UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:

THE STATE OF FOOD SAFETY TECHNOLOGIES TO ENHANCE PUBLIC HEALTH

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TRANSCRIPT OF PROCEEDINGS

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P R O C E E D I N G S

January 13, 2004

MR. DERFLER: Good morning, everyone, and welcome to Omaha. Welcome to our meeting on new technologies. We're going to start the program off with a small deviation. I'd like to introduce Dwayne Metz, who is the Acting Director of our Technical Service Center in Omaha, who would like to welcome you to our city.

MR. METZ: Thank you, Phil. When we started planning this meeting several months ago the -- we started talking about locations and time, and decided we were going to have it today. You know, the middle of January in Omaha. And I said, "Who in the world came up with that timeframe?" They said, "Well, Mr. Derfler did." And I said, "Well, that answers that." We want to thank him, actually, for picking this week because if we would have been here last week, for those who are from out of town, it was like a 20 below wind-chill factor, and we had five inches of snow on the ground. So thank you for selecting this week though. Let's appreciate that. I just want to take a couple minutes and just, for those of you who don't know where the Technical Service Center is, it's actually located close to this location. We're on 13th and it's the big glass

building over there between Harney and Varnum. And we do encourage industry visitors when you do come to town. We're on the third floor. If you want to stop in and visit with us, you're always welcome. And what I do suggest is that you do call in advance. If there's a particular person that you would like to talk to, make sure that they're available. But we do encourage the industry to, you know, to come in and visit because I personally think it's nice to put a face with a voice on the phone. It just adds a little bit more when you're having a dialogue and communicating on the issues. Another thing we normally do is we try to have as many staff officers as possible to attend these meetings. But a little incident occurred in Washington State around December, which forces us that we're getting a lot of phone calls. So we have very limited folks that are here from the Tech Center. But during breaks, in the hallway, if you -- we do have nametags. If you want to discuss any issues with the folks that are here, feel free to do that. As an example, on an average, we receive anywhere usually around 8 to 900 phone calls a day, incoming and outgoing combined. And I didn't have the phone logs, but guessing on the number that came in yesterday, I think they were averaging, I would guess, around 14, 1500. So the staff is over there working

diligently, answering those calls, and providing guidance to the field. So that's why there's not as many folks here as the normal. So without taking any more of your time, I just want to welcome you to the -- to Omaha, Nebraska for those of you who are out of time, and hope your stay is pleasant, and come back and visit us whenever you can. We're going to need some help. Our football team, I don't know where we're going with that one, but that's the big -- that's the big thing here in Nebraska right now, is Husker football. So take care. And, Mr. Derfler, it's all yours.

MR. DERFLER: Thank you, Dwayne. I'd now like to introduce our administrator, Dr. Garry McKee, to make additional welcoming remarks to you. Dr. McKee was named Administrator of the Food Safety Inspection Service on July 23, 2002. In this position, he oversees the policies and the programs of the Agency. Dr. McKee has more than 30 years of experience in the public health field. From 1999 to 2002 he was Director and Cabinet Secretary of the Wyoming Department of Health. He has served as the Chief of the Public Health Laboratory of that department, and as the Director of Sanitary Bacteriology of the Oklahoma State Department of Health. He has held many other professional positions. Additionally, Dr. McKee has been a member of

the Board of Scientific Counselors, the National Center for Infectious Diseases, and the Association of State and Territory Health Officers since 2001. From 1995 to 1998 he was Chairman of the National Laboratory Training Network for the Association of State and Territorial Public Health Laboratory Directors. Dr. McKee.

DR. McKEE: Okay, thank you, Phil. Well, having grown up in Oklahoma, when we talk about football and new challenges in the West, that's certainly dear to my heart. As everyone knows, Sooners stub their toe at the last minute. But I think that the rivalry between Oklahoma and Nebraska has always been one that has always been exciting. Well, I'm certainly glad that everybody could make it this morning. I think it's probably warmer here than it is in Washington D. C., or will be, so it's great to be here, and I think it's an opportunity for us to have this kind of dialogue in Omaha, where we have our Technical Center, where we look at it and evaluate our technologies. Today's meeting on "The State of New Food(Safety)Technologies to Enhance Public Health" is an exciting look into the future. We have a similar broad group experts to share with us the latest science and strategies toward making our food supply even safer. Before I begin, I want to remind everyone that as tempting as it might be to discuss all

the BSE events that have been developing over the last couple of weeks, we do not want to take away from our discussions of technology and innovation. I would appreciate it if we could all work together to keep the discussion, today, on our original topic. As you probably know, when I came to Washington to join FSIS, that I came from the public health field, as Phil mentioned, and I've concentrated my efforts at FSIS as Administrator on making FSIS into a world class public health agency. And, at FSIS, we know that the only route to true public health is through the use of solid science, including a strong focus on technological innovation. I'm not here to support technology for technology's sake, but I believe that when technology can be used to improve public health, and it's been proven safe and effective, then it's worth promoting. Much has changed since 1906, when Upton Sinclair's book, The Jungle, which portrayed unsanitary conditions in Chicago slaughterhouses, spurred passage of the Federal Meat Inspection Act. "I aimed at the public's heart and by accident, I hit the stomach," is what Sinclair often said about his book. At the time of "the Jungle," animal diseases were much more prevalent than today, and they were the focus of the new inspection program. Since then, animal diseases are better controlled, and

the risk of illness from microbiological pathogens such as E.coli O157:H7 and Listeria monocytogenes is a much greater concern. And controlling these pathogens and others has required new ideas and new technologies. Many of you are aware of our establishment of the new technology staffing section within FSIS last August. This group expedites the implementation of safe interventions at slaughter and processing establishments. When we completed our risk assessment for Listeria in ready-to-eat products last year, it struck me how important interventions are in mitigating risk. I believe that we must encourage the use of safe and effective interventions. And one way FSIS can do this is to ensure that we facilitate the process. Our new technology staff is an experienced team of 12 veteran employees. People who serve as a single portal of entry for all submissions. We designed this group to better manage the new technology process and allow for implementation as soon as possible. They are also making sure that all FSIS personnel are aware of new technologies and where they are being used. I'm happy to report that we have received over 30 proposals for new food safety technologies since last spring. To increase the pool of new technology submissions we've developed a new technology web page, where parties may

submit their information on line. We also have established an email address, which is FSISTECHNOLOGY@FSIS.USDA.GOV, for interested groups to learn more about how to have their products or ideas considered. We are also working closely with our sister agencies to implement effective validated technologies. The addition of lactoferin to our toolbox of food protection methods last year is an example. We must not let bureaucratic red tape stymie the introduction of new technologies. Food safety advances can't languish in the bottom of our overfilled in box. We can help make that streamlined by allowing you to help us in this effort. As new technologies are developed they must be validated. Publication, alone, is not enough to show safety and success. While FSIS will encourage and support new technologies, you must follow and follow through with your end of the activity as well. Correct validation is expected and, in deed, required, as our agency will verify the results that you submit. If we work together to develop effective technologies, there is nothing we can't achieve. Technology and innovation have helped to improve public health through food safety in countless ways. Interventions like refrigerated railroad cars, food thermometers and antimicrobial washes have brought us into the food safety present. The question is what

will take us into the food safety future? Today we're going to present updates of FSIS technology initiatives and provide a forum for discussion on a variety of relevant topics. You'll hear about the benefits and challenges that new technologies present, as well as examples of new technologies that are being used to improve food safety in the United States. I know we're all looking forward to hearing about these technologies from our speakers today, so I'll limit my remarks to challenging you to focus on what our technologies may be in the future for food safety. I am very passionate about this. I think this is the way to the future to improve the most safe food products in the world, in this country, and I know that's a challenge that we're all ready to step up to the plate to accomplish. So, with that, I'll turn it back over to Phil, and I think we'll have a great day of dialogue and comment. Thank you, Phil.

MR. DERFLER: Thank you, Dr. McKee. Next on our agenda was supposed to be Dr. Elsa Murano, the Under Secretary for Food Safety. Unfortunately, she's not going to be able to be here. So what we're going to do is go into the substantive portion of the meeting. I guess I'd just like to give you a little bit of an overview of what the meeting's going to be before we get

started. The first part of the meeting we're going to have three speakers from FSIS, who will try and give you some insight into our program, our processes, hopefully, to help you facilitate your process. After that we intend to have some speakers from major trade associations as well as our manager for Technology Transfer, who will, hopefully, establish a context in which to consider the role of new technology and the advances that we hope new technology can play in the future. And then we'll go into a series of three panels. First on meat, second on poultry, and then the third on sanitation, to talk about some of the developments that are under way. Our goals from this meeting are to try and get some input from you on how FSIS can improve what it does with respect to new technology. Outside, there's a display, and one of the things, the handout that's available at the display, is this report enhancing public health, which sets out Dr. Murano's vision for food safety. And in there there is a discussion of what we're trying to do with respect to new technology. What we'd like to learn today is how we can do it better. Second goal today is to try and make you aware of some of the developing technologies that are out there. And the third goal today is there's a particular bent and a particular orientation toward

small and very small plants today. Particularly, how we can make sure that some of the new technologies make it and are able to be utilized by small and very small plants. So, with that, I'd like to introduce Mr. Patrick Burke. Mr. Burke is the Senior Officer of the New Technology staff at FSIS. He served at FSIS since 1985 in various capacities, including Director of the Industrial Engineering and Ergonomics Staff, and Branch Chief in the Inspections Systems Development Division. And Dr. Burke's talk will be -- provide you with an introduction to the Agency's new technology program. Mr. Burke.

MR. BURKE: Greetings! While I anticipate that this presentation will be a lot different from the last two I did. One was in Belgrade, Yugoslavia, and the other one was in Beijing, China, where I needed the help of several interpreters to get my message across. Here I'm on my own, and I'm pretty sure those interpreters made me sound a whole lot better than I was. And right now I don't even see my presentation. Here it is. [pause to set equipment up] Well, let's start now. Anyway, the New Technology staff. When the New Technology staff was formed later -- earlier in the Year 2003, one of the main goals for us was to foster the development and facilitate the use of new

technologies. One of our major goals. And throughout the next three of mine and the next two presentations that follow me, we'll give you an idea of how we're going to do that, how we're doing it, and how we plan to do it. Now, one of two things that we're also going to cover in my presentation here are what is New Technology? And the second, why would a company work with FSIS? No smiling. New Technology is defined as new or new applications of equipment, substances, methods, processes or procedures effecting the slaughter of livestock or poultry or processing of meat, poultry or egg products. Now, you look at that definition. That definition covers everything. But we, necessarily, don't want it to cover everything in that sense. We're not here in the New Technology staff to deal with any kind of prior approval. What we want to do is put four qualifiers associated with that definition. The first qualifier requires a change in the Agency's regulation. If your new technology that you want to introduce into your plant or establishment needs affects a regulation, you need to come to us. Then we will check to see, basically, if you can do that technology, we can give you a waiver. But we only will give you the waiver if the technology does not affect product safety. The second qualifier is it affects the inspection

procedures. Now inspection procedure is a little different because our inspection procedures are not in our regulations. It is what our inspectors are doing on the inspection floor. The technique how they do the inspection. What they look at. How they look at it. The sequence they do it in. If your new technology is going to affect one of those operations, you need to still come to us because then we have to deal with our inspection force, tell them how to do it, and smooth the way over for this. The third one is affects the safety of the Federal Inspection Program personnel. Obviously, if we got some kind of a chemical, radiation, or any kind of item that's going to cause any kind of safety problems, we've got to make sure, before you do your technology, that the appropriate guidelines are followed so that people are safe. And the last one affects the safety of the product. Because it does look kind of obvious on this one. We want to make sure that whenever new technology is affecting that product out there, it still has to meet all the other regulatory guidelines that are out there. And then eighth is the product is safe when it goes out. Now, I'm going to go ahead and give examples a little later on, exactly what I mean for each one of these four. So what it comes down to, if intended new technology will have an effect on any of

the four areas of regulatory interest to FSIS, then the establishment or plant will need to notify the Agency, either by notification or by protocol. Now, one of the first questions says what is notification what a protocol is? Well, Doug Palo is going to let you know about that later on. But let me give you, first, an example of a new technology associated with a regulatory change. New technologies for reprocessing a contaminated poultry carcass is on line. Some of you probably already know about this operation, where basically a contaminated product is going to be -- go down a line, and after microbial spray was put on it, in fact, we've got that's out in the field right now. Rhodia and Alcide. The products set cavinated birds with past birds would be processed through these systems, and they get inspected, zero tolerance, finished product standards, all before they go into the chiller. Now what's happening is the fact that they're using antimicrobial spray was not the issue here. The issue was we're letting a contaminated bird go down the line. And we have -- we had to give a temporary waiver of FSIS's regulation on contamination of carcasses. And here it is, 38.9381.91B1. And it is required to allow poultry carcass to be reprocessed on the main processing line. We had to give a waiver to that because that

