might use something that can take that infrequency.

So one of the recommendations that they emphasized was that there could be a need to actually collect more data, so that these relationships are easier to find.

Especially, the committee commented on the need for collecting data that has been purposely generated with a risk-based inspection system in mind. What FSIS is doing at the moment is using the data that they already collected because of their regulatory programs, but perhaps they

should think beyond those regulatory programs and actually collect data for the purpose of the risk-based inspection system.

So, just going on to some of the indicators, the use of pathogenic organisms and the use of salmonella verification testing, that was, like I said, the limitation of using them as control process indicators is the infrequency of events, which you actually want. You want the trend to be going in that direction, but, for this purpose, it is not really a great indicator.

Another problem with the report was that FSIS did not provide some of the underlying assumptions that come with the methodology that one uses with the pathogen detection methods, but, in general, they thought the use was appropriate. It just makes sense to be using pathogenic organisms as an indicator organism. The problem is that even with data analyses such as Lift Analysis, these relationships really weren't easy to find. So the predictability of these process control indicators, the data doesn't show that they are able to predict problems, but it makes good risk management sense that they use them.

Another process control indicator that is worth

mentioning is the use of rate of non-compliant reports. Now, this is one that gave actually the best predictability of future problems, and, of course, one of the reasons is that you find more non-compliant reports, so you are able to find those relationships, but it had also a few things that we thought they could be improved.

One of them is that the writing of these reports is very subjective. An inspector might decide to do it. A different inspector might decide not to write a compliance report. So, therefore, there is something to be done there in order to train the inspectors in a way to avoid these problems.

Then another problem, we thought FSIS could improve the data analyses if they could actually do the analyses by commodities or by establishments but not integrating all the data together.

I put all of them together, even though they are very different indicators, but, in some way, they are similar because they reflect a past problem.

So public health-related recalls, enforcement actions, and outbreaks, these are the kind of process control indicators that found no relationship whatsoever

with a future problem, but yet, again, it makes sense to include them as process control indicators because they show that a problem has occurred because, in the law of frequency, it is very difficult to find relationships, but the committee thought that it made management sense that even if they don't have data to prove that they can predict a future problem, that just because they are so related to public health, they should be included in the list.

Okay. So, with these findings, the committee provided like 17 recommendations. I won't go through all of them, but these are some of the areas that they focused on. One of them was on clarity -- clarity, articulating what they want to do, articulating what the purpose of the algorithm is, what the data analyses that they are doing are, and what kind of data you are using. That was just crucial. We are talking about transparency. This is the first line where they really needed to improve on it.

Then there were also recommendations on perhaps, like I mentioned, considering different indicators might have different importance instead of all of them having the same.

Collecting data that is specifically for the

purpose of designing a risk-based inspection system is an important consideration that they agency should also consider.

And finally, the development of a process by which they can validate these risk-based inspection systems, I think the proposal mentioned something about it, but they really didn't have a process by which they were going to validate it.

I was going to say something about the Public Health Attribution Report, just two very short comments. One of them, the data that emphasized was used in order to develop the attribution model was appropriate, but they could use more data that others have generated. That was one of the comments that was made. Then the methodology to attribute public health to salmonella is still not in its prime time. So that also was needing more work. A major comment on this was that the agency needed to collaborate with others that were also working towards the same goal.

That is all I have. I think I am way past my time. If you have any questions, I would just answer them later, so thank you.

MS. KOWALCYK: Good afternoon. My name is Barbara

Kowalcyk, and I am Director of Food Safety for the Center for Foodborne Illness Research and Prevention. We are a national non-profit health organization dedicated to preventing foodborne illness through research, education, advocacy, and service.

As we all know, foodborne illness is a serious public health issue that affects millions of Americans each year at a large cost to the American public, which I won't go into. USDA's FSIS is charged with the oversight of safety of meat and poultry products in order to protect public health, and that is why we are here today.

Of course, as we all know, the effectiveness of any meat and poultry regulatory program is dependent on its ability to protect public health. This was recognized in the 1990s, and this is actually a quote from "Ensuring Safe Food from Production to Consumption" from 1998 at the National Academies. So this was recognized, and in 1996, PR/HACCP was adopted by USDA and FSIS to provide consumers with a higher assurance that meat and poultry products were being monitored using robust scientific methods.

To meet that end, FSIS also developed and implemented microbiological testing programs to identify

contaminated products, monitor process control, and evaluate the effectiveness of prevention strategies and inspection programs. The data from these microbiological testing programs provided the basis for public policy decisions.

I did think it was important to take a moment and just go over statistical process control, which is at the heart of PR/HACCP, since I am not sure that everybody actually knows what it is.

SPC is the application of statistical tools to the improvement of quality and productivity. One of the interesting things about SPC is it actually has its roots at USDA. Walter Shewhart is kind of the father of Statistical Process Control. He was then followed up by Edward Deming, who spent many years working at USDA. I won't go into the long story, although it is very interesting. I strongly recommend you read "Out of the Crisis."

But the basic idea here is that you monitor variation in your process, and there are two basic types of variation in your process. There is those inherent in the process, so you will never have a consistent process that produces the same product identical all the time, and then there is an uncontrolled variation.

So what you do is you set the control limits, and these are in the red lines at the top and at the bottom, and they are called your upper and lower control limits. You monitor your process over time, and when it goes above or below these control limits, it indicates that your process is out of control, and that there is something going on. Either you changed supplier or an input changed or maybe a machine is faulty or something happened, and you should go back and look at your process. And this is the whole premise of HACCP.

It basically goes to the next slide, which, if you have studied Statistical Process Control, it is the Plan-Do-Check-Act process. It basically says we are going to have continual improvement, and over time, those control limits will come in closer and closer to our target, and we will have a good, tight process that is well controlled.

So the first thing you do is plan ahead for change, analyze and predict the results. Then you actually do it. You execute your plan, taking small steps in controlled circumstances. You check the study results, and then you take action to standardize or improve the process.

Now, I think one thing that is important to note

here is that Statistical Process Control cannot take care of defective process. You can consistently produce a bad product, and you can be very good at consistently producing a bad product. So that Statistical Process Control doesn't take care of that, and many people, I think, don't understand that point, and it is a very important point.

So this process, HACCP is based on this. At first, HACCP worked really well. This is the preliminary 2008 FoodNet Data which came out in April of this year, and we saw good progress up to 2004. There were a lot of good changes. The incidence of foodborne illness went down. In fact, I know several people have brought this up in the earlier panels, and I thought it might be worth going through.

So, for STEC -- and I know it is hard to read off of this slide -- for STEC, compared to the 1996-1998 baseline -- this is STEC O157 -- there has been a 25-percent decline, with a confidence interval going from negative 39 percent to negative 8 percent.

I am a statistician, if you aren't aware of that, but that indicates to me that things have gotten better. The incidence has gone down, but, if you only look at the

past 3 years, there has been a 1-percent increase. Now, the confidence interval there is negative 15 percent to 19 percent, which indicates we don't really know what is going on with E. coli O157 in the past few years, but, certainly, there hasn't been much change.

With salmonella, there has been no real change since 1996-1998 baseline. They have shown a 4-percent decrease on average, but the confidence interval ranges from an 11-percent decrease to a 4-percent increase. That contained zero. So, to me, that indicates that there certainly has been on change there since 1996 to 1998, and in the past 3 years, there has been a 6-percent increase, and the confidence interval there ranges from zero to 12 percent.

Campylobacter, I am not going to go through all the confidence intervals and things, but campylobacter has decreased since 1996 to 1998. But there has been no substantial change in the past 3 years.

Listeria monocytogenes, yes, we have seen a decrease since 1996 to 1998, but, again, no substantial decrease in the past 3 years.

Vibrio has increased since 1996 to 1998, but,

again, there has been no change in the previous 3 years.

What this demonstrates is that up to 2004, we were making progress, but that progress has stalled, and our progress towards reaching the Healthy People 2010 goals has plateaued.

The other thing that these slides don't show is that the highest rate of illness is occurring in our children which, of course, is a horrible thing. They are one of our vulnerable populations, and we have an obligation to protect them.

So, obviously, everyone has been very concerned about this, and FSIS, I think, recognized this and proposed that we move toward risk-based inspection in, I think it was, 2006.

Basically, what risk-based inspection is -- and Maria went over it quite in detail, so I won't bore everyone with the details again -- it is a science-based, data-driven system, with the idea of using robust data to assess the risks, weight the public health risks, allocate resources appropriately, and then continually update and improve.

Basically, the idea here is let's try to predict where our problems are going to happen before they happen

and take corrective action.

The topic of today's symposium, I think the title was "What Do Recent Changes Mean for Food Safety in Meat and Poultry Inspection?" and so the big question is, is FSIS headed in the right direction.

Throughout 2006 and, I think, through 2008, FSIS has held a number of public meetings that have been well attended, particularly on RBI. They got RESOLVE involved and did a very thorough report trying to solicit input from all the different stakeholders, and that is certainly a move in the right direction.

They have proposed a new approach to testing, particularly in beef trim, and they have proposed N-60 sampling. I just want to take a moment and talk a little bit about N-60 and FSIS's proposed new approach to testing in beef trim.

Right now, FSIS tests once a year, maybe, or so. The verification testing programs for salmonella, E. coli, and LM basically capture a plant's performance at a specific point in time on a specific day. So they are only catching one of those blue points on that slide, and then they come back a while later.

FSIS traditionally has looked at each one of those blue points independently, rather than looking at it over time, and you certainly get a different picture, depending on which blue point that you pick out. So FSIS is proposing let's not just look at each salmonella test as a snapshot, let's look at the whole picture, and I think that that is a very good thing.

In terms of N-60, continuous sampling would be idea, and I would love to do that, but sampling is destructive, testing is destructive. So we can't do continuous testing. So we have to have some sort of compromise, and traditionally, what FSIS has done is collected one 325-gram, or something like that, sample and used that, but, as everyone here knows, you have a heterogeneous distribution of pathogens in the food supply. You have really decreased your probability of finding pathogens if you just take one sample.

With N-60, what they are actually saying is let's take 60 smaller samples that equal the 325 and test that. Well, it is not what I would like to see, but it sure is an improvement. You have increased the probability that you are now going to detect pathogens if they are truly present,

and that is our goal. Let's move towards a sampling program that detects pathogens when they are truly present, but I think that this is a really important step.

Now, the devil, as Maria said, is in the details, and we still have to work that out, but a move in this direction would actually, I think, provide us a better picture of what is really going on at meat and poultry establishments.

So the next thing is development of a data warehouse, which I am not going to spend a whole lot of time on, but FSIS has been working with, I believe it is, Carnegie Mellon to develop a new PHIS system, which I think will help. It is not just enough to collect the data, but you have to store the data in a manner that is accessible and integrated. So this is a step in the right direction. Of course, again, the devil is in the details, but this is in the right direction.

Improve data sharing. FSIS in the past year signed a memorandum of understanding with ARS and, I believe, CDC to improve data sharing of salmonella isolates between VetNet and PostNet, which, again, is a good step in the right direction, and they took the initiative to

commission the NAS reports, which Maria reviewed. I think that that is another important step.

Of course, there's lots of challenges. The first one is -- and I think we have heard about it from every speaker this morning -- the lack of data. I am going to touch upon this a little bit more in a minute, but lack of data is a big, big problem. There is also inadequate surveillance, both from a public health perspective and from a microbiological testing perspective, and this gets back to the fact that we are really not doing enough microbiological testing in the establishments, and we are not doing it on a frequent enough basis, so that we can better discern that pattern that I showed you earlier in that SPC chart.

Inappropriate use of data. Now, I am a statistician. So I have to comment on something that I really wasn't planning on commenting on today. I always tell people you don't become a statistician because you want to be popular. Right? You are usually telling people bad news and telling them what they can't do with their data, and the response is let's kill the messenger.

Since 2003, people have been using the Salmonella Verification Testing Data to demonstrate that the prevalence

of pathogens in the food supply have decreased, or specifically, the prevalence of pathogens in meat and poultry products have decreased.

I have done congressional briefings about this, I have met with the USDA, with the Secretary of Agriculture, I have met with FSIS and said that this is an inappropriate use of data.

On FSIS's website, it specifically and clearly states that the verification testing program data is regulatory in nature and only provides a picture of what is happening from a regulatory standpoint at a specific plant at a specific point in time. It clearly says this data is inappropriate for making year-to-year analysis.

Now, I think FSIS really needs to develop that data, so that they can make those year-to-year analysis trends, but the regulatory data that they have really cannot be used for that purpose. You have different establishments being sampled from year to year. I think Maria touched on this before. If FSIS wants to make those types of analysis trends, I think that is a great thing, but they need to develop a testing program specifically designed to do that.

I think there were two or three presentations that

talked about the use of the verification testing program data in this manner, and I really felt that I needed to comment on it a little bit more. Hopefully, I won't run out of time.

There is still insufficient data sharing, even though the MOU was signed. I have talked to many, many different people at many different public agencies, both at the Federal, State, and local levels, and one thing that I continually hear again and again is that there is no data sharing. CDC doesn't know what FSIS is doing. FSIS doesn't know what FDA is doing. FDA doesn't know what FSIS is doing. The State and local people don't know what anybody else is doing. We don't really have an integrated approach.

Of course, there is the lack of research capabilities, which is one cause that I am particularly interested in. Sometime in the 1990s, I believe someone declared FSIS was not a research agency, and, therefore, all research was done over at ARS.

Now, I understand the reason why we want to separate regulatory agencies from our traditional research arms, but, as a regulatory agency, I think their hands are tied behind their backs if they are not able to do research

because research is defined as anything as simple as method validation.

Quite frankly, doing the statistic analysis necessary to implement RBI could be defined as research, and I think that what we really need to do is address this lack of research capabilities at FSIS and make it a priority for the agency. This is not research in terms of, oh, let's go out and develop some new method. This is really research that supports the regulatory function, and they are hindered by their lack of ability to do that.

Of course, insufficient resources, we all know that all the Federal agencies, everyone, has lack of resources these days, and while FSIS has better resources than FDA, they still do not have enough resources to do the regulatory and public health functions that they need to do.

So I am going to just talk a little bit more about data. It has come up again and again. I titled this slide, "Data, Data, and More Data Gaps," because I think what it comes down to is the lack of data.

If you read the NAS reports -- and I strongly recommend you do -- it is a recurrent theme through all of them, and it is something that I think the consumer groups

and industry has been talking about, at least since I started working in food safety, is the lack of data.

Of course, most stakeholders agree that food attribution data is critical to the development of an effective RBI system or Public Health Risk-Based Inspection System.