regulation says you've got to take the bird off. Now we're saying, but before we gave that waiver, we made sure, through laboratory and preliminary data, those birds would be safe and wholesome before they went into that chiller. Now the second one has to deal with the procedure changes. The inspection procedure change. Modified rail inspection in cattle slaughter, which changes the height of two rail inspection stations to a high inspection station and a low inspection station. What is that talking there? In our regulations, you've got line speeds and you've got the number of inspections per line speeds. In some cases out in the field you have the regulations require two rail inspectors on a line for getting line speed. Some variations on that is, basically, you have a high rail and a low rail. Where one, the inspector did all the high portions of the carcass, and another inspector did a low. Now, if they meet the regulatory criteria of that, they have two inspectors. But our procedure was changed. Instead of an inspector doing the entire carcass, inspectors were -- inspector doing an entire carcass, one inspector was doing top half, one inspector was doing a bottom half, which was all right. But they have to come to us because, basically, they were changing the height of the inspection stations. And it's not -- that is not

specified in the federal regulation. But variations -- this variation affected the inspection procedure. So they had to get permission. We had to make sure we trained our help with the inspectors so they know what was going on, so they can perform this. Now, an example where sometime it's like inspection platform was not -- actually, it was not a procedure change, but a regulatory change in poultry inspection. We tell you in the regulations that an inspection platform has to move 14 inches up and down in the vertical. If anybody wanted to change that, that's a regulatory change. But if somebody wanted to change what the poultry inspector was actually doing, that's a procedure change. In our third qualifier, use of an ultraviolet wave length for antimicrobial purposes. Ultraviolet radiation can cause microbiological harm to program personnel. Even though the process has been approved for use, the system must be evaluated to ensure adequate safety procedures. So we're saying here, yeah, procedure's fine, you can put it in there, but we want to see the technology to make sure you've got the safety precautions in there so nobody gets harmed. And the last one, the product safety. Establishment may wish to use an antimicrobial spray that has judged to be safe by FDA on its products. The establishment does not want to declare the use of

the ingredient in its labeling. There are questions, and the questions are basically from our side, as to whether the substance meets the processing aid definition. There's a processing aid definition. They don't have to label it. The establishment must be able to demonstrate why the substance is a processing aid. Here's a nice example we just had recently. How many of you've heard of lactic acid? How many of you have heard of 5 percent lactic acid on carcasses, beef carcasses? Normally, what we had, it was approved that 2-1/2 percent was okay to use on meat chilled and hot beef carcasses. We had an establishment want to come in and use 5 percent. They had to send the data in to show us preliminary laboratory test data that 5 percent met the definition of a processing aid. They did. And we got that one. They're being -- and they're using it right now out there. Now, let's go to my slide now. Why work with FSIS? First answer is promote awareness of new technologies in official establishments. If we, as a regulatory agency, know of the technologies that are being used out there, and they are being used out there in effect, to basically increasing the product safety, we're all for it. And by letting us know about it, we can let others know about it. We know it's effective. And, basically, it comes down to a win/win situation for

all of us. Product is safer. We want it safe. You want it safe. You sell it. We're safe. And eat it. The second one, provide a fair and uniform assessment process of new technologies. Now you might this hard to believe that, in the old days, sometimes you had different groups evaluating new technologies, and they might have different evaluations on this thing. I know it's hard to believe, but we decided that we needed all the technologies to come through one organization. What we do there is that we're using the same criteria to evaluate it, going through the same process. Everybody goes through the same process, looked at by mostly the same people, and the same technical review team. And I used the technical review team, and that, of course, will be covered later on, exactly what we're talking about in that group. So everything becomes fair and balanced. Third one. Respond to questions regarding the use of new technologies. In the past, we get a new technology out in the field, I get a phone call from a district manager, an IIC, a company employee. What are they doing here? How come they're here? Why are they changing things here? Of course, we know about this and, of course, it went through the evaluation process. I can answer the questions. We can allay a lot of the fears that are out there about a new technology. But in

addition, as part of their procedures, when somebody introduces, especially in an in-plant trial, we're going to send, or have been sending, one of our staff members out there. Preferably, the one who will actually help evaluate the procedure, to help smooth over the initial start of the in-plant trials. So we get a dialogue going between the company, the plant, our inspection force. We want to make sure that you get good opportunity and a fair opportunity to evaluate your in-plant trials. The fourth one. Encourage the development and utilization of new technologies. If we do the first three correctly, and we will, well what it means is that it establishes a plan so why new technology will come to us, because we promote, we're providing good assessment, and we're responding. When things go well, people, of course, start introducing those new technologies. I'm glad to say that we have been responding well. And the last one. Be cognizant of the need to re-examine current regulations. That's mostly for our side because we're seeing a lot of technology coming in a particular area that would trigger us, saying maybe we should look at this regulation a little carefully, a lot more, and find out where the trend is. Maybe we need to change something. How do we respond? Hopefully, respond better. And

these are the five reasons this should work with FSIS and new technology. And that concludes my presentation. Thank you.

MR. DERFLER: Thank you, Patrick. There will be an opportunity for questions after the three presentations that you're hearing now. We're next going to hear a presentation on FSIS initiatives and new technology, and that presentation will be made by Mr. Lynvel Johnson. Mr. Johnson is the Deputy Director of the Technical Assistance and Correlation Division at FSIS's Technical Service Center here in Omaha. He served -- he has served in the Agency since 1985, working first as a slaughter inspector in Kentucky, then as a processing inspector in Los Angeles. Mr. Johnson has held numerous positions within the Agency, including Process Inspection Coordinator and Staff Officer for the Office of Policy and Program Development and Evaluation. I don't know what that is. Anyway, Mr. Johnson.

MR. JOHNSON: You'll have to bear with me today. I have a small cold, so if the medication starts kicking in, I ramble. Just throw something at me and I'll try to get back on track. Today I'm going to talk about, basically, what is FSIS doing to encourage new technologies in the development and use of new technologies. As a public health regulatory agency, the

agency is committed and encouraging new technology, especially if it enhances public health, and also food safety. In effect, this has been evident over the past year in the development of our regulations. With the issuance of the pathogen reduction HACCP final rule, the Agency shifted away from a command to control approach to one that gives industry greater flexibility to innovate in order to meet food safety requirements. And what that regulation, in the development, HACCP plans, HACCP analysis, it gives the plants the ability to make the decisions they need to make on what is going on in their process and address the food safety hazards and control those. Within the preamble of the pathogen reduction final rule, the Agency stated its food safety goal. And that goal is reduce the risk of food-borne illness associated with the consumption of meat and poultry by ensuring measures are taken at each step in the process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood to occur. So in the preamble, we're discussing that we want industry to come up with new technologies and procedures to control food safety hazards. To achieve this goal, the Agency outlined a food safety strategy that was addressed in the preamble, again, of that final rule. Two of the

elements of the strategy are specific to the Agency's commitment and our talk today. And let's look at that first element. The first element was adoption of food safety performance standards that provide incentives for innovation to improve food safety and to provide a measure of accountability for achieving acceptable food safety results. Since the publication of the pathogen reduction final rule, the Agency has worked to incorporate performance standards into the new regulations, as well as converting existing regulations. What is a performance standard? Well, a performance standard is a performance standard set that results -- sets the results to be achieved, but not the specific means used to achieve those results. So, in other words, we're allowing the establishments to be innovative in how they meet the intent of the regulation. Instead of specifying how to do it, we're saying, this is what our standard is and this is what our requirement is, and allowing the plant to develop the technology that they need to to meet that standard. And this initiative started with the sanitation requirement final rule. The sanitation requirement's final rule is intended to eliminate unnecessary differences between the meat and poultry sanitation requirements and to make the sanitation requirements

less prescriptive, and to allow more innovation on the part of industry. And this was published on October 20, 1999 and, again, set performance standards for sanitation. So instead of telling the plant exactly what room temperature should be, or how to clean their plant, it allows the plant to determine what they need to do to meet performance standards in sanitation.

A second rule that came out was the incorporating performance standards into the cooked beef, roast beef, cooked corned beef and poultry. Cooked poultry final rule. And this final rule established performance standards for lethality and stabilization, which spelled out the objective level of food safety performance that establishments must meet, but allow the establishment to develop and implement processing procedures customized to the nature and volume of their production. This is unlike previous requirements for those procedures or products that mandated step-by-step production measures. And if you remember the previous regulations on roast beef and cooked corned beef, the Agency specifically said how you were supposed to produce your product, requiring time, temperature of steam and so forth. Now we have a performance standard for lethality stabilization. How you meet that performance standard is up to the plant. And many of plants have gone to

process authority and developed a number of cooking operations and cooling operations or procedure that now meet the standards, but are much more flexible than our old regulation. The second element of the strategy was to remove unnecessary regulatory obstacles to innovation and one way we've done this, on February 11, 2003 FSIS procedures for notification of new technology Federal Registry notice was published. The purpose of this notice was to encourage industry technological intervention in the meat and poultry industry, establish new flexible procedures to actively encourage the development and use of new technology and provide a central location in the Agency to handle new technology. So, as Pat was saying, that previously we had many program areas looking at new technology. Now we have one area where you can go, one-stop shopping. With this we published a directive, FSIS 10,700, Revision 1. This informs inspection personnel about the procedures that will be followed to notify the field regarding the use of new technology for in-plant trials conducted at official establishments. Again, this is a new thing. It's always good to include our inspection force and to communicate with our inspection force because they're the ones working with you. So the more information they have, more communication they have, the better it's

going to be. The new technology staff also issues a weekly report, and it details requests received and pending, the no-objection letters that are issued, protocols that are required, and protocols that are approved. And this weekly report goes to the district offices and the district managers, the Deputy Associate Administrator for Field Operations. It comes to the Tech Center. We get a copy of it. Front-line supervisors, deputy administrator for office up here. And this ensures that all parties are informed. So when we get a call from an IIC, where a new technology is being implemented into the plant, if they call the Tech Center and have some questions, we'll have the information, too, to discuss with the IIC or at the plant. So we're finding that's a lot better as far as communication. Now all parties are on the same level. Within that weekly report, some of the information coming out so far, notifications that have been received. We have 22 notifications. Six of them are pending. They've approved 14 of those notifications. And then more information is required on two of them. For protocols, received ten protocols so far. Seven of them are pending. At this point none have been approved, but there has been three that an objection letter has gone back to the plant. And I guess that

gives them now the ability to re-look at their technology, make maybe some changes, and then go back to the New Technology staff. There has also been a web page developed, as we talked about earlier, for you to communicate with the New Technology staff on new technology, to ask questions, submit protocols. The New Technology staff has also worked with or has cooperative agreements with 18 universities and working with these universities to develop innovations that could be implemented in small establishments. Also working with the universities in obtaining information through surveys, as do some of the interventions and technologies being used today. And we're also trying to find out what is going -- what is out there today. What have the plants been using in the past? And we'll hear more about that later. Some examples of the projects that are on line right now, one is a validation of post-processing pasteurization treatments for use in very small plants processing ready-to-eat products, development of training materials to assist meat and poultry processors in preventing Listeria monocytogenes contamination in RTE products. And a third one is impact on hide interventions and cleaning on the microbial quality of beef carcasses in small and very small establishments. So those are just three examples

of the 18. And I'm sure there will be more coming as we work with more universities. So that's just a quick overview of the Agency's commitment on new technologies. We certainly are committed, especially if it's going to enhance food -- the food safety, and as we progress, we hope to get better at implementing and looking at these new technologies. Thank you.

MR. DERFLER: Thank you, Lynvel. Now we'll come to the third and final presentation in this portion of the program, and that's a review how FSIS reviews new technology. And that presentation will be made by Mr. Douglas Palo. Mr. Palo started his career as an animal laboratory manager at Hofstra University. He then joined the Food Safety Inspection Service in 1980. Since that time, Mr. Palo has worn many hats. He began his FSIS career performing inspections at meat and poultry slaughter establishments in several east coast states. Next he performed import and export inspection functions at the largest seaports in the country, and he supervised import inspections in the Midwest. He's been at headquarters since 1987 in the capacity of Staff Officer for Imports, and also as a staff officer in the Office of Policy and Program Development. Without further adieu, Mr. Palo.