FSIS has done some work in this area, but it makes some very questionable assumptions in my mind. Most of the attribution models that have been developed so far are based on outbreak data. You are making the assumption that outbreaks are representative of sporadic cases, which is not necessarily an appropriate assumption.

The vast majority of foodborne illness cases are sporadic, not outbreaks, and we need to have a better understanding of the attribution of all foodborne illnesses, so we can really develop good food attribution models, and, of course, hand in hand with doing that is putting in place product tracing. Without an effective product tracing system, we are not going to be able to determine which illnesses were caused by which products. If we put product tracing in place, that will help us identify what is happening in the sporadic cases which will help us build

effective attribution models.

Of course, microbiological testing, I have touched on that a couple of times. I won't say much more about it at the moment, except that we do need more microbiological testing. I don't believe that you can test safety in products. That is not what I am getting at here. I am just going back to that point again that you need to do more continuous testing and have a better picture of what is happening over time, instead of the selected snapshot once or twice a year.

Inspection data. Maria touched on this a little bit. We don't really have a whole lot of data on our inspection activities in terms of how it could be used to develop a risk-based inspection system.

The NAS report recommended the development of NRs, which, as Maria noted, had the best predictability, but the report recommends that FSIS development an NR specifically aimed at getting data to support their risk-based inspection system.

However, based on what I have heard so far, FSIS really is not planning on developing any NR specifically for this purpose at this time, and I think that that is a real

shame. We need to better understand what type of inspection activities are going on, so that that will allow us to determine which inspection activities are having an impact. If we don't know what is happening, how can we know if they are having an impact?

Of course, that goes hand in hand with industry data. Now, industry data, there's two categories of industry data. One is the data that industry collects themselves, which I am not going to talk about today, but, also, FSIS could be collecting data on industry practices. What is the amount of product that they are producing? What sort of interventions do they have in place in the plants? If you are going to develop this risk-based inspection system where you are going to try and predict where the problems are going to be and you want to -- and I think one of the gentlemen from the industry panel had touched on this -- is we really need to look across plants and say what seems to be working and what doesn't, and maybe these are things that we should be recommending to all plants. I think that that is a good point.

Until FSIS understands who is producing what, when, how much, and how they are doing it, it is going to be

very difficult to move to that type of system.

Finally, surveillance data, I am not going to talk about this a whole lot, but we do need increased surveillance data at the State and local leve, and here I am specifically talking about public health surveillance. These programs are suffering, and they really are going to be the key to helping us develop the food attribution data that is going to tie all of these other pieces together.

Of course, one thing that I think is important to note is data gaps increase uncertainty, and I think that that is a very important point. We need to understand that improving our data will improve the process.

So how do we fill in the data gaps? I wanted to bring it back to the Plan-Do-Check-Act cycle. When I first came to food safety, I had studied statistical process controls as an undergrad and graduate student. FSIS is really not too bad at "Plan" and "Do," but kind of forgot the "Check" and "Act" part.

But we do need to go back. The planning part is you have to define your objectives. You do that first. There is no sense in wasting taxpayers' money and wasting time collecting data that is not going to fit the purposes

of what you need. Then you develop a sampling plan. I am going to go over sampling plans in a minute. Then you carefully collect and verify the data. You validate it. You use an integrated approach, and you are transparent. Then you go back and check and act and share the data with other people. This will help you complete that entire cycle.

I am almost on my last slide, and I am sure I am out of time.

I wanted to say something about effective sampling plans because planning your testing program or whatever data you are collecting, planning up front will save you a lot of time, money, and heartache. I have seen a lot of people who haven't done the right planning, and there is nothing worse than having collected all this data to find out that you collected weight, but you forgot to note whether it was in pounds or kilograms, and you had to throw it out.

So a robust sampling plan will be, one, designed to meet the testing objectives. The second thing is ensure that samples that are collected are representative, and representativeness is very important. You can't do 100-percent testing. So you have to collect a sample and

then take those results from that sample and generalize them to the entire population.

If you do not collect a sample that is representative of the entire population, then you can't make that generalization, and you have really missed an opportunity.

People can take advantage of this issue of representativeness or non-representativeness, and I have told people you can probably find something that will happen in little, old, blue-haired ladies who drive purple mini vans in New England, and it will be true for that population but not true for the rest of the country. This is the point I am trying to make here. If you do not have a representative sample of meat and poultry establishments and what is going on, you will not get a correct picture of what is going on in all establishments at all points in time.

You want to minimize bias, and, again, this is something that is important. I have never been in a meat and poultry establishment, but if you collect your sample on the first shift, first thing in the morning, my bet is your results are going to be a little different than on the third shift at the end of the day, and you have introduced, then,

a bias. There is no amount of testing and sampling that you can do to overcome that type of bias. It is built into your data, and it will skew your results.

You need to address potential statistical problems, specifically this heterogeneous distribution of pathogens and seasonality. If you look at the microbiological baseline surveys that were done in the 1990s, a lot of them were only done in the spring and fall, missed the summer months, and didn't actually capture seasonality.

You need to ensure sample size is sufficient to provide an appropriate level of confidence and power, and I would love to have more time to talk about confidence and power because I think a lot of non-statisticians don't understand what those are, but, if you do not have sufficient power to detect pathogens if they are present, just because you don't see them there doesn't mean they are not there.

Many at FSIS, I am sure, has heard me say many, many times that absence of evidence is not evidence of absence. If you have a sampling plan that has 20-percent power, you are probably not going to detect pathogens, and

it is not because they are not there. It is because you didn't have the power to detect them.

One thing that I think FSIS could do to greatly improve transparency is start reporting what their confidence and the power is of their testing programs. Confidence and power gives people a way of measuring the effectiveness of a sampling plan and evaluating whether or not it needs to be improved or whether or not it is adequate and puts the results into perspective.

All of these things will, as I said before, ensure generalizability and interpretability. I am not going to go over again what generalizability is, but I have been asked many times to define it. It basically means that what you want to do is you are doing an experience, whether you are collecting microbiological samples for meat and poultry products or collecting NRs or doing public health surveillance, and you want to make sure that you can take that sample that you have collected and generalize those results to the entire population that you are interested in, and if you haven't done a good job at developing your sampling plan, you are not going to be able to do that. In the end, you will have wasted taxpayers' money and time.

This is my final slide. This is from the "Ensuring Safe Food from Production to Consumption," an NAS report from 1998, and it has seven points. I thought it would be good.

The one thing that struck me is the attributes that they define for an effective food safety system are many of the attributes that we have talked about here today.

The first attribute is it needs to be science-based, have a science-based foundation using risk analysis, and, of course, we are here, 11 years later, talking about implementing RBI, and it was something that they recognized. We are making progress, but we need to go a lot further.

Adequate surveillance and reporting. We still have issues with this, and product tracing would go a long way to both of these. Also putting more resources into our public health surveillance systems would improve that.

Focus education and research, which Dan brought up, and I would have loved to have Dan's slide to put up next to this slide to put up next to this slide because a lot of his points go right hand in hand with this.

Effective, consistent regulation and enforcement,

this goes to many of the points that were raised today, talking about developing better NRs, also talking about performance standards, a refocus on HACCP. This all goes into an effective, consistent regulation and enforcement, and, of course, the response and adaptation to new technology and changing consumer needs, which Dan touched on, adequate human and financial resources which continues to be a problem, and as many people have noted today, we need collaboration and transparency, and the seventh one is partnerships between State, Federal Government agencies, private sectors, consumers, and academia.