MR. PALO: Good morning. I am Doug Palo, and

Phil has just introduced me, and I work with the New Technology staff in the Office of Policy and Program Development for FSIS. And I am here this morning to discuss how the New Technology staff manages the Agency's review of notifications and protocols from establishments or companies for in-plant trials of new technologies and oversees the conduct of such trials in federally inspected meat and poultry product establishments. I also will be discussing the Food and Drug Administration and FSIS joint review of new ingredient technology. As Lynvel just spoke about, the New Technology staff also works cooperatively with state and academic institutions in developing, identifying and evaluating new technologies that are economically viable for small and very small plants in order for them to meet the food safety requirements. The New Technology staff is developing standard operating procedures, developing a SOP. It will serve a couple of purposes. First of all, make transparent to interested persons how the Agency will respond when it receives a notification of a new technology from an establishment. It will also facilitate cooperation among the various parts of the Agency involved in the review. The purpose of this talk is to give you an insight into the process that we follow today. I'd like to give you a little bit of

background about the whole process. New technology generally enters the Food Safety Inspection Service New Technology process as a notification or a protocol, as we mentioned briefly earlier, with the -- from the other speakers. When a company plans to use or sell a new technology for meat, poultry and egg processing, FSIS has established procedures for plants to notify the Agency so that the Agency has an opportunity to decide whether a pre-use review of the new technology is necessary. The documents used to notify the Agency are called notifications. If FSIS decides that the pre-use review is necessary it notifies the company that the in-plant trial will be required. The company will then be advised to submit documents describing in detail its experimental design and data collection plan for the in-plant trial. This document is called a protocol. Now I'd like to talk a little bit about notifications. When establishments or a company is interested in using or selling a new technology, submit a notification to the New Technology staff describing the operation and the purpose of the new technology, the New Technology staff will acknowledge the notification by return facsimile or mail and assign a tracking number to it. The New Technology staff, in consultation with the Technical Review Team, will determine whether the use of the new

technology could, as Pat Burke described earlier, one, adversely affect product safety; two, interfere with FSIS inspection procedures; three, jeopardize the safety of the Inspection Program personnel or require a waiver of regulations. For initial notifications, the New Technology staff will make every effort to review that information and issue a letter to the establishment or company within 60 calendar days. If none of these apply the New Technology staff will issue a letter of no objection to the use of the new technology in all FSIS regulated establishments. If the proposed use of the new technology could affect any of the four conditions, the New Technology staff will advise the establishment or company that it needs to submit a protocol so that there can be a full pre-use review of the new technology, including an in-plant trial. One such example may be when a company would like to change the way chicken carcasses are hung on shackles. But this method of hanging appears to interfere with FSIS inspection procedures. If an in-plant trial is necessary, a protocol will need to be submitted. This protocol should be designed to collect relevant data to support the use of the new technology. Now I'd like to talk a little bit about the formation of the Technical Review teams. A project manager is assigned to each new

technology submission. The project manager reviews the notification of protocol for general acceptability and completeness. Additionally, the project manager maintains the notification or the protocol working files and serves as a coordinator of the Technical Review Team. The Technical Review Team draws in agency experts in relevant scientific disciplines to participate as a technical review team on the Technical Review Team. The various types of expertise that may be necessary is clear from this slide, which lists the various disciplines that we draw upon. As you can tell, you see, as it's said, many times we'll go to the Microbiology Division, the Residue Branch, Inspection Enforcement Initiative Staff, the Labeling and Consumer Protection Staff, the Data Analysis and Statistical Support Staff, the Technical Service Center right here, and Environmental Health and Safety Branch. One such example of selecting the appropriate disciplines would be if a new chemical caucus wash technology was presented that helped reduce the microbial count on beef. In all likelihood, the New Technology staff would request assistance for review from our Microbiology Division to determine if the objective of the technology is feasible for reducing our microbial count. Or we may go to our Residue Branch to determine if there would be

any harmful residue in the meat tissue. Or, possibly, our Environmental Health and Safety Branch to determine if the chemical would jeopardize the safety of inspection personnel. When a review of a protocol for an in-plant trial occurs, usually the full Technical Review Team will be required. This may include the addition of our Data Analysis and Statistical Support staff, the Technical Service Center, Inspection Enforcement Initiative Staff, Labeling and Consumer Protection Staff, or our Labor Relations Branch. Technical -- now I'd like to talk a little bit about how the Technical Review Teams function. The project manager will act as the facilitator of the meetings of the Technical Review Team and coordinate between the establishment or company and the Agency. The product manager will distribute the relevant information that he or she receives from the establishment or company to the Technical Review Team with instructions for review of the notification of protocol. The project manager will work with the team to ensure that the establishment's or company's documentation for the intended use of the new technology or in-plant protocol is reviewed expeditiously. Each team member's comments are gathered, reviewed and edited by the project manager for a response to the establishment or company. If there is a

disagreement among the Technical Review Team, the project manager will work to obtain consensus. The project manager will also provide the Technical Review Team with the establishment's or company's responses to the Technical Review Team's comments. Now I'd like to talk a little bit about protocols. As in the submission of a notification, when an establishment or company submits a protocol to the New Technology staff describing the in-plant trial of the new technology, the New Technology staff will acknowledge the protocol by return facsimile or mail and assign a tracking number to it. The New Technology staff, in consultation with the Technical Review Team, will evaluate the scientific design of the in-plant trial proposed. If the protocol is scientifically acceptable and will not adversely affect the safety of the product, the New Technology staff will issue a letter granting authorization for an in-plant trial to commence at a single plant. If the New Technology staff determines that the protocol does not provide the adequate information to make a determination for conducting an in-plant trial, a letter will be sent requesting additional information or clarification. One such example may be that the protocol does not include an adequate sampling scheme or does not explain how the technology will meet the

company's objective. If the in-plant trial requires a waiver of any provisions of FSIS regulations, the submitter must request and obtain permission from the Agency before proceeding. FSIS regulations, specifically Title IX, C.F.R. 303.1(h), 381.3(b) and 590.10, authorize the FSIS administrator to waiver, for limited periods, any provisions of the regulations to permit experimentation so that the new procedures, equipment and processing techniques may be tested to facilitate definitive improvements. No waiver can be granted if the new technology conflicts with the provisions of the Federal Meat Inspection Act, the Poultry Inspection Act, or the Egg Product Inspection Act. Prior to the implementation of an establishment of a company's in-plant trial, the Agency may request orientation and training for the new technology if based on the in-plant trial to submit plans to petition FSIS for a change in the Agency's regulations to permit the use of the new technology. Then as part of the trial, the submitter will need to collect information that will assist the Agency in justifying a change in its regulations and in performing a rule-making analysis required by law in executive orders such as Executive Order 12866 in the Regulatory Flexibility Act. FSIS will expect the submitter to provide data throughout the in-plant trial

for the Agency to examine. Data may take several forms. Laboratory results, weekly or monthly summary production reports and/or evaluation from Inspection Program personnel. The project manager will oversee the conduct of the in-plant trial. Members of the Technical Review Team may also conduct on-site visits to the plant for observations and monitoring during the in-plant trial. The project manager and the Technical Review Team may review data collected during the in-plant trial for evaluation in determining the acceptability of the new technology. If, at any time, the Agency determines that the in-plant trial results in product being produced that presents an increased risk to food safety or to the safety of Inspection Program personnel, the trial will be suspended or ended. Now I'd like to talk a little bit about the in-plant process. In-plant trial process. Upon completion of the single in-plant trial, the New Technology staff will review the data and final report from the establishment or company and forward it to the Technical Review Team for evaluation. After the final evaluation of the establishment or company's report, the New Technology staff may recommend additional in-plant trials or reject or accept the use of the new technology in an FSIS-regulated environment -- establishment. I'm sorry. Additional in-plant trials are recommended if,

during the trial, the objectives of the new technology could be conclusively demonstrated that multiple in-plant trials are usually required when an establishment or company petitions the Agency to change the pertinent provisions of the regulations. After the conclusion of the multi-plant trial, which requires a regulatory waiver, the establishment or plant will need to petition the Agency to amend the regulations. The regulatory waiver will allow the establishments or plant to use the technology until rule making is complete, unless problems arise. When amendment of the regulations is required, the establishment or plant must provide an acceptable data collection and submission scheme for monitoring the performance of the technology pending publication of an amended regulation. And, finally, I would like to speak about the Food and Drug Administration and Food Safety and Inspection Service joint review of new ingredient and additive technology. The FDA and FSIS have streamlined the process for the review of new ingredient technology. Now, when a new technology such as an ingredient or additive enters FSIS, new technology process, as a notification of protocol, and it has not been approved by the FDA for food safety, FSIS will forward the notification for protocol to FDA. FDA will then take the lead in

reviewing the new technology and coordinate the review process with FSIS. Conversely, if a new technology intended for use in meat, poultry or egg products enters the FDA new technology process, and it is not approved by FSIS for suitability in a commercial environment, FDA will forward the notification of protocol to FSIS. FSIS will then take the lead in reviewing the new technology and coordinate the review process with FDA simultaneously. This dual review by the two agencies has streamlined the review process, eliminated the need for separate rule making, and expedited it significantly. I hope this talk of the review of new technologies has helped both the establishments and companies better understand the process and our standard operating procedures. Later, during the question and answer session, we would like to hear from you any suggestions on how we may improve our procedures. Thank you for allowing me this time this morning to discuss this important topic with you.

MR. DERFLER: Well, here we are. This is the opportunity for questions. What we've tried to do is lay out our process for you as fully as we can so that you can understand it, and if you have a new technology that you want to use, or are interested in advancing. If you have any questions, the speakers would be happy

to accept them now. If you do, just walk up to the microphones. I guess that will be the best idea. Wait, let's -- Randy first. I don't -- if it's not working. No? You're on now.

DR. HUFFMAN: Great. Okay. Thanks. Thank you very much for the review. And I have, in my presentation later, I've got a couple recommendations that you've already addressed now in your talk, so I appreciate that. One thing. You mentioned a weekly report that is generated for, it sounds like, internally for inspection purposes. Is there a way that, and this weekly report, I assume, gives everyone a status update on any notifications that are in process. Is there a way for industry to have access to that in some form?

MR. PALO: We're in the process. We're looking into that. It's our desire to try and make it -- make the reports publicly available. There's a question about whether we would be disclosing confidential commercial information. And so we've been in discussion with our Office of General Counsel. And it's our goal, by the end of this quarter, to reach a resolution in this issue and, hopefully, to be able to post the reports.

DR. HUFFMAN: Great. Thanks. One more question. You mentioned the web site. We did a search

yesterday and I can't find it. Am I missing something, or is it actually up and running?

MR. PALO: Certainly.

DR. HUFFMAN: Okay.

MR. BURKE: If you go to the FSIS web site, it's not easy. It's not easy, but there's the official first hot button you get to mentions some -- you click on there, and it brings up a menu. You'll have the new technology. Well, it will bring you to that site, which includes our three documents. The notice, the guidance document and our FSIS directive.

MR. TEAT: The last, or that first question, was somewhat what I'm asking, is if you have priority technology that you want to protect and you think that might give you a competitive advantage, how do you approach this and keep that confidential?

MR. PALO: Well, right now it would be confidential. And what we're trying to do is develop procedures that will allow us to, you know, to protect confidential commercial information and yet, at the same time, provide as much information as we can to the public. So what we're engaged in is a process of trying to figure out how to balance that with our attorneys. And as soon as we get something, we do intend to make the information available to the extent that we can,

consistent with the Freedom of Information Act.

MR. DERFLER: Mr. Corbo.

MR. CORBO: In terms of the transparency of the process, is there any way for the public or interested parties to comment on the process of the various technologies that are being evaluated?

MR. PALO: At this point the answer would be no, except if we need to change our regulations, there will be a public process at that point. If once the -- if in point of fact we can publish our weekly report, then there will be an opportunity for people to see what's going on and to comment.

MR. DERFLER: Dr. Johnson.

DR. JOHNSON: I think it's great. We were actually having the discussion earlier, before the session started, about the FDA and the FSIS working jointly to try to help move technology through. And everybody at the table is shaking their head because they know the next little thing we're going to talk about here. It's also very encouraging that FSIS has said 60 calendar days, we'll try to get there. And that's great. Back years ago we didn't have that, and it was months and months. And, as Patrick had said, this division had it, and this group had it, and you're running back and forth trying to coordinate acceptance

of everything. In the agency reviews, your working together, do you put, when you know it's a meat and poultry technology that can advance certain public health concerns for meat and poultry, do you work with FDA to try to speed through the process? We've heard about budget cuts. And I think everyone out here will tell you, from the meat and poultry industry, as well as the technology providers, we appreciate the need to provide the science, but sometimes, as someone said, it gets lost in an in box. Is there any type of coordination with FDA on moving things forward, or is it strictly looking at the safety and the suitability that the two agencies are working through?

MR. PALO: Well, can you hear me? Well, I don't know if you can hear me on this microphone. You can? We constantly will call the appropriate people in FDA who has a, say a protocol. And we'll check in with them. Say, it's been a few weeks, and how are things coming along? We will have that continued dialogue to try to move things along, and we understand people have other things on their desks, but we do stay on top of them now. Since it is all in one group and, you know, one-stop shopping, I think I heard, we know we can coordinate it better, and we constantly call the appropriate people and say, where are you on the

process. And then, at the same time, we will get back to the company, itself, and say, this is about where we think it is now. We are at this step in the process, and we're trying to move it along. So that the company's aware of it, and that they can plan also. So we're definitely keeping the dialogue open now. It's much more than it has been in the past, and I've seen it actually result in some favorable reviews by the technology provider, which, many times, did not come in a kind way to us. But we seem to be turning a corner. We're trying to really expedite the process.