So I think we all agree on what the attributes are, and what we need to focus now on is how we work out the details. I think FSIS is headed in the right direction, but there are some significant challenges that they need to overcome in order to do this in an effective way with the best use of taxpayers' money.

That is all I had. Thank you. If you have any questions, I will be happy to take them later.

MR. PAINTER: Good afternoon, everyone. My name is Stan Painter. I am the Chairman for the National Joint Council of Food Inspection Locals. I am here on behalf of

the union, representing the union.

It is good to be here. I appreciate the opportunity to speak to everyone. I don't have a slide show. That maybe good or not good for your benefit. I guess that remains to be seen.

An old country preacher that I grew up with said to get up, speak up, and shut up, that after a certain point, no one hears what you say anyway. So I am going to take my watch off, and I am going to lay it down and hopefully stay within the time limits.

I want to touch base on some of the things that are concerns for the food inspectors and the people in the field. I have heard a lot of talk just in the time that I have been here, and I apologize for being late. I had a prior commitment. I actually was supposed to have been on leave this week. Nevertheless, that is the consistency and the application in the field.

The agency has tasked the inspector with applying processes and procedures, and, yet, the training is still lacking. Inspectors get to a certain point in their career, and the agency says, "Okay. If you haven't been to training by now, you don't need it. We are not going to send you."

A training program was developed a number of years ago called FSRE, Food Safety Regulatory Essentials, and I have not spoke with one inspector yet that has not gone to this training that didn't say that training was a good program, but this is the problem. When you go to the training and you bring up something that the inspector says my supervisor says to do so and so, then the instructor then turns around and says, "Then don't do what we just told you. You do what your supervisor says."

The union has brought this to the agency's attention, and we had a commitment that those types of things would stop. That has not stopped as of today. When you develop a good program and you want it applied, you need to enable the person to be able to use that process, and that goes back to the consistency that I have heard today regarding the NR writing.

I am going to speak a little bit about the NRs and the smoke and mirrors. Barbara always does a wonderful job with statistics.

The number of NRs are not an accurate reflection of what actually goes on because you may have multiple NRs under one number, and it is not an accurate reflection. You

may have one; you may have a dozen. But it is recorded as one deviation, and in the past, that wasn't the case if you documented each and every incident.

The agency uses this to say the process is working to say the NR rate is down, and no, the NR rate is not down. The way that it is recorded is down.

I have heard some talk as well about the MOUs. The MOUs are abided in a manner that is better than what we saw. In about 1996, I know I was involved in negotiations with what was called "pre-HACCP," SSOPs, and in about 1997, the latter part, HACCP was going to kick in.

The union bought on to a concept that HACCP would be an enhancement to inspection, not a replacement, and almost immediately, that was out the window. Certainly, the union feels as thought microbial testing was an outstanding portion of HACCP. We support the E. coli testing, the testing for salmonella, things of that nature, but without a physical presence, it is like removing State troops and turning the highways into the Audubon, where human nature kicks in. We are driving down the road, and how many people look down and they are going 78 in a 70-mile zone, and they are going to pull over and give themselves a ticket?

Folks, ain't going to happen. Well, this same incentive kicks in with documenting your own non-compliances. The union is of the opinion, HACCP has not worked, HACCP has never worked, but could HACCP work? It could, but I don't see HACCP working under the current structure.

That leads me into the next thing with FSIS versus FDA. We have heard a lot of comments lately regarding FSIS is the premier agency in comparison to FDA. I wouldn't argue that. In comparison to FDA, we are, but why would you want to go down the same path as FDA? In the opinion of the union, that's exactly where we are headed.

I see as a union, the agency criticizing FDA and the level of inspection, the amount of inspection, and the way they inspect, and, yet, we are headed exactly that same way.

A lot of people will say the union has just concerns over numbers. I am not going to say we are not concerned over numbers. You can't say that I am just going to stop eating. You can say I am going to stop drinking, I am going to stop smoking, I am going to stop taking drugs, but we can't stop eating. We all have to eat, and we want

our products to be safe. That is the main goal of the food inspectors. That is the main goal of the union. We want to certainly be able to eat a safe product, and I know that is the same goal as the plants as well.

Staffing has been a critical issue. We have some places that we are less than a percent of staffing shortages at this point in time, and we still have places across the nation, such as the Northeast, that produce a lot of product, that we are still over 19-percent vacancy rates.

Inspectors are gold go in the front door, wave at them as you go through, and go out the back door. Folks, that's not inspection. That is some kind of drive-by inspection. You spend less time at the drive-through at McDonald's than you do at a plant.

An inspector was assigned 21 plants to go to in one day -- 21 -- and because the agency says that inspector was assigned 21 plants to go to, the plant was covered. Just because there was an assignment does not mean there was coverage.

I am not saying that happens every day. No, it doesn't happen every day, but, if you have a sick child or you have an elderly person that gets sick, that one day may

as well be a thousand.

Our union is working with our parent union, AFGE, and another council on a trace-back issue, and the issue is USDA wants to have farmers, if you have 20 cattle, to ID every cattle, every cow, but if you are on a feedlot and you have 200 cows, you should identify one cow. We are of the opinion that is not something that we should be dealing with or buy onto because, certainly, in looking at trace-backs, last April we were in a meeting and we were talking about the shedding of E. coli, thing of that nature. Certainly, the ID-ing of the cattle would certainly help with the trace-backs for E. coli. It would certainly help with the trace-backs for the BSE.

So we are trying to see what we can do to come to a happy medium here and certainly not put the burden on the small farmers and make sure that everything is done in a fair and equitable manner.

I want to talk a little bit about PHIS that relates, and it also relates to RBI, things of that nature. Today, as it started on October the 3rd of 1999 in Guntersville, Alabama, product is being produced that goes out the door, a ready-to-cook product that is never

inspected by an inspector.

It has been brought to the agency's attention a number of times. There has been nothing done about it. So there is a potential that you could guy and buy a product that was never inspected.

Product zooming down the lines at more than 200 a minute, with one inspector sitting at the end of the line, and that is inspection. The inspector is told, "Don't touch the product." Number one, it would probably be dangerous at over 200 a minute to even try to touch the product. It goes by so fast, it is a blur, but, yet, you are supposed to be able to see diseased product. You are supposed to be able to see fecal contamination as well or any other thing that might render that product not wholesome.

We have not supported HIMP based on those things and certainly do not support risk-based inspection. In our opinion, HIMP hasn't worked, so how is risk-based inspection going to work? Risk-based inspection, in the opinion of the union, is nothing but an inspection of HIMP, and an inspector today has the ability to go into a plant, spend as much time as they need.

Dr. Raymond, when he was the Under Secretary of

Agriculture, he and I had this debate a number of times. The inspector will evaluate how much time they spend. Under this risk-based inspection concept, if this goes in, this will actually dictate the amount of time spent. So there will be no flexibility on the part of the inspector, and it would just almost take an act of Congress in order to get the times changed in order to be able to meet the services for the consumers. If the plant were to have a question, you know you are going to be limited in trying to answer the concerns of the plant.

The agency needs to put out policies that are understandable because the plant and the inspector is where the rubber meets the road. The agency expects the inspector to implement what comes down as far as policy. Then they expect the plant to adhere to the policy as well. It needs to be understandable. It needs to be to where that we can enforce it and where we can live by.

A concern that we are dealing with right now and we hope that it is not another situation of a watering-down process, as most of you know, we had a situation that happened out in California with the Westland Hallmark plant regarding humane slaughter and humane handling. The agency

is developing a policy, as we speak, or they had already developed a policy, and we are in the process of dealing with it now, of doing a pen count, to count the numbers of head of livestock that is to be slaughtered, which the union don't oppose that.

I think everybody needs to know, including the plant, how many cows or hogs or whatever livestock is that goes through that pen at that one time, but this is our concern. Our concern is that that one act can now turn into you count the number of head of cattle or livestock. You also do your antemortem at the same time, as well as your humane handling. One-stop shop does all three.

So we are trying to deal with that now in a concept. The agency has given us that to negotiate over, but that is a concern. That is a huge concern for the union because -- you know, I am going to be honest with you. There has been a number of things that have happened that the union feels like that the one that gets thrown under the bus in the inspector, and, hey, the chips need to fall where they may. If the policy is not accurate and the policy is not to whether the people can live by it, the plant can live by it, and the agency can live by it, something needs to be

done.

The agency, based on an OIG report, promoted 17 people into positions at a cost of $1.45 million per year just in salary alone, not including benefits. Based on an OIG report, the agency's interpretation was they needed more supervision.

At this point in time, I represent about 7,500 bargaining unit people. There is about 2,500 managers. That is one for three. I don't understand the concept. I don't understand the concept. How many people does it take to supervise an inspector? I would encourage people to write their Congressman about that.

I have read the OIG reports. To me, that was not the intent of the OIG reports to hire 17 new GS-13 supervisors at this cost when we have the staffing shortages that we have at this point in time.

The policy and development, at one point in time, the union was involved in policy. When an agency issued a new directive, they would give us time to review and comment on that directive. That is no longer. I think at one point in time, the plants were able to do the same thing as well. No more.

I would like to see both concepts come back because the inspector and the plants have to be the ones to work together, to actually live with the policy. So we would certainly like to see that come back and would encourage the agency to do so.

The clarity of the regulatory enforcement, that goes back to some of the things that was mentioned earlier, and that is regarding don't do as I do, don't do as you're trained to do, do what I tell you to do.

So we feel as though, we being the union, the agency needs to lead by example, and if you have a policy, the policy is the policy and move forward.

Most of my time is up, and I will be happy to answer any questions that anyone has. Thank you. I appreciate the opportunity to be here.

[Applause.]

Panel Discussion

Question and Answer Session

MR. WALDROP: Thank you very much to the panel.

I would like to ask the other panelists to please come to the front. We have a little less time for questions than we were hoping, but I think we can get a few questions

going.

As folks are coming up, I would like to just kind of pull out a few of the key issues or themes that we heard repeatedly throughout these presentations. One is, obviously, the importance of continuous improvement and constantly trying to move forward. Part of the purpose of this meeting is to focus in on what the agency has been doing and how we can continue to move forward, but you also see that in the plants as well in terms of trying to improve their processes.

Performance standards was brought up by several folks and how we can use those to continue to improve the process. Data, of course, was an obvious theme that kept popping up in everybody's comments. We heard about needing more data, relevant data, useful data, attribution data -- I think Bob, Maria, and Barb all pulled out attribution data as being important -- and then the appropriate analysis and use of that data to be able to improve our system.

Collaboration with stakeholders is another key theme that continued to be raised not only with industry and consumer groups but also with the State and local regulators and the inspectors and then, of course, communication with

all the stakeholders and making sure that everybody is sort of on the same page.

I have several questions, but I am going to skip those and go straight to the audience and see if folks in the audience have any questions.

MR. CORBO: Hi. I an Tony Corbo of Food and Water Watch.

First, a comment. Bob Reinhard's presentation in terms of reticence about using the term "risk-based inspection," I think the reticence is still very valid, with me especially. Even in our discussions with FDA, the dummy in me still has a problem with the concept, and oftentimes, in the meetings that the consumer groups have had with the FDA, I have had a hard time using the term.

Chris Waldrop has actually tried to play the ventriloquist as I am trying to describe a process that is risk-based inspection without using the term. So I still have a problem, especially in light of the exercise that we have gone through with FSIS over the last several years.

So my question is to Dan Engeljohn. In light of the letters that you have received from the NAS regarding where you are at and complementing the presentation that Ms.

Oria gave today, it does not seem to me that we are much further along than where we were a couple years ago, the multiple treks to George Mason University. Where are we? Are we any closer to having a system that is actually going to work?

MR. ENGELJOHN: I believe that we are actually further along than where we started simply because we have received input as to what our weaknesses are or what the vulnerabilities are and what we need to fill in terms of knowing more about the data that we have or collecting better data.

So I think the issue about knowing what data we have and the process of analyzing it, I think that has been improved and has further improvements to be made.

In terms of implementing it in the form of deploying resources differently within plants, that has not progressed. I would say that is still on the books to be defined as to what we do and how we do it because I think it is critical that the data be there first and that we actually can use it and actually know what is going to happen before we put that in place.

So I think the issue about internal things, like

scheduling verification tests or using the data to suggest that we need to do a food safety assessment earlier, I think that, yes, we are much further along today than what we were.

So I think the time that we had in terms of getting the feedback from stakeholders has been extraordinarily valuable and necessary and was a good thing to happen, but, in terms of implementing it to just take our resources from one facility to another, no, that hasn't progressed, and I think there is still quite a bit of time before we would get there.

MR. WALDROP: Dan, can I do a follow-up, since I have the mic over here?

[Laughter.]

MR. WALDROP: In terms of those NAS recommendations that Maria did sort of highlight, how is the agency going to absorb those, and then how will you communicate with the public in terms of which ones you decide are appropriate to follow, which ones you may disagree with and not follow? How is that process, so the rest of us understand how you are going through those recommendations?

MR. ENGELJOHN: My understanding of the recommendations made and where we are with that is that I know that there has been a significant amount of time going over the comments made and addressing them.

Erin Dreyling is here, actually, who is principally working on addressing those issues.

Quite frankly, I don't know if there was anything that was suggested that we would disagree with. I think everything there was stuff that we need to deal with, and I think our plan is to deal with them.

If I am not mistaken, I think our intention is to make soon, relatively soon, a posting of that information. We wanted to run through the process of always with peer review and so forth, but I think our intention was to make known how we would respond.

Erin, I don't want to put you on the spot, but I think it is important perhaps for you to just tell us what we are doing.

MS. DREYLING: We are doing a few things in response to the review that Maria went over.

First of all, we are revising the report we discussed. We have now begin to use the term "public health

decision criteria," that we got from NAS and also from some of our other stakeholders, that our approach to making risk-based decisions in our establishments should be termed "public health decision criteria," and that is the term we are using.

We are revising our report in response to the NAS comments. I think I need to clarify how we are proposing to use what we laid out to NAS. We are proposing to use that to inform when we do food safety assessments and when we would do a new inspection procedure in some of our establishments. So we are not proposing at this time to increase or decrease inspection across establishments or to move inspectors from one establishment to another based upon what we laid out to NAS.

Also, we are going to do a number of statistical analyses to try to better show predictive relationships between the criteria that we laid out in the NAS report and the future behavior of that establishment, and we also do feel, though, that the criteria we are using to make decisions about when we do FSAs is what the agency has been doing for many years.