DR. JOHNSON: Thank you. And, if I could, just one more question. I appreciate that you've done a lot to try to keep the field folks involved with what's going on. You know, the guidance material, the directives, notices going out. But this type of information, I think, is very valuable, too, for people to see how the Agency is encouraging technology. And I don't know how. I know a lot of the written material, when in the field, kind of gets shoved under the desk or wherever until we have time to read it. But if there's some way you can focus on this with your field inspectors, I think that would be great. It could really help at the in-plant level.

MR. PALO: Yes, Alice, the report we put out,

the weekly report, goes to all the field operations. Goes to the district managers. And we've said if we, in fact, have a trial going on, in-plant trial going on in a particular plant, the circuit supervisor gets a copy. And so we're hitting most of the high levels on our general. On the specifics, we're going right down to the plant level, even calling up the IIC to let them know what's going on. Well, that's one of the ways. But you're right that we're trying to keep the communication open as much as we can and broaden it as much as we can. And, hopefully, like Phil said, once we work out some legal issues, hopefully, that we can bring that forward to even the industry.

DR. JOHNSON: Thank you.

MR. BURKE: We've been through a lot of this process over the last couple years and a lot of different meat products with our technology, and I applaud you for the simplicity now. It looks like an ease that -- it looks like we've gone through that process. We still have a few things or areas we want to go through, so it looks like it will be expedited. Appreciate that. My question is related to labeling and whether Dr. Post's office still handles the labeling, particularly for temporary waivers of labeling and that whole process, so maybe you can talk about that a

moment.

MR. DERFLER: Okay, the answer is we've sort of redistributed the labeling of work. The temporary permit is still done through -- the temporary for label -- for temporary label approval is in the whole label approval process. It's still in the labeling and other consumer protection staff. However, the coordination of the ingredients with FDA has been transferred over to the New Technology staff, and they'll be doing that. So that's the division. However, one of the things that we're stressing really hard is there needs to be a lot of communication among the staffs within OPPD and within FSIS. So there is a lot of communication back and forth. Okay?

MR. HEIMBACH: Yeah. My name's Jim Heimbach. I'll actually, probably, find out the answer to this question day after tomorrow, but I can't resist the opportunity to asking it right now. I do want to congratulate you on your coordination with FDA. I did the regulatory work for lactoferin a couple years ago, and the coordination was wonderful. I'm in the middle of bringing a new antimicrobial to market. We just met with FDA last month, and we're meeting with a joint meeting that FSIS has set up with the Consumer Protection Labeling group, is who we've been contacting.

But they've coordinated with their technology branch that we're having on Thursday of this week. I'm not a hundred percent clear. As I understand, unless we have an issue with safety of inspection personnel, or one of the other of the four criteria that were outlined before, I don't believe for a new substance that would be a GRAS substance reviewed by FDA for safety and by FSIS for suitability, that we would have to file a formal protocol with you beyond the standard suitability document. But I'm not completely clear about that.

MR. BURKE: What we like to do on a situation like that we like notification. What the notification does for us it's explains, in a sense, what you just said. You've got this lactoferin. Basically, you're going to tell us why it's not affecting all those areas. Then we become aware of it. We know that then that you're doing this. If questions come up from the field about this subject, we know about it. If we don't get a notification and we get a call, we can't explain anything, we can't help.

MR. HEIMBACH: Yeah, I'm sorry. I mean we're coordinating with you...

MR. BURKE: Oh, yeah.

MR. HEIMBACH: ...on this and all the information demonstrating the efficacy and the lack of

organeleptic adverse effects and so forth and so forth will be presented. I'm just trying to make sure. I mean we'll do a former GRAS notification to FDA that they'll share with you, and that notification will include the efficacy data. And I'm just trying to make sure I don't have to file a separate protocol document with the New Technology group.

MR. BURKE: The only reason people come to us in those sort of circumstances have been if people want to claim that their product is a processing aid...

MR. HEIMBACH: Okay.

MR. BURKE: ...and so, therefore, it doesn't need to be declared in the label. And then that would be one of the things we'd be interested in.

MR. HEIMBACH: Okay.

MR. BURKE: But, otherwise, no.

MR. HEIMBACH: Okay. Thank you.

MR. BURKE: Yes.

MR. DERFLER: One of the things that I was reminded of that I didn't say is if you have a question, if it would be good if you identified yourself before you asked it. It's a little late now. If you asked a question, it would be nice if you stopped by the guy in the back who's recording it, and we can have a complete transcript. Any other questions? Well, thank you for

your questions. I'd like to thank each of the presenters for their presentation. And now we're just going to have a brief shift as before we go into the next panel. This isn't a break. You should bring your nametag along. We'll call everybody when we're ready. I apologize for the interruption. As Dr. Johnson pointed out, it's kind of ironic at this meeting on new technology that we're technologically challenged. But anyway, we're now going to come to the portion of the program called Food Safety Challenges and Benefits of New Technology. And the first speaker will be Dr. Alice Johnson. Dr. Johnson is currently president of the National Turkey Federation. Her responsibilities at the Turkey Federation include overseeing implementation of the federation's strategic plan, as well as promoting members' interest in marketing, legislative affairs and the regulatory areas. She serves as -- on the National Advisory Committee for Meat and Poultry Inspection, providing guidance to the Secretary of Agriculture on issues such as product standards, labeling and inspection practices. Dr. Johnson came to the National Turkey Federation from the National Food Processors, where she served as Vice President for Food Safety Programs, directing food safety activities related to food inspections, passing inspection and crisis

management. Dr. Johnson.

DR. JOHNSON: Thank you, Phil. Introductions always make you feel so old, don't they? You think, man, have I really been around that long? And I have. I do have to say something about the whole football discussion. Not that it is -- it's professional football, but we in the D.C. area have a team. Now, up until two weeks ago, we would never have admitted we had a team. But last week we had some exciting news. Joe Gibbs is now back as our coach. And then one of the commercials over all the playoff hoopla I saw where they were -- had something about, well, you've got six months to get your story straight. And Coach Gibbs actually now has six months to get the story straight. That's all we're talking about in D. C. and Virginia, where I live. If you ask about a former Cabinet Member, O'Neill, they'll go, "Huh?" But if you go to president of the Redskins, they go, "Oh, yeah." So we do have our priorities straight. I do want to thank FSIS for inviting me, and Martha Workman for calling one day and saying, hey, let's go to Omaha in January. And I do appreciate Dwayne arranging the weather so that we are not at minus 20. I had to miss that. What I'd like to do is talk a little bit about food safety challenges in the poultry industry. And I'd like to go back from some

of our farm challenges to what we always hear, the little phrase, “farm to table,” “farm to fork,” “farm to plate.” However you want to phrase it, there are food safety challenges within the production chain when we’re talking about meat and poultry products. And I have been asked to talk specifically about poultry. And I guess it’s no surprise to anybody, when you look at food safety challenges from the farm to the table, you know, you can -- everybody can sit there and say, food-borne pathogens. And while science is inconclusive on what role animal agriculture plays in antibiotic resistance, everyone has a responsibility ensuring that we are doing everything possible to control any type of resistance that may be developing. And one of the things I think that’s very important that is a key food safety challenge at the consumer level is, of course, food safety education. Dr. McKee kind of started my discussion here. If you’ll remember, back in the early days, when Mr. Sinclair was writing his book and talking about slaughter house and some of the problems that were associated with the slaughter house, some of the challenges were considered to be, typically, animal disease. And animal disease concerns were the major public health focus of the day, and that was the 4D, and it consists of bad dying and disease in downed animals.

And that was, in essence, the reason why USDA came about, was to keep these animals, both meat and poultry, out of the food supply. It was the disease, itself, at that point, that was mostly considered to be the public health concern. What the poultry industry has done to address that challenge, and I think we have to say it's worked, when we look at USDA condemn rates and the number of diseased animals that are actually presented for slaughter, we've started off with some new innovations and technologies just in vaccination, and in figuring ways to keep the birds healthy. We look at some of our flock management. And if you look at some of these poultry houses now, there are ventilation systems, there are TOM [ph], there are heating and cooling controls, and there are various different systems in place that help to make the environment the birds live in one in which a bird can be healthier. You've also got hatchery controls, as well as just basic breeding controls. Breeding animals that -- to try to help promote resistance to certain diseases. And, as I said, you can see with USDA numbers, it's worked. No longer do we consider the animal disease, itself, to be the issue. Some of our on-farm challenges that we need to look at, basically, vertical transmission. There's been some research that shows that you can't have

pathogens from a hand to an egg. And Dr. Nelson Cox has done some work in that. You'll have to forgive me, but I have to make, "which came first, the chicken or the egg," or in my case, the turkey or the egg. So we start from this general. We've got an animal, and we are going to have pathogens. Even in the cases where you can, in a hatchery, have pathogen-free, salmonella-free, once they've become -- come in the environment, all that's wrong. So we have to do something to control the poultry houses. Poultry houses, you have chickens, you have litter, you have animals that are drinking, that are eating, and that are in contact with one another. You've also got pests. You've got rodents, you've got wild birds, you've got insects, you've got people coming in and out of houses. And you also have concerns, as I said, with the food and the water, as well as the use of antimicrobials. I'm sorry, antibiotics to consider for microbial resistance. How have we addressed? As I said, even with Salmonella-free poults, we still can't guarantee that's the way they're going to stay. Once we introduce them into an environment, contamination occurs. We've looked at vaccinations, we've looked at sanitation, both in the hatcheries, as well as in and around our houses and our means of transporting poults as well as birds to slaughter. Litter has been done.

There's been a lot of research done on litter and the pecking of the birds in the litter. The birds walk around in the litter. What can we do to keep the moisture content of the litter where it doesn't promote pathogen growth? You've also got certain technologies that have come about, or innovations through litter treatments. And while they make no claim on food safety concerns, the litter treatments help to acidify the litter and make an environment that isn't -- that's unfavorable to pathogens such as Salmonella. We've also had Salmonella-free feed. And we've done a lot of work on water. What is the best type of waterer that won't leak, that will promote the animal to drinking, but won't allow for puddles and water build up in the litter? We've also looked at some research that's been done on acidifying water, which helps to control the pathogen within the animal. Once you have the pathogen established in the gut of the animal, then you have the shedding if an animal is stressed or diseased, and animals pecking at litter. Another innovation that I think is one of the most promising is the use of probiotics on competitive exclusion products. Let's give the animals, the poults in this case, or chicks, a culture of bacteria of the good bugs that help keep out the bad bugs. There are lots of companies and groups

that are working on researching this. I know there's work being done at the University of Arkansas. I think Athens has done some work as well. And you've got some companies that are trying to work through the process. And when we look at trying to get approval on this thing, we go back to FDA approvals and it gets very difficult. And there's a lot of concern with trying to identify the bacteria and what is considered to be a very low presence of the good bacteria, being able to isolate those out. And I would definitely encourage USDA to continue the work that ARS is doing on the use of bacterial starter cultures and try to move forward and work with FDA on getting some of these approvals through. So other work that's also being done is on phages. They eat the bad bugs. And I think that shows some very promising work as well. All of these can help us with preventing introduction of pathogens into the gut of the bird, as well as help with keeping the bird healthy. When we look at some of our in-plant food safety challenges, of course, the first thing that comes to mind would be our food-borne pathogens. In poultry, we have a lot of concerns over Salmonella, Campylobacter, and, of course, Listeria in our cooked product. When a bird goes to slaughter, as everyone knows, it's eviscerated. There are concerns with the

gut and gut leakage. You have cross contamination concerns with birds piling up on belts. There were concerns with birds in the chiller, birds in the scalders. And you've also got concerns over people handling. Just human contact of birds going here, there and yonder throughout your plants. I think it's pretty amazing. Turkey industry is not quite as automated as the poultry industry. But if you go in the poultry plant, and you just stand there and look, I mean it's just amazing how anyone could think up an eviscerater. I mean who did that? A transfer machine, automatic transfer machine. I made the comment about the eviscerater one day, and somebody goes -- Alice. It was, obviously, somebody who stood there and hand eviscerated all these chickens. And it would probably be pretty easy that you could think you could automate this thing. There's been a lot of advancement in equipment over the years in poultry. We have looked at counter flow scalders and chillers. We have antimicrobial surfaces on the equipment. The picking fingers. You've got modernization the total evisceration line. And most of your chicken plants, now, you don't see birds dropping from the picking room on a belt being piled up. You've got automatic rehang. You eliminate a lot of the contact with bird to bird as

well as people hanging. You also eliminate the time it takes to get the bird down the line, which is also productive. One of the things that I don't think the poultry industry gets a lot of credit over is chiller management. I'd like to just say right now, chillers are not evil. I know in the past -- I know in the past that chillers have gotten a bad rap. Chillers, scalders. We've talked fecals, too. And I'm going to show you a picture of the old days. I'm going to show you a picture, a little bit later on, of the new days. The poultry industry has done a lot through the chiller. The chiller can now be used, when properly managed, as an intervention to help reduce pathogens. And there has been some work on that. I know the National Turkey Federation worked with David Caldwell and Alan Byrd in Texas, and showed that, with proper management, with proper interventions, that you can make some dramatic improvements in your profile, microprofiles on your bird through chiller management. And that includes some of the substances. The antimicrobials we're putting in there, as well as the counter flow. And you've got cleaner birds going in. The whole approach from the poultry side, as well as the red meat side, is a multiple hurdle approach. You know, you start at the first, and you handle birds in an appropriate manner.