Those establishments are the ones that are not in

compliance with our regulations or clearly have bad behavior, and we, therefore, think it is totally public health protective to go to those establishments to do a food safety assessment or to have our inspector do a more comprehensive procedure in that establishment.

So that is a very brief review.

MR. ENGELJOHN: We are going to make that information known. Right?

MS. DREYLING: We will be revising the report, and that will come out publicly. I am hoping by August that we will have that report out publicly.

ATTENDEE: Chris, while Erin is here, could I ask two quick follow-ups?

MS. DREYLING: Sure.

ATTENDEE: Among other things, the NAS said it really had inappropriately used the term "algorithm." Are we going to flush "algorithm" now, since it is not an algorithm?

MS. DREYLING: Well, the NAS report is a bit conflicted in that. They say that an algorithm is a set of criteria with which you made decisions. We have laid out a set of criteria to make decisions with, but in order for

simplicity's sake, we are going to call our approach public health decision criteria. So we will not say that we are doing a ranking algorithm.

ATTENDEE: Algorithm is usually based on a mathematical formula.

Then you are quoted in one of these reports saying that supervisors will also be trained to use a more streamlined inspection review process. Can you tell me what that is?

MS. DREYLING: An inspection review process?

ATTENDEE: Yes.

MS. DREYLING: I think what that may be referring to is that we were asked during one of the committee meetings about how inspectors are reviewed by their supervisors, and there is IPS process where inspector supervisors will review the NRs that they write.

ATTENDEE: Thank you. Thank you. I understand that. That is exactly what this is. Thank you.

MR. WALDROP: Stan?

MR. PAINTER: Let me just give some clarification. The IPS process is not about reviewing the NRs that are written by the inspector. The IPS process, there is a

directive that came about from the agency in about June of 2002, and this IPS process is just an overall assessment that is used as a guide to rate the inspector for their required performance rating. IPS processes are done on GS-7's, and the agency doesn't even allow the GS-7's to write NRs.

So the IPS has really nothing to do with the NR process. Even when GS-7's find violations, they should be written up by someone else. The agency doesn't even write those up on an NR, someone that can.

MS. NESTER: I am Felicia Nester with Food and Water Watch.

Since this is about the direction that FSIS is going in, I just wanted to take the opportunity to state my favorite things that FSIS has done recently. The meetings last year on E. coli and traceability, some of the new notices and directives that increase the sampling of trim, the sampling of ground beef, the Directive 6410.1, which describes at least for the first time, in the interest of transparency, a consumer, someone who is not as well versed in all of these issues, as most of us here are, can look at 6410.1 if they would ever want to do that and find out the

specific things on the slaughter floor that can cause real problems. That is the first time I have seen it in FSIS literature, and I think that is a real step in the right direction.

A lot of people mentioned transparency. I think that is real critical. We have all been involved in this RBI process for a long time. I find it disturbing that the NAS report says that the committee found it a challenge to evaluate the adequacy of indicators of process control, dot, dot, dot, without a clear understanding of the rationale for the general approach. That is a very polite way of saying what the heck were you thinking when you gave us this piece of paper, and it is disturbing because we know that there are a lot of resources being expended on this process. We had a lot of public meetings. It is disturbing that it takes so many years and so much encouragement for the agency to focus on things that some stakeholders brought up early on, the issue that the limitations of the data were not clearly spelled out, the assumptions behind the data were not clearly spelled out, after we had all of these public meetings.

So I am focused here on transparency. How is it

transparent?

Dan, you had one of your slides that said every animal is, quote, "afforded a critical inspection before/after slaughter processing," and then Stan tells us that in HIMP plants, the birds are flying by at 200 a minute. The inspectors are not allowed to touch them, not allowed to look at anything but the front of them. They don't see the back. They are not allowed to look at the inside, and the viscera is not inspected.

So, in the interest of transparency, for the public to be involved in this process, how do those two things square? I see a problem there. So those are my comments, and now I have got one question for Mr. Dopp.

You were saying that AMI is very interested in getting more plants to hold product, so that it is tested. So a potentially dangerous product does not get out there, and that will prevent recalls. Right?

MR. DOPP: It will reduce the number of recalls that occur, yes.

MS. NESTER: Right, based on testing. We will still have recalls based on illness.

What is AMI doing about the fact that most of the

testing, most of the positives that FSIS finds, are at the tiny little plants that have the tip of the ice berg of the product? Is AMI concerned about the ice berg? Are you concerned about the fact that when that little plant holds that product, it won't make it in the news that that 4,000 pounds tested positive, but are you concerned about the 10,000 pounds behind that or the 400 pounds that they find at the small plant and the 10,000 pounds behind that? And are you concerned about -- what are you doing about creating a pressure on the slaughter plant to clean up? Because otherwise, with your plan, recalls go off the front pages. We never hear anything about it, and the public doesn't understand that contamination is still going through the system and is not being traced back to the cause.

MR. DOPP: Well, your question presupposes that there is contamination that is automatically going through. I am not sure I would agree with that.

The point of the test and control request -- first of all, let me back up for a second. We encourage every plant to hold product whenever it is tested, and that is regardless of whether the testing is done by FSIS or whether it is their own testing.

I mean, as many tests as the agency runs, as many samples as you pulled, 80-, 90,000, whatever it is on a given year, the industry pulls millions. It takes millions and millions of samples. You know that.

We encourage everybody that you always, always, always should hold product to get sampled until you get results, whichever way you want to go. Positive or negative, you know what to do with it. That is fine.

I am not telling you that on occasion, something doesn't -- there are a couple of examples in the last couple of years where a couple of the larger companies shift product, had a recall because they had shipped product. It was shipped by mistake, but I can guarantee you that the company policy is we don't ship anything until we get a result back.

The purpose of our request is to avoid -- yes, you are right. Most of those recalls are smaller operations. There is one recall that the agency has got up there for 1.5 pounds of hot dogs. It is in nobody's interest to take the resources that are necessary to go through that exercise when they could be devoted elsewhere. That is the simple fundamental point of our request.

Those resources, both from an agency standpoint and from a company standpoint, can be better served, allocated elsewhere, if you have a simple policy of hang onto the stuff if it has been sampled, period, end of discussion. That is the simplicity, what we were attempting to accomplish.

MS. NESTER: That didn't really answer the ice berg question.

Between '98 and 2003, about two-thirds of the recalls came from plants that did not slaughter product. They processed only. So they were processing somebody else's bad product. So what are you doing about the ice berg?

MR. DOPP: Well, I guess you are sort of linking our request of test and control to that other issue. I don't think they are linked.

Our request is simply, again, to keep the product under control. What everybody should be doing to produce better, safer product is unrelated to the test and control issue. That is just the way to manage what gets out the door. I mean, that goes back to making sure that your HACCP plans are adequately designed, that it is structured

properly, and it doesn't matter whether it is E. coli or listeria, whatever it may be. I think you are mixing apples and oranges a little bit, at least that's -- maybe I am missing something.

MS. NESTER: Yeah, I think so.

The question is the impetus for your pressure on FSIS. What are you trying to accomplish?

MR. DOPP: Let me give you a very specific concrete example of what we are doing, and I will give it to you in the listeria context.