The technology has improved so that you are doing things differently. And there's not one single step in a poultry facility that you can say, bingo, that's it. It's a hurdle approach, which all of these different technologies and advances have worked to help reduce Salmonella and Campylobacter numbers. Antimicrobial rinses and washes. In the early days, we took an antimicrobial through to the technology group. I think it was probably one of the first outside of chlorine. It took about eight months to get approval on that, simply because nobody knew and nobody understood. Now it takes a lot less time. And this chemical is still being used, and it's being used effectively. But it's encouraging to see that the progress that's been made within the Agency, as well as the progress that's been made within the industry to try to move forward with some of these. We have a lot of rinses and washes that we use, and we've come a long way with the best way to apply those. Some of our new equipment and applying the rinse cabinets, the inside/outside bird washer. They've all made things a lot easier. Also, we're able to keep things moving. And in the poultry industry, I think that's the key. Don't have turkeys or chicken carcasses hanging around waiting to go down the line before they start the temperature reduction, and I think that's been

a key. I attempted, very poorly evidently, to show just some of the equipment that's been used. Some inside/outside bird washers. And you can see the nozzles. And I'd like to talk of -- let's go back to this if we can, since it's all fuzzy. One of the things that I think that's really improved the whole process with the technologies is the ability to go beyond, do the regulation waiver. And for the Agency to be moved forward with looking at things. I think that most of the poultry industry would agree that the moisture regulation, or retained water in meat and poultry products, when it first came out, I think everybody thought, of my gosh. But with the elimination of the concern over added moisture from the adulteration part by the Agency, where the company has to label, it's allowed us to open up a lot of these interventions which are making a difference from a public health concern, as far as our rinses, how we're using our rinses, where's the best place to apply the rinses. We're still not adulterated product. We're still within our food safety concerns on our pathogens. We're still labeling product. But we're out of, oh, don't touch the chiller, don't do anything, because what if it adds moisture. And I think the Agency, this reflects a shift the Agency is going through, into the public health arena. When we

talk about other in-plant challenges, we're looking at the cooked product side. We've heard about some of the high-pressure treatments that seem to be very effective. Those things have become more and more practical. And, basically, it's because industries have worked to try to make them more practical. You've got a lot of ovens that are being used now to reheat services once up to prevent cross contamination. Again, you've got equipment rinses for slicers. And then you've got the whole issue of pasteurization, be it sting, be it irradiation. Some of the keys, I think, to addressing the in-plant food safety challenges, and I know most of you will go, oh, no, here she goes again. I think HACCP has really allowed the poultry, as well as the meat industry, to move forward with process control and being responsible, and has put the Agency in the appropriate space as the verifier. You give me the appropriate information, you give me the data, and we all joke about how much data is enough when we're dealing with some of the Agency officials. But HACCP has really made it so that we can actually move forward with some of these innovation or technologies without having the regulatory obstacles. It's a true move, in my opinion, toward the science-based controls that both the industry and the agencies are hoping to get. I think we are -- we do

have better process control, and we're able to look at things differently. I think the HACCP inspection models has done a lot to move forward some of our slaughter technologies, and I'm interested to hear some of the imaging technology that we're going to hear a little bit later this afternoon. Again, I think the less you handle birds when they're going down the line, probably the better off we're going to be from a microbial standpoint. And I think one of the big advantages that we've seen over the years, as far as the technologies and promoting technology, is public awareness. You know, it's okay to look at some of these rinses and say, well, you know, maybe that will work. Maybe we shouldn't be afraid of that. Maybe it's not going to affect our food, except in a positive way. We have had some very recent struggles, and in talking to some folks this morning, there are several rinses that are still out there that we'd love to see concerns over from on the part of FDA. And while we all appreciate the need to be sure the science is appropriate, and we can validate what we're doing, no one has any problem with either FSIS or FDA making those kind of claims. We do think that things should be speeded up a little bit. Just as kind of a side note, I was told that there's been some research done that says within using your

mouthwash once a time -- one time a day is equivalent to what this product will -- the residue that will be left if you ate 90,000 pounds of poultry. Now, not that we're opposed to anybody eating 90,000 pounds of poultry, but, you know, -- and it's not a matter of FDA not approving science. It's just a matter of timeliness. And I would encourage the Agency to work through those issues with FDA. Some sort of SOP where periodically, the Agency talks to FDA and tries to time table out how long an approval process is going through would be very useful, I think. There are a lot of folks in the poultry industry who are waiting some -- on some of these interventions, and consider them to be very appropriate in helping to achieve the goal of pathogen reduction. And I would encourage the Agency to work through that. I'd also encourage the Agency, and I thought I had a slide, but hey. Oh, you know what? That's my wonderful chiller slide that you're not going to be able -- it was good. I'm -- I can tell you that, on the standpoint of the chillers, we've gone from simply filter socks to extremely complicated equipment with micron loops, in which you pull water out of a chiller, and it looks just like the water in D.C. Well, maybe -- maybe better than the water in D.C. And, you know, I thought the first -- when I first saw this

picture with these interventions, I thought, ooh, everybody's going to think I'm showing the four a.m. early morning chiller chat. But it was actually at the end of the shift, and the water's very clear. And, you know, the chillers have become something that's a very useful tool in pathogen reduction instead of in the cross contamination issues we faced. If we look at challenges from a fork, so to speak, I think some of the big concerns we have, of course, are the reduction, the prevalence of pathogens even on the raw products that reach the consumer. We have certain packaging materials that help us achieve that. We can educate the consumer on handling, and as well as cooking temperatures. Some of our temperature pop-up thermometers, while they're not to be solely relied on, they help the consumer to become more aware of pay attention to the time. And we just need to start trying to focus both the poultry industry, as well as the Agency, on getting the consumer message out so that it's not something you think about just because Alice shows up at the cookout, and now we have to wash everything three times. It becomes a regular habit. Again, some of the -- at the table, we had -- we have modified atmosphere packaging, which not only helps with our shelf life and keeping product fresh. It also has some advantages from a pathogen

standpoint. Certain formulations that have been developed. Certain ingredients that help inhibit pathogens so that if a pathogen is introduced in a cooked product, that it inhibits the growth of that pathogen. Temperature devices and food safety education. I think the Agency, in the Partnership for Food Safety, has done an excellent job. A little Fight Back in Thermy are excellent role models. I actually had a chance to meet -- saw Thermy at the Kennedy Center. It's a pretty awesome thing. He almost took out a chandelier, but that was okay. His backup band, Thermy, was pretty good too. Some of our future challenges, as far as food safety technology goes, again, consumer education, both on the part of the industry, the Agency and the media, should be a key priority to keep food safety in the forefront, to not let people think just because certain things have been done, that they can do whatever they -- they can leave the turkey in the car while they go to a soccer game. A big challenge that we see in the turkey industry, I'm not going to implicate the chicken guys on this one, and the Agency is, but we've never done it that way. This includes things like looking at technology. This includes things about -- we talked about, well if it affects inspection. And USDA has moved forward with if

it affects inspection but can have an impact on public health concerns, then we can do it differently. Simply because we've done it for over 40 years. And I think if you ever stand in one of the HACCP inspection model projects, and you look, and you think, wow, who would have ever thought we would have gotten away from, hey, when I came in it was three inspectors. Somebody was at the mirror, and then you had the viscera inspections. And I think it's really made an improvement. Regulatory obstacles. I would encourage the Agency to continue to move forward with making regulations consistent with HACCP, looking at a science-based approach. Definitely, in the past, we've had regulations that have been an obstacle to technology. And I think, with the new group, and the Agency's commitment to moving forward, we can erase this as one of our challenges. And the lack of cooperation in research, we've still got to keep everybody coordinated. When you read in some of the documents FSIS has put out, and some of the technologies, well, you know, the industry could do so-and-so in hide, or, you know -- and we may very well feel that way sometimes, but that's not the way we get it done. We can't be suspicious of changes, we can't be suspicious of technology when it's presented to us. It's not a way to try to get out of anything. A lot of

the folks will say, oh, you're rinsing everything away. Again, the multiple hurdle approach. We're not rinsing away all the sins of the raising the bird, you know. I know I do everything at home to try to minimize my exposure to bacteria, but yet before I eat my wonderful turkey, I wash my hands. So, you know, the rinsing, the -- we can't be suspicious of why we move forward with technology. And I think that we need to move forward and continue to do research. There's been a lot of good work done. AMI Foundation continues to work with different groups and grants and try to encourage research. So, with that, I will be quiet. I just want to say thank you, guys, again.

MR. DERFLER: Next we'll hear from Dr. Randall Huffman. Dr. Huffman joined the American Meat Institute in January of 2000. He manages the AMI's Foundation Food Safety Research Agenda, assists members in finding solutions to food safety and quality challenges, and serves as the liaison between AMI and various scientific organizations. The AMI Foundation has funded research on E.coli 0157:H7 control, both on the farm and within processing facilities. Among various responsibilities, Dr. Huffman has been part of the AMIF with Listeria intervention and control task force in the Beef Processing Practices Task Force that developed and

conducted multiple in-depth training workshops for industry and government.

DR. HUFFMAN: Thank you, Phil. I appreciate that introduction. And, I guess, for the last couple weeks, like many of you in the room, I've also learned a lot about BSE's. But, with that, I won't say any more about it, since that's what Dr. McKee asked us. Here it is. Well, good morning and thank you very much for having me here today. I want to thank the organizers from FSIS and the invitation to address you briefly. And, as Alice mentioned, we were asked to talk about both the challenges of food safety in our industry, as well as the benefits to new technology. So I'll briefly give you a perspective from the American Meat Institute, which I represent. I actually represent the American Meat Institute Foundation, as Phil mentioned. And the American Meat Institute is the oldest and largest trade association representing the meat industry. We've been around since the early 1900s. And our members process over 90 percent of the meat products in the U. S. I'd first like to really applaud the FSIS for, first of all, organizing this event. But more importantly, beginning to put structure around the process of new technology approval and raising the awareness of the importance of this process. We, obviously, recognize the value of it,

and, hopefully, we will continue to see improved information sharing and streamlining of the process as we move forward. This is a great -- I guess it's not the first step, but certainly is a large step toward -- toward this process. So challenges. Just to get everyone on the same page, probably not telling you anything you don't already know, but we do have significant challenges in harvesting livestock for meat and poultry products, as Alice has pointed out. Just briefly, our industry processes over 85 billion pounds of red meat and poultry products a year. That's a huge number. Forty-seven billion pounds of that comes from red meat products. And that is -- that product is produced by harvesting over 135 million head of cattle, sheep and swine. And that doesn't take into account the poultry side of the equation, but just on the red meat side. So it's obvious that the harvest of these animals requires a significant amount of effort on a daily basis to both slaughter them in a humane fashion, handle them in a humane way, and then produce products that are safe for our consumers. I really wouldn't have to say anything else. I think it's implied in that process, itself, there are huge challenges to produce products safely, given that environment. But to try to define this in a little more context, using the HACCP approach,

we generally look at hazards in three different categories. Chemical, physical and microbiological. I think it would be an oversight for us to not consider the importance of both physical and chemical and hazards in our processes. Over time, we've seen a dramatic improvement in the elimination, or at least reduction of these potential risks in our food products, enhanced engineering of equipment, processing lines. Better information about how to process products has dramatically reduced the hazards associated with both physical and chemical risks. Better methods of detection have helped us along the way. Metal detection, x-ray devices that are very useful, have improved our ability to minimize those risks. But I think most of us in the audience recognize that our greatest challenge in our industry stem from microbiological risks or hazards in the process. As we all learned in our first microbiology class, organisms only need food, water, and proper -- proper temperature, and a little bit of time, and they can survive and grow. And, obviously, meat products present the perfect environment for bacteria to thrive. So we have that challenge in front of us at the beginning. And, certainly, in some cases, pathogenic bacteria such as E.coli 0157:H7, Listeria monocytogenes, Salmonella.

Various strains are potential hazards, microbiological hazards, in our processes that we have to deal with. I want to briefly show some data that some of you have seen when I talked before. You've probably seen a few of these graphs. But I think it's worth going over again, and I've updated them with the most recent data that I could find. And just to start off talking about E.coli 0157:H7, this is the summation of the data from FSIS. Routine sampling of ground beef in federal establishment since the inception of the project back in 1995 through the end of 2003. And a couple of things that are important to point out about this graph so we understand the data, if you don't already know these things. In 1998, about midyear, FSIS increased the sample size for this program from 25 grams to 375 grams. So we think that that contributed in some measure to an increase of the percent positive 0157 samples. Then in '99, I think it was, yes, in July of '99, FSIS adopted the more sensitive analytical method using immunomagnetic separation, which, again, contributed to, we believe, at least in part, contributed to an increase in percent positives in these samples, both in the year '99, where about half of the year we had that increased sensitivity, and then in 2000 was the first year where we had that complete -- did a complete year. So it

appears that the prevalence peaked somewhere in 2001. But again, I think it's important to recognize that this is below 1 percent positive for all the samples taken. Approximately 6 to 8,000 samples a year are collected in this program. And what's encouraging, of course, is the downward trend that we see since 2001. Why this is occurring, we can probably make a few educated guesses. Hopefully, technology played a role in this. We think that, certainly, it could be a factor. It's difficult to measure. But we certainly hope it is. We do know, in 2002, fall of 2002, industry, at the -- because of the new directive from FSIS, began 100 percent sampling of all trim destined for ground beef production, and elimination of any positive lots. So we believe that that probably contributed somewhat to this line, but we can't rule out the impact of new technologies, better implementation of those technologies, had on that reduction. We certainly hope that these lower values that we've seen in this past year, in 2003, will continue going forward. More importantly, what's the impact of E.coli 0157 on human health? And for a good snapshot of that, we look to the CDC and the foodnet data. This graph just depicts the rate or instance per 100,000 population for E.coli 0157 illnesses in the nine central sites at the Food Net Program. So it's a good

surrogate for illness rates across the entire U. S. population. It's the best we have. This green lines indicates the healthy people 2010 food safety objective, if you will. It was set in the year 2000. And that was set at an objective of one illness per hundred thousand population for E.coli 0157. It's important also to note that this program recognizes illnesses from all foods, not just meat products. So, with all that explanation, what do we see from this data? Well, probably not a statistically significant decline, but if you use your imagination, I think you can maybe show, at least some downward pressure on that data. At least it's not increasing. We can certainly say that with some confidence. So our -- or the things we're implementing in plants, the new technologies, the increased surveillance in testing, are they having an impact on public health? That's a question that we really need an answer to. I don't think we can answer it with the two graphs that I've just shown. But it's the best indication that we have. And so we need to continue to search for ways to answer that question. Briefly, on Salmonella, in sampling ground beef, we see a significant decline from '98, where it was about 6 percent positives, down to the last year of data that I had was 2002, just a little over 2-1/2 percent. In the

instance of food-borne Salmonellosis, in the Food Net Program, definitely, we see a flat line, no declines at all related to this. So we've got some work to do to get down to this National Health objective of 6.8 illnesses per hundred thousand. Now, it's again emphasized that this is not just measuring illnesses from meat and poultry products. This is from all food-borne illness. The final pathogen that I want to provide some data on is Listeria monocytogenes in ready-to-eat meat and poultry products. And this data, again, is the FSIS routine monitoring for ready-to-eat products since the inception back in 1990. I will point out that any of these FSIS programs aren't necessarily developed to provide a statistically valid sample of the entire red meat/poultry population, but it some indicator that we have. And, over time, I think it's very valuable information. And, certainly, we see a dramatic reduction in these percent positives for Listeria in our ready-to-eat products over time. And, hopefully, we can continue to see that number decrease with the implementation of the interim final rule to control Listeria. So what about Listeriosis in units? And here we do, definitely, see a statistically significant decline, and we're actually coming very close to the National Health objective that was set in 2000 and,

actually, was modified by President Clinton in a radio address. So he actually reduced it even further, and we're coming very close to that health objective. So that's very encouraging for Listeriosis. So that gives us kind of an overview of at least three of the microbiological hazards that are challenges to our industry on a daily basis. So what are the benefits of new technology in helping us achieve safer food? Obviously, the most important benefit is that we enhance the safety to consumers. Reducing illness is the primary benefit of any new food safety technology. That's pretty obvious. There are a couple other benefits that I think, you know, are ancillary that shouldn't be overlooked, and need to be pointed out and many an industry recognize this. This is a graph that I have shown before, and some of you probably have seen. And it just -- I only show it to just to paint a picture of the impact of re-calls on our industry as a whole. This is an example of the deli meat category, cold-pack category. This is data collected by A. C. Nielson. For a quarter, the second quarter of '98 through the second quarter of 2000. And this happens to be during the span when there were -- when there was at least one call for ready-to-eat meat and poultry products. So, briefly, let me explain the graph so you follow what's going on

here. The red line represents total pound sales for the entire cold-pack category. And those numbers are depicted here on the right axis. And then the green bars represent the percentage change in sales in that quarter from the year previous. So we see a percent change value here. A re-call occurred in late ’98, early ’99, and we see a dramatic reduction in the percent or pounds of sales for the entire category. Not just the company involved in the re-call, but the entire category of deli meat. And we see a reduction for two quarters in the percent, percent section, the percent change in sales over the previous year. So the fourth year is that re-calls within our industry have dramatic financial economic impact on our industry as a whole. It doesn’t just affect the company that is involved in the re-call. And it’s important to recognize this, and I think our industry has recognized this, and has been working diligently to share best practices and new technologies. Just to reconfirm this, we also have the data for the hotdog category from A. C. Nielson during a similar timeframe, ’98 to 2000. And there were actually two re-calls during this period for hotdogs. And we see, basically, the same effect during this, after the re-call, the same loss of sales, that are sales that are probably lost forever. Even though

confidence does come back, and sales return to normal levels, those are sales that were lost in several corridors that have a financial impact on companies involved in producing those. So, certainly, I make this point just to show that technologies that improve food safety not only help us make products safer for consumers, but they also, potentially, can help contribute to the bottom line. Another benefit, ancillary benefit, of new technology is helping us achieve regulatory compliance. And I just point out the end or final rule for control of Listeria in ready-to-eat products as an example. This took effect back in October, and we're all in the process of implementing that process. It's important, first of all, to point out that this is a regulation that I feel does a great job of encouraging development of new technology. It has incentives built in that encourage the industry to come up with new and better ways to produce ready-to-eat meat and poultry products. So, in that sense, it's very positive. But also, the benefits of new technology help us to, not only with this regulation, but with many other regulations, help us to achieve compliance with those regulations. So, just briefly, those are three benefits that I see in the new technology process. At the risk of leaving out many technologies that have been

successfully implemented, I just made a quick bullet list of a few that came to mind, certainly not an all-inclusive list. And we're going to hear talks later about some of these. But here's a quick list of some successful technologies that have been implemented in the industry in various places. The use of organic acid rinses on beef and pork carcasses. Steam pasteurization caplets that are in place in many beef processing plants. The use of irradiation in ground beef. Fecal detection devices. I think we're going to hear a talk a little later about these methodologies. The use of antimicrobials in ready-to-eat products have become adopted in many cases, and many are still pending. The use of various post-lethality treatments such as heat treatments infrared treatments have all been successfully approved and implemented. There's a few that have been brought to my attention that are pending in some form. Now, some of these may or may not have been submitted to the Office of Technology for review or approval at this point, but, certainly, these are some things that I'm aware of that are in the pipeline. And some of these, obviously, FSIS, probably doesn't have direct control over at this point in time. But the petition to improve irradiation in ready-to-eat meats is still pending at FDA. It has been since I've been

employed at AMI for the last four years. So I guess they'll keep it on the list until it is approved. A very new application of irradiation is currently going to be in the process of being researched, and at some point there might be a petition or some notification to seek approval for this. But irradiation of the carcass surface. On the pre-harvest side, use of chlorine in supplementation to reduce pathogens in the live animals. Again, that is a technology that my understanding is is that FDA, but certainly anything that FSIS can do to encourage that approval would be helpful. Organic acids on pork carcasses was brought to my attention by one of our members. The increased level from 2-1/2 percent up to 5 percent. That would be a very encouraging thing to see that move forward quickly. And also another issue that was brought to my attention was the use of new chlorine dioxide generating devices in brine solutions. So that was a very short list, and certainly not all inclusive. I did my best working with many of our member companies to come up with a list of some recommendations that we could provide to the Agency. And many of these you've already addressed in your talks this morning. So I appreciate that, and point out that there is web access to the approval process. And we did a search yesterday and couldn't find it, but maybe that

just shows my ineptness at searching your web site. So I'll definitely look for that when I get back. But, certainly, we think that's important. You mentioned this morning, a standard operating procedure for the process. We'd certainly encourage that. A written SOP, so that we all understand, not only you understand internally. And it sounds like you do understand the process internally at FSIS. I think it would be helpful for the industry and all potential submitters of new technology to also understand that process thoroughly. Recently, the risk analysis, Risk Assessment Division, developed an SOP for the risk assessment process, and I think something along those lines would be very useful, and we would like to comment on that SOP. It would be nice, within this portal, that the web site, to have a list of all the improved technologies. I'm assuming that is there, but since I haven't seen it yet, I don't know. If it's not, I certainly would encourage that a list of all the technologies that have been approved would be there and updated on a regular basis. Obviously, this was pointed out already this morning, but we'd certainly encourage that FSIS work to further streamline the coordination between FDA and any other regulatory agencies, that they be involved in the approval process. It doesn't seem, and from my

perspective, that FDA has the same sense of urgency that we need on some of these approvals, and anything that FSIS can do to encourage that would be helpful. FSIS should prioritize approval activities based on the various food safety needs and should avoid delays in urgent technologies. I think that goes without saying, and maybe that should be part of the SOP, some mechanism to make sure that happens. My last bullet there, FSIS Office of Technology should work to communicate with stakeholders on a regular basis. Meetings such as this are great. And I'd encourage -- encourage you to continue to look for opportunities to share what's new with the industry. This is maybe something that wasn't mentioned in your talks this morning so, hopefully, I found one thing that you weren't already thinking about. But it would seem appropriate to us that the Office of New Technology staff be involved in the development of FSIS and ARS research priorities. At least contributing information to that process when those research priorities are established on a regular basis. FSIS should provide incentives for companies to adopt new technologies through the implementation of policies that reward companies for implementation. The Listeria final rule is one example of a regulation that attempts to do that. We would encourage more of that. Finally, this

point was brought to my attention by one member. That consideration should be given to meeting approval of substances already listed as graphs by FDA, as long as bacteria side effect can be demonstrated. This point was addressed in an earlier question today. So just to summarize, in the future, our industry, to be successful, we're going to need new technologies. There's no question about it. They've served us well in the past, and they will, obviously, serve us well in the future. We're going to need multiple interventions, multiple validated interventions throughout the process, through slaughter through processing, using antimicrobial ingredients and antimicrobial processes and mostly validate treatments. And, finally, to summarize, our challenges are to minimize the occurrence of microbiological as well as physical and chemical hazards. And benefits are enhanced consumer safety and satisfaction of our buying customers. That's the critical benefit. But I think it's also important to point out that technology is not going to get us there alone. We're going to have to continue to, as an industry, implement best practices, and work on training and sharing of information within our industry to achieve safer products. So, hopefully, we'll establish enough hurdles so that those bugs just can't make the

last one. So, with that, I'll stop. Thank you.

MR. DERFLER: Thank you. Okay, next we're going to hear from Dr. Lynda Kelley. Dr. Kelley has worked in the fields of animal health and food safety for 20 years, over 20 years. Dr. Kelley has clinical experience in food/animal medicine, both in academia and in private practice. She worked for FSIS for ten years as a veterinary diagnostic pathologist. She's also supervised food safety methods development in the laboratory in the USDA Agricultural Research Service. Dr. Kelley is currently the Strategic Manager for Research and Technology Transfer for FSIS. Dr. Kelley.

DR. KELLEY: Thanks for letting me come. I'm excited to be in Nebraska today. I don't know too much about the Nebraska football team, but I have to make a comment that you've got a very much a national treasure here in Nebraska. And I think one of the reasons the meeting was scheduled here was because of the Tech Center. But last week I was fortunate enough to visit the Meat Animal Research Center at Clay Center and Hastings, Nebraska. And that is a national treasure. It really is. Even though I was here in the minus 20 degree temperature, it was worth the trip. I will say many new technologies have been developed for the red meat food safety have taken place here in Nebraska.