I think, Bob, you are the one who mentioned we have done 22 or 23 listeria workshops in the past 8 or 9 years. Bob serves on the faculty, as does John Butts, as does Bill Sveim, as does Randy Huffman, for example. A bunch of company people, they are the faculty. They are out there sharing their information with what -- 2,000, 2,500 people have attended those workshops over the past 8 or 9 years, and it is bearing fruit. We are not seeing the kinds of outbreak. That is an example. We are actively engaged in this, though. So we are doing a lot of things by way of education.

Now, are we getting to everybody? No, probably

not because not every small -- for example, not every federally inspected establishment is a member of ours. I wish they were, but they are not.

But to suggest that we are not doing everything, I think is inappropriate, and those are just a couple of examples.

MS. NESTER: Can I just say one last thing?

MR. WALDROP: All right.

MS. NESTER: I am not suggesting that you are not doing anything. I am suggesting that you are pushing the recall policy because you want to stop the bad news, but you don't want to go back and take -- you don't want FSIS to go back and cure the problem.

MR. DOPP: I would respectfully disagree. That is not the purpose of the request. It is simply to eliminate the -- it eliminates the number of recalls. It allows agency resources and company resources to be reallocated and redirected.

I just have to disagree that we are not trying to bury something. It is that simple.

MR. WALDROP: Barb, did you have a --

MS. KOWALCYK: Dan, did you have a comment?

MR. ENGELJOHN: I would have just two short responses on the issue.

The first is perhaps a plea to understand more about the consumer, as well as Stan's issues from the inspector, the issue going back to him because I do think that there is a need for us to get on the same page as to what is it that is actually critical to inspect on a carcass, and particularly if it is young. If it is birds from a flock and it is a young flock, as opposed to older birds, and the disease condition that might be there versus an older flock, I think there are critical differences there, and, presently, the HIMP program is not for the older birds. It is for the younger ones that generally are healthy.

So the issue of what actually is public health-related versus some of the quality things which, frankly, many of the inspection tasks that we do are quality-related, so we really do need to get on the same page there, and I think that can answer part of the question about what is or isn't inspected and is the viscera important.

So I think there is a need to refocus. We haven't

actually talked about that for quite sometime, and I am happy to reengage in that discussion. So I would like to get at that.

But at the issue of, again, doing what we need to be doing to get at risk, using "risk" perhaps inappropriately, but it is the best term I have, we recognize that O157 is creating a lot of problems for us. We started at ground beef, and we really do need to move this system back, but we have said we are going to start a program which gets at the issue of product that is moving in the market that hasn't yet been through perhaps all the interventions that are applied to trim or through the sorting program that occurs through disposition CCPs.

That will help us identify, again, more information about the slaughter operation, which is where the problem is occurring.

We also said that we are intending to find a way to utilize the industry's data that they are collecting when they get information about suppliers that indicates there is a problem from that supplier. We don't do anything with that today. It doesn't trigger any FSIS response to go back to that supplier, and we know we need to do something about

that. So we are building a process to use that, and it is a process to, in part, encourage the testing that is identifying problems, but right now we are only responding in the STEPS program to the FSIS data.

There is a wealth of data that could be better used to get back to a problem sooner. So I think that gets at two of your issues anyway.

MR. DOPP: Can I add a thought to that?

MR. WALDROP: Sure.

MR. DOPP: The comment prompted me to think.

Again, in response to your question and sort of implicit in this is that we are trying to hide the ball a little bit, frankly, which I obviously don't agree with.

If the company has to hold the product and there is a positive result, there is nothing that prevents the agency from, one, if they implement the policy we have asked for, there is no recall, but that doesn't preclude FSIS from going back upstream and doing exactly what you are suggesting. So I fail to see how this request that we made in any way adversely affects anything.

MS. NESTER: My first question was what are you doing. Are you encouraging FSIS? Are you participating?

MR. DOPP: In what respect?

MS. NESTER: You are talking about wanting to work with the agency to push the policy. Are you pushing FSIS to go back? Are you pushing for the policy?

MR. DOPP: Actually, what I was asking for was an opportunity -- and Stan said this earlier, and I couldn't agree with him more. There was a time -- first of all, I am troubled by the regulations and notice and directive.

MS. NESTER: Me, too.

MR. DOPP: Well, I think we all are - which has been around for 10 or 12 years at least, if not longer, and Stan is right. There was a time when the industry, the inspectors and others got an opportunity to take a look at a notice or a directive and say, you know what, the objective here might very well be fine, but how you are going about it, it won't work.

Bob is a good example. There are a lot of smart people in the industry who don't necessarily disagree with the objective or the target or the goal of the agency, but we disagree sometimes with how they want to go about doing it because there are some people, with all due respect, Dan, in the agency who have very little, if any, experience in a

plant.

Now, there are a lot that have some experience, but the fact of the matter is there are people who are writing some of these policies, some of these documents, that have never been in a plant and don't really understand how it would work and how it could be made to work better if we were given the opportunity, but we are not, and that is sort of my fundamental thesis when I was suggesting collaboration is something that ought to be considered a lot more carefully.

MR. HIBBERT: A quick comment on that, if you have a situation where Mark gets to look at the directive and Stan gets to look at the directive, then Felicia is going to be very unhappy that she doesn't get to look at the directive, and if she does, then somebody in the back of the room is going to be unhappy.

The answer to that is the good old-fashioned process called --

MR. DOPP: Rulemaking.

MR. HIBBERT: -- Notice and comment rulemaking. The agency goes on record, and anybody who gives a damn can say whatever they please on the record, and the agency has

to deal with it.

MR. WALDROP: We are going to go to Barb and then we will --

ATTENDEE: Let me just comment back on this.

MR. WALDROP: All right. Go ahead.

ATTENDEE: I have been trying to get it in.

Hibbert suggested we ought to go back to notice and comment rulemaking, and I want to know if there is anybody on the panel who thought that was a bad idea or anybody in the room who thinks it is a bad idea.

[Laughter.]

MR. ENGELJOHN: I will speak to the issue.

I think it depends on what you are going to call notice and rulemaking and the complexity of that.

If we are talking a Federal Register document, FSIS can't manage an inspection program on a day-to-day basis, unlike other agencies that regulate and much differently. I don't think it is a manageable system, but if the issue is to get at what is notice and comment and it is a fair opportunity for people to give input before you implement something and adjust it is provide the notice or directive as a draft form, get comment on it, modify it, and

then say there is an implementation date.

If that is what you are talking about, I would wholeheartedly support that. We don't do that now. I would say we stopped doing a form of that because we did used to do that to some extent.

ATTENDEE: Briefly.

MR. ENGELJOHN: Because there was an abuse of a system, and it identified a vulnerability for the agency for which we stopped it, but I personally think that it would benefit everyone to make the information known in draft form ahead of time. This is what we are intending to do, take comment on it, modify it, issue it on an implementation date that is feasible and practical.

As a policy person, I think that would be great. I can tell you that there would be strong opposition to that, but times are different. I really think that if we are going to get at this transparency, we are going to get this collaboration.

If I could add one little minute to this answer, we have built in an obligation for FSIS to identify up front what objectives we want to achieve by the policy that is issuing, so that we put in place a mechanism to measure its

effectiveness.

Again, it is an opportunity to tell us whether or not we have identified the right objective and how we are going to measure that and then hold us accountable for making it known what our results were.

I think it is an opportunity. It is one for which we have not entertained of recent, but I think it is a new day.

ATTENDEE: Well, if you ever get an Under Secretary, that will be our first chance.

[Laughter.]