Everything. Mohammed Koohmaraie is here today. I'm excited to see him in the audience. And he will be speaking later today. But the technology for the steam vacuum was developed in his shop. He was responsible for that. And the technology that was used a few weeks ago to determine parentage, and the fact that the BSE cow was sired by a Canadian bull. That technology was developed in the MARC. So when it comes to winning the Super Bowl, I think Nebraska has been at the bowl and has won for many years. And I think, looking at the team that's here this year, I think we'll have a good year next year as well. So thanks for letting me come and speak about technology. Some of the challenges that we face. We do have the safest food supply in the world. We're very, very fortunate. But we're not there yet. We still have food-borne illness in the United States. And I think our goal in the public health sector is to reduce the number of illnesses as much as possible to keep pushing the envelope. And I think as we look at developing new technologies, one of the things I'd like us to keep in mind, that we do sit in the lap of luxury. We do have the safest food supply in the world. But as we look globally, many nations are not that fortunate. So, as we're developing technologies for the future, I think many times we can

think about what we can do for other countries as well. Some of the challenges that we face are understanding of many pathogens. How they persist in the environment, or how they contaminate the food supply. And one of the examples would be, as you look at in poultry, and Alice has talked about Campylobacter and Salmonella in the poultry products, and some of our pre-harvest intervention strategies have been so successful. Stan Bailey, who is in the audience today, was one of the key scientists that determined that work at the hatching cabinet would actually impact the numbers of Salmonella that we saw in finished product. So that was a key area that we could target in our intervention strategies. We aren't as fortunate in Campylobacter because we don't understand the microbial ecology of Campylobacter in the poultry flocks. We're not -- we've not made those same strides in pre-harvest interventions to be as successful on Campylobacter. So a lot of the work still needs to be done there. And I think Campylobacter would probably need more safety and protection technologies to help us understand that so that we can make as many strides in Campylobacter re-harvest as we have in Salmonella in poultry. How they contaminate the food supply, that's a concern. And I think Listeria is a prime example of that. Many times, we still don't understand all the

different ways that our environment can contribute to post-harvest contamination of Listeria. For some pathogens, we don't know how much must be present in foods for there to be a risk of illness. One of those examples, again, is Campylobacter. We're not able to do human testing now because of the problems with getting brought there, even in strains that were not supposed to cause these long-term sequela. So we need to look at other models. And I think a successful test for like in vitro toxicity was the Drays Test. We used to test cosmetics. Rabbit size, regardless of if we knew what it was going to be caustic or not. And now, because of corneal cell lines that were developed at Hopkins, we can do a lot of our in vitro testing on that. It's a very sensitive out site for toxicity. We'd like to have similar models like that in the food world. And I know people are doing a lot now with GI cell lines to look at in vitro testing for food pathogens, and that would be useful, particularly in things like non -- the non 0157 shigatoxin. Shigatoxin producing E.coli. Not all those are pathogenic to people. But what are screens that will tell us which ones of those are ones that we need to be concerned about in the food supply? For other pathogens, we don't have the ability to detect their presence in things. You know, this is a common example

of that. For many of the food-borne viruses, we don't get to have technologies to detect those in foods. Another challenge that we face today in food safety is globalization of our food market. Increasing quantities of imported food flow into this country daily. And the rising volume of imported foods dramatically increases the number of potential sources of food contamination. We benefit from the imports. We have lettuce and strawberries and raspberries and exotic foods year round, and it's delightful to have those choices, but it really challenges us in the food safety arena to make sure those foods are safe. We want the same level of protection for consumers for both domestic and imported food. The food safety world has changed since I've been in it. It used to be that most of the majority of the food that we consumed was prepared in the home. That is no longer the case today. And if you just look at your neighbor, as you're in your parking lot on the way to work on the interstate, you can see most people consume their breakfast on the way to work. And it's enlightening to me to realize that 50 cents of every food dollar is spent on food prepared outside the home. That really changes the way that we need to look at food safety. As more food workers become involved in preparing our meals the opportunity for disease causing

here is also increasing. The delayed time before consumption and the lack of refrigeration, that's going to require even lower pathogen loads on our foods as we have a new meaning for the "meals on wheels." Antimicrobial additives and preservatives are more important as we make sure that pathogens don't increase in the foods as they're stored before they're consumed. And the innovative packaging is going to play a role. I'm excited to hear about what Marlene Janes is going to say today because I think that may play a role in foods that are consumed and their shelf life. We need to be very concerned about that. Another food safety challenge that we face is even though we've done a lot, spent a lot of emphasis on food safety education, we have food safety web sites set up for training, we have report outbreaks that are on the web, we still have food processors, restaurants, food service workers, supermarket managers and consumers that are unaware of how to protect food from the food-borne contaminants. So we need technology that will provide innovative ways to educate our food handlers. Another challenge that we face today, and this is growing, is the population with increased susceptibility to food-borne infections. It's increasing. One-fourth of our population in the United States now is immunologically challenged. That's a

tremendous number of people that have lowered immunity due to HIV and AIDS, those on medication for cancer treatment or organ transplantation, pregnant women, young children and the elderly. And the consequences of food-borne disease are also particularly serious for those with inadequate access to healthcare, such as homeless people, migrant farm workers, and others of low socioeconomic status. Many of them are similar to those in other countries. If they develop food-borne illness and become dehydrated, this is a life-threatening illness for those who don't have healthcare. New food-borne pathogens have emerged over the past ten years. And as our world changes, and as animals are in closer contact with wildlife, as it's pushed in closer to where we live, and crowded with people, we will continue to see newly emerging food-borne pathogens. Some of these organisms can't be readily protected either to a lack of suitable methods or their spreading occurrence in foods. So we need robust, validated methods for many food-borne viruses, for some bacteria, for new key levels in pesticides and for emergent pathogens. Certain pathogens are increasingly associated with resistance to traditional controls such as heating, refrigeration and acid. And the physiological and genetic basis of resistance are not understood well enough to prevent

breakthrough of these newly emergent pathogens, that research is needed to guide improvement in traditional techniques and the development of new interventions to control these emergent pathogens. Prevention of pathogens in food requires an understanding of how food becomes contaminated during the production, processing and distribution. So the computer or visual imaging is important because we can see as food goes through the processing plant, where contamination is taking place. With this imaging, it's going to be important to make sure that these are correlated with microbial contamination of the carcass so that we can speed that and use the digital imaging as a method of more sensitive detection. For microbial sampling, we need more rapid methods, and I think one of the things with rapid methods, as we have the test in home technology now, and this is something that was mentioned this morning, that now when lots of trend that are going forth grinding. Now they are being tested. Those lots are being held before they go into the food supply. But I think in order to assist them, we need more rapid methods that can work with them. Right now, I think the lots are many times held, what, up to 18 hours or longer? Is that right? Yeah. So that's a -- that's a -- that's a cost to the industry. So if we have newer

technologies that we can give them an answer in a short amount of time, that would assist industry in this test and hold process that has dramatically reduced the number of recalls that we see of 0157. One of the things that we need is better enrichment procedures because we have rapid -- we've got PCR technology that can give you an answer in four -- two to four hours. But the problem is you've got to be able to get that pathogen out of the food matrices so that you can detect it. So better enrichment procedures, better select processes to get -- and better sample. The sample handling is the crux of the matter. And so we need better sampling matters for testing of the product. Contaminants are introduced into the food supply at numerous points along the way from farm to table. And I mentioned Stan's work with the hatching cabinets. Mohammed has done a lot of work with hide pulling. And other intervention strategies must also be developed for steps from farm to table. Research and microbial ecology of food-borne pathogens with the goals of limiting initial colonization of animals. And Alice mentioned the technology challenges we've had with competitive exclusion cultures that have been very effective with Salmonella, but we've not been able to get them into approval and into the marketplace. We'd

like to see that take place. Other probotics, development of vaccines. And with Salmonella we didn't think it was much of -- as much of an issue, but now with E.coli 0157 we're seeing that the animal feeds may very well be a significant source of the food-borne pathogens in the food supply. We need to develop new techniques for eliminating animal feeds as a source of those pathogens. New methods have been developed to reduce or eliminate pathogenic microorganisms from agricultural animals before slaughter. And we've mentioned the sodium chloride. That's an effective method for ridding the animals of 0157 before they go to slaughter. We need to see that approved in the marketplace. Many technologies have been developed for decontamination of meat carcasses and poultry carcasses. We have thermal decontamination, a hot water spray. It's exciting the sales with FSIS from '87 to '97 and now back, and it's exciting to see many of the new technologies and innovation strategies that are present in the plans. And I think are responsible for many of the reductions in the pathogens or the carcass. There's a tremendous difference from the pathogen line that's on the carcass, on the hide, and then when you look at that carcass at the end of all the intervention strategies. What a delight to see the quality in the carcass that's

coming out in the finished product. Hot water spraying, pasteurized steam, steam bath and spot cleaning, chemical decontamination with many of the chemicals that are safe. The hot washers and, as Randy mentioned, the submergible, multiple hurdle technologies. Okay, knowledge and solutions. I think we also feel more and more we're looking at ionizing radiation. Some of the problems have been limited availability and consumer acceptance. And the most widely used, right now, is with spices, herbs and seasonings. Most of those that we use have been irradiated. And we're seeing more use in fruits and vegetables and poultry. And more recently, meat and shallots have been approved. And we're seeing the use of these products in healthcare facilities for the people that are immune compromised. Technology solutions. I think we can expand the search on new methods of decontamination of meat and poultry and egg products. One of the technologies that was developed for Dogro [ph], for the Department of Defense, nano-emulsions where soybean oil is made into a nano-emulsion because it was good for decontaminated surfaces for Anthrax. We're now seeing that applied to shell eggs, and it's exciting to see these type of technologies applied to the food safety industry. Some of the new technologies for chilling that can be applied

to poultry to reduce the Campylobacter life. So I'm excited at where we are today. Again, the technology for the test and hold, the computer imaging systems, and more effective disinfection schemes for processing equipment and facilities. Improved food attribution is something that I think we're going to have to address to get the food-borne illness decreasing more pulse net. That takes advantage of the fingerprinting of bacteria, has been a key to rapidly detecting and containing numerous outbreaks of food-borne illness. It's led to significant recalls in multiple states. We'd like to see that expanded to more states so that we have earlier warning when we have a problem, and to look at other technologies that will even be more sensitive to fingerprinting such as the MAP [ph] were. We need increased sampling for surveillance of imported foods. And I think that could be automated with new technology. And we need new methods for testing as new food matrices hit the U. S. market. And the tracking technologies exist and are being adapted for use in the food industry. Now the parentage technique that I talked about that was used recently could be used. That same type of DNA trace back may be able to be used for food-borne pathogens as well. So I'm excited about the state of technology and research in the U. S. today, and I

think as we employ these technologies and work together, industry, regulatory agents and the research world, I think we're going to make even more exciting progress in the future. Thank you.

MR. DERFLER: We're about 15 minutes behind schedule, but if anybody wants to ask questions, let's do it now, and then we'll take a break. Any questions of the panel? Sure. Okay, let's come back at 11:30.

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[Recess]

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MR. DERFLER: We can get started. What we're going to do now is shift gears a little bit, and we're going to start focusing on some specific technologies that are being developed specifically with respect to the rest of the morning to meat. And the first talk will be on detection of fecal contamination on carcasses by Dr. Mark Rasmussen. Dr. Rasmussen is a microbiologist and research leader of the Pre-Harvest Food Safety and Enteric Diseases Research Unit at the National Animal Disease Center, ARS, in Ames, Iowa. His research specialty is digestive physiology and rumen microbiology in that national center. His work is directed toward hazards caused by bacteria and toxins that give rise to disease in domestic livestock and

humans. Current research projects include rumen acidosis, ecology of E.coli in the ruminant track, gut metabolism of planned secondary compounds, and development of carcass inspection imaging technology. Prior to his ARS appointment, Dr. Rasmussen was a research scientist at Eastman Kodak in Kingsport, Tennessee. Dr. Rasmussen.