MR. ENGELJOHN: I didn't want to come off as it is a bad idea. It is a bad idea if you are talking Federal Register documents, but if you are talking about a different process, I think that that absolutely is the best thing for all of us. It is just not being considered.

ATTENDEE: There could be a grading system. I think the complaint earlier -- and we really heard it across here -- is that one regulation 13 years ago now and everything else done by directive, it is not a good way running the system.

ATTENDEE: Okay. Well, I think that we have an

opportunity for progress here if we can --

MR. WALDROP: If nothing else, this meeting has pushed us in that direction perhaps.

MR. ENGELJOHN: But I would characterize it as Dan Engeljohn thinks it is a good idea, just so it goes on record.

ATTENDEE: I apologize for butting in, but I didn't want to lose that train of thought.

MR. WALDROP: Barb, do you have anything in there?

MS. KOWALCYK: Without reengaging the conversation again, I just wanted to comment on the discussion that was happening earlier.

I support test and hold, but it comes back to this inappropriate use of data, and that is the point I wanted to tie in.

With the advent of test and hold, which is a good intervention, you are going to see the salmonella verification testing positives go down automatically. So that is why I made a big point that you can't then turn around and say, well, the prevalence of pathogens in meat and poultry products have gone down. It is just that you have developed a better way of catching them. They are

still there. You are just not finding them.

That is why I get very concerned about the use of the salmonella verification testing data and recalls, for that matter, and using those data to assess risk and to build attribution models and say what is going on in meat and poultry products because there is a bias built into them right from the get-go, and I think that that is a problem. There needs to be a way to deal with it and encourage, while at the same time, encourage plants to use, test, and hold because we do want to make sure that contaminated products don't reach the marketplace, and if that is a good way and we can use those limited resources somewhere else, then let's do it. We have to then be careful about how we use that data and what it actually means.

MR. WALDROP: We are about out of time, but we will take one more question, if the panel will indulge me, and then we will have to wrap up.

MS. BUCK: I am Pat Buck, and I am with the Center for Foodborne Illness Research and Prevention.

First of all, I would like to thank the panelists, and I would like to thank whoever sponsored this meeting today because I thought it was very, very informative.

I think the thing that I kept hearing throughout this whole thing is the lack of transparency, as Felicia pointed out, but also the lack of data, and I think the challenge that is going to be for all of us is to really become proactive and allow the data to be developed and to allow it to fall out the way it is going to fall out.

There is going to probably be some false leads at first, and I am just concerned that the industry or the agency is a little apprehensive and nervous about taking the data, taking us to the next level, where we will get this food attribution data, so that we can start making the models, so that we can start doing the interpretation and the analysis that is vital to produce, say, food in the 21st century. I think it is a big, big challenge, and I am really encouraged that with some of the things that were said here, I am really, really encouraged that you are interested in collaborative work together.

Dan, I don't know if you realize, you really got beat up here today.

[Laughter.]

ATTENDEE: That was really nice of you, Dan.

[Laughter.]

MS. BUCK: But I am encouraged. I am very encouraged. Thank you, Chris.

MR. WALDROP: Bob, you mentioned attribution data. I didn't know if you wanted to make any comments in response to that.

MR. REINHARD: Collecting data makes everyone nervous, and the problem is lots of time you collect data, and then you realize you need to collect more data or that you need to do something differently with your data than you assumed when you started collecting data.

People just have to get over that. Everyone wants results from the data immediately when they go collect it because they think whatever you are going to do will lead to the answer, and it doesn't always do that. It is a very time-consuming process. It is almost like a lifetime commitment, so we are going to keep collecting data, and then we are going to eventually, scientifically, statistically, put the data together, so we then can understand how this system works. It is a very complicated system.

I have collected lots of data, had lots of different statisticians. I am not a statistician, but one

time in grad school, I did prove statistically the Earth is flat.

[Laughter.]

MR. REINHARD: I had a little paper on it. So that was my one lessons I do remember learning in statistics.

Getting people together, they will say the data means something different to everybody, but lots of times, the data says we don't know what the data says, and I think it is very difficult. It is a step we have to take. It is a place we have to go.

Lots of the data, there is industry data that either say FSIS's data is very good and very on target or it is not. With the listeria, with the salmonella, there is hundreds of thousands of samples. I have seen compiled industry data. They are very close.

So, when you get into just looking at their verification data to industry data, it is very statistical, which is every shift randomly every day for long, long periods of time. Their data is not far off over time. Any snapshot in time, it is not good. You can't use that, but, over time, their data is actually very good and very close,

in my opinion.

So I think there are opportunities there, but it is just a commitment.

MS. KOWALCYK: I agree with you. Collecting data is lifelong, and as a statistician, I have heard it all. Statistics is considered black magic, what they say, "lies, damn lies in statistics." It can get abused and misused, and one of the ways that you prevent that from happening is by defining your objectives up front, laying out your sampling plan, and then following your sampling plan, rather than letting the data lead the way.

You actually have a plan that is based on theory, and you follow that. It is a lifelong, and that is why you have this Plan-Do-Check-Act, and it never stops. We are probably never going to get to zero pathogens, but we can get really close, and we can always improve. But it is going to mean this lifelong collection of data, and this is why I keep harping on the sampling plans and defining the objectives because that will prevent this abuse and misuse of statistics, which is a valid concern.

MR. ENGELJOHN: If I can add just one point that is a little different than what has been raised, I would

characterize that FSIS traditionally has had fear of actually collecting data. I mean, we just simply didn't collect it because then you had to figure out what you were going to do with it, and, in particular, when it comes to looking at pathogens in product, the fear of who is going to criticize you for not doing something about it, I think you are pushing us in the right direction of collect the data, figure out if over time there is a change, and then make sure that you have got a place to develop policy that is affect to address the issue, as opposed to you don't collect it at all and wait until there is a problem and then automatically then move forward.

We have simply got to change that stance. So I would say the data that we have, we tried to come up with a good plan for. We can do so much better, but I am more worried about the fact that we have this inability at times to just move forward simply because what are you going to do with it, and I think that is where you need to be pushing us to help us over there.

ATTENDEE: Well, there were some suggestions at public meetings a couple of years ago to find some way, some structure that would make industry comfortable with having

unidentified source data be put into a pool of data in order to give FSIS some more good numbers, and it seems to me there ought to be a way to work out a structure that would protect individual companies and get those numbers into a place where there can be some use for it.

I don't know if there are any models for that elsewhere in government or not.

Maria is shaking her head no.

MR. ENGELJOHN: I do think it is a trust issue, and we really need to get beyond that and just move forward as well. I think that is a bigger problem.

MS. KOWALCYK: I have to go catch a plane, but I think the answer is, yes, there are ways that you can do that. It will take time, and it will take trust, and it will take collaboration, but there is data collected on people all the time that is then brought together and presented in a public manner on the drug side of things, and that is protected information.

So there are ways that you can do that. It is just a matter of the will. I think that one thing that struck me, at least the past couple of years, is I think you are right, Dan, but it is going to take a cultural change is

what we are talking about, and cultural changes are painful, and they take a while to adjust.

MR. WALDROP: Well, I am obviously a terrible moderator, but I felt the conversation was so robust that I didn't want to interrupt it.

So I would like to thank the panelists very much for their participation and for staying throughout this.

[Applause.]

MR. WALDROP: Thank you, all of you, for sticking around and participating, and have a good evening.

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