DR. RASMUSSEN: Thank you. I am glad to be here today. I thought we had a lot of construction going on at Ames over at the University, and then, of course, on our USDA campus. But downtown Omaha seems to have us beat. We came down a one-way street the wrong way last night trying to get to the motel. So when there's a bus coming at you, you realize you're doing something wrong. So, yes, today, I just want to briefly describe our work with detection of fecal contamination on carcasses. Primarily, beef carcasses. And I'd like to acknowledge Tom Casey, who's in the audience. He's also at PMABC and a member of the Emerged Development Team, Al Gatz, is also here. So if there's any particular detailed questions about the technology, I'm going to punt them over to Al. When we first started this project, well it's been over five years ago now, Tom and I, these were some of the issues that were -- had arisen at the time. In fact, that FSIS had declared

fecal contamination to be -- to be at zero tolerance. A lot of people were working on coming up with specific bacterial tests for detection, contamination. And we were thinking about it differently. Could we come up with more general contamination or cleanliness tests? And that's where the idea of looking at markers in feces came from. So we developed this to the point. Little did we know that it was going to take quite so long to commercialize something. You know, as scientists, you think, well you have a great idea. You do a little -- a few experiments to prove the concept, and in the story, you know, you put it in a package and send it out. But now it has since taught us there's, you know, that science is about 5 percent, perhaps, of the process in getting some sort of product out to market. So, anyway, when we first looked at the specter of various samples of cow manure and GI track digestant and so forth, this is the kind of information we obtained. Initially, we were looking over here in the 500 ampere range. That's because we were looking for a specific code factor in some bacteria we got in cattle called mathenogens [ph], that is known to fluoresce. But when we actually ran the samples we saw this huge peak over there or red region of about 670 nanometers. And our colleague at Idaho State is actually a photo chemist in the Chemistry

Department, really focused in on that and said that would be a very useful possibility as a marker. So, to make a long story short in terms of what's going on there, any kind of animal that eats green plant material, they're consuming large quantities of chlorophyll. And in the digestion process, chlorophyll is degraded where the isoprene tail is removed from the ring structure and the metal line is taken out of the center of the ring. And, as a consequence, you get down here to some very fluorescent molecules. In particular, for animals, and in our case, the fecal detection, fioforbides [ph] seems to be the predominant molecule that is very fluorescent. In terms of just giving you some demonstrations, then also this is some of the things we did to convince ourselves that this had the potential to work, we took, basically, a commercial gel imaging system and modified it by putting different lamps in it and so forth, and using the CCD camera. And, in this case, we took a chicken leg and smeared some feces on it. And in panel "A" that's the chicken leg in broad spectrum light. Panel "B" is looking at the spectrum at the important labeling of 675 nanometers. And Panel "C" is looking at it at 610. I should bounce back a minute. On this spectrum, we do a subtraction of a wavelength in the lower six hundreds

from the predominant wavelength of 675, so it gives us a cleaner image. And then, finally, “D” is that correct image where you track those two wavelengths. So, essentially, all you see is the dirty spot in the meat, itself, meat goes away. So in conjunction with Jake Petrick [ph] over at Ohio State, as I mentioned, our colleague, we went through a design process to build a prototype that we could use to demonstrate this concept to people. And this is simply a schematic of this using a fiber optic. As the excitation light goes down this fiber optic, then the return light, the fluorescent light, also comes up that same fiber optic, goes through a series of dichrotic mirrors to the photo multiplier tubes, and then the image is analyzed. This was our first bench-top prototype, where we were cycling off light from a big laser, and there’s a lot of black electrical tape used there on our PVC pipe for our light chaser. Ultimately, we got that onto a little portable model, which didn’t provide nearly -- simply provided a digital readout, so when you passed over a dirty spot on a sample, the numbers went up. And then when we moved away from it, the numbers went down. So we took this out on the road, showed people, if they’re interested, eventually, in searching around for a collaborator and somebody that helps commercialize this, we ended up with

Emerge down in Florida. And one of the reasons was that they had done other interesting imaging projects in the past. Both these were infrared imaging systems. This one for on-board ship detection system for boats in fog and so forth. The Navy was having problems, I understand, running over wooden boats over in Asia because the radar didn't pick them up very well. Small wooden boats. So this allowed them to have another way of seeing out in front of the ship. And then also, they developed a very sensitive infrared camera for the horse racing industry to look for sore joints and so forth like that and leg sprains. Here is another demonstration of that in broad visible light. Here we've got both a vial of our standard chlorophyll metabolite light and, obviously, dirty piece of meat. And then this is the same image, but it's only looking at it in the red region, in that 675 nanometers of light. Again, we built -- again, Al primarily built a larger prototype which we took to a university, a meat plant, in order to further develop this. And this is simply when the excitation light is on in this chamber, shining on a carcass. This is what that initial prototype looked like. There were two light sources. Those larger blue with bluish colored windows. And there were cameras in the middle in that smaller window.

And this is another emerge fellow, Rick Blake, who was also involved in the development of this. And again, similar to the chicken image, here is a series of images on a carcass, where you've got the process image as the final point, where you're seeing, primarily, just the contamination spots and not a lot of background. Here is an example where they trimmed off a piece of contamination, but in the process, they smeared it with a knife, and so you can still the -- some of the smearing that was left on the carcass. Here are just some other images again. What was learned down at this university meat plant was that at times you could even see handprints put on a carcass when they pushed the carcass along or something. This, obviously, wasn't a commercial plant. They were doing this on a kind of a specialized basis for us. And they were doing their darndest [sic] to make a clean carcass, but were surprised when we still could find some things. So, anyway, in terms of coming forward with actual full-scale commercial design for a full carcass scanner, this is a drawing that Emerge developed to demonstrate how this thing would look. There could be based on a tower system with three different modules put together. And this is the final product as opposed to where here it shows mercury vapor, special mercury vapor lamps as the

excitation source. That turned out to be problematic in terms of shut -- turning up -- turning on the system, cooling needs and so forth. And there wasn't as long a life expectancy on that, on that light. And so they ultimately went to blue diodes. And this is the current prototype that's in the Excel plan up at Schuyler. And there's about 40,000 blue diodes in each tower. Al tells me now that the tower is going to have, what, over a ten-foot viewing height. This one was a little shorter at the time it was first put in. It didn't see quite that -- quite that distance. And this is simply some other views of it. As the carcass half comes by, it's triggered, and the diodes all flash. Those dark spots in the middle of the diode array are where the cameras are. And, of course, that then picks up the return fluorescent light off of that -- off of that carcass. In addition to the full-scale carcass on a design, Emerge has also come up with a handheld unit. This has been a little more challenging in that it doesn't have all of the bells and whistles and control features. But up at the top you'll see, on the box above the little TV screen, there is a distance sensing mechanism in there that you do a green light when you're at the appropriate distance. And this is simply some views of using that handheld on various parts of a

carcass. And there's Al down there looking at a shank on a carcass. So we get a lot of questions about how sensitive this is. First of all, I want to emphasize this is not a bacteria detector. I mean this is detecting a marker in feces. Now, obviously, feces is one of the major ways in which bacteria contaminate a carcass. But there are, obviously, other ways. So bacteria have arrived on the surface of a carcass by other means. We're not going to see them with this, with this technology. The other big question we have -- had because we were relying on green plant material with a diode for a signal, there were questions about feedlot diets in the United States where it's predominantly corn. And so Emerge, we hooked up to some feedlot nutritionists, and we brought in samples from all over the country of various feedlots, and everything from leftover food waste, cooking waste, that's a predominant part of diets in some localized areas, to your standard corn, soy, and for the most part, with sufficient sensitivity of the CIS system, there's still enough marker there to see. Because most every ruminant does get some green plant material. And we even did an experiment at our lab where we took a -- some cows on put them on straw diets. And it takes about two to three weeks to flush the GI tract of green plant

material where you don't see any signal left in the feces. Simply because of the bulk in the rumen and so forth, it takes a while to clean the system out, so to speak. In terms of fluorescence, sensitivity depends on many things. As I mentioned, diet, the intense state of the excitation line, how long you want to integrate your signal for. And these are simply numbers that we did at trying to arrive at this. Certainly, with our pure compound, we could do that with an animal or concentrations and still get fluorescence. And we also took feces and, basically, started weighing it out in smaller and smaller quantities to do detection. And the bottom line, I guess, is commercial designed is certainly more sensitive than visual, which is the current standard for looking for -- so, in summary, then we've used chlorophyll metabolites as our surrogate marker for fecal contamination. It's sensitive. It's useful because it allows real time detection. It's useful for quality control of process improvement. I mean in addition to railing off carcasses, our -- just one of the primary strengths, we believe, of this system is that it gives information. Information in order to adjust the process upstream, so that there's prevention as opposed to I've got a dirty carcass, what do I do with it now? And the feedback that we get from Excel at

this point is pretty favorable. They're seeing improvements in their meat product quality to the point of where they have given Al and Emerge the go ahead to install this system, this large, full-scale system, in the rest of their plants. So I think most of the shakedown has taken place out at Schuyler, and he's got a final commercial unit that's ready to be stamped out, and so we've also been looking at this in addition to beef, to other animal species, and also human application. Just to give you kind of a gee whiz photo of some of the volunteer's hand, in which we diluted out sample of the fingers, but to acknowledge that we weren't the first to think of this. Larson found this back in the early nineties, although maybe he didn't know exactly what the technology would be and how to implement it. And I'm not sure we would implement it quite in this manner either. We are looking at that possibility. So thank you.

MR. DERFLER: Thank you, Dr. Rasmussen. Next we're going to hear from Dr. Mohammed Koohmaraie. Dr. Koohmaraie has responsibility for post-harvest food safety at the Roman Fresca U. S. Meat Animal Research Center of the United States Department of Agriculture's Agriculture Research Service. He works closely with members of the meat industry to design projects to

address food safety problems relevant to industry. The focal point of these projects is the development of methodology to assess the prevalence of key food-borne pathogens and intervention strategies to reduce or eliminate these pathogens from the meat food supply. And he also responds to the research needs of FSIS. Dr. Koohmaraie.

DR. KOOHMARAIE: Good morning and thank you for the introduction. I'd like to make a small correction in the program. It says small plants. All of our effort so far has been directed toward the large plants, and we'll be working with anyone that's interested to extend that to small plants. In fact, one of the earlier FSIS colleagues there's a university that's working on small plants. I would love to know who that is so we can help. This is the elimination of reduction of E.coli 0157:H7 as a pathogen in red meat, is one of the major focuses for Agricultural Research Service, which I am employed by them. So since 1999 we have been working in the plants and trying to determine the source of E.coli 0157:H7 on beef, and more importantly, the method by which 0157:H7 is transferred onto the carcass. We had done a tremendous amount of work that, basically, convinced us that hide was a major source of E.coli 0157:H7. Before going too far, let me

show you the -- most of you are probably familiar with this scheme. I'm going to be showing data just after the hide is removed. These numbers are going to be very large or big, a prevalence. But don't be alarmed. This is basically the baseline for the interventions. And, in fact, when you get those numbers, you will agree with what Lynda said on how far we have come in terms of eliminating or reducing 0157 on beef. I'll show you some of the data that convinced us that we should focus on the hide. These are eight different plants, a number of observations for each of these studies. This shows the hide prevalence. You can see they're very high all the way from 77 percent to 29 percent. Then you see, on the last, on the carcass, this is just after the hide was removed. This is the area we sampled to basically determine the transfer onto the carcass. This is another data set that we looked at 0157:H7 in three different processing plants throughout a year. And first you will see the hide, first column. Second, species. Third is carcasses after the hide removal, and then you see the post wash. If you look at pre-visceration and look at feces prevalence and hide prevalence, I think you would agree with me that feces cannot be the source of 0157:H7 that ends up on the carcass. For example, in spring we had 78 -- 73 percent

on the hide, 3.9 percent of feces, and about 39 percent on the carcass. So we wanted to test this hypotheses because it's very important for our hypothesis to be correct because this is going to set the direction where we're going. And it's important to recognize that these are about the same time, that it's a community who are deciding what to focus on. For example, we were talking about putting -- giving something to cattle two or three days before slaughter to eliminate 0157 in feces, then take them to slaughter. Well, hide, hide is a main source of 0157. That hypothesis will not really hold. So to test this hypothesis we used chemical de-hairing. And I want to emphasize, the only reason we used chemical de-hairing because this is the best way that we could test our hypothesis. So we went to Future Beef Operation, which we're operational at that time. We sampled 240 carcasses. We treated, we sampled the hide, sampled the hides before they go into chemical treatment, so we sampled the control and the hides before any -- control and chemical de-hairing before any treatment, then we sampled the pre-visceration carcasses. And then the -- 0157:H7. For those of you who do not know much about chemical de-hairing, basically, carcasses are stung, they're put through this large, long L-shaped cabinet, and they go through

chemical de-hairing, and the carcasses de-hair very much like a harper, just when they come out. Again, I'll be showing data from hides and carcasses after the hide removal. This is the hide from controlled. We combined controlled and de-haired carcasses. There was no difference for hide. There was about 78 positive on hide if we did not do chemical de-hairing, 50 percent of the carcasses were positive for E.coli 0157:H7. Without the chemical de-hairing, only 1.3 percent were positive. Clearly, these are other indicator organisms, which I'll not take great time to discuss it too much in the interest of time. But, basically, they're all going that -- going the wrong direction. So it basically proved that our hypothesis was correct. And I want to emphasize again, the sole purpose of this experiment was to demonstrate the validity of concentrating an industry-wide effort on hide intervention to reduce or eliminate 0157 from the red meat supply. For the -- reason chemical de-hairing is not feasible, and so we began a project to work with many industry partners to develop alternatives to chemical de-hairing. We knew the concept was good, so we wanted to know what other chemical intervention we could use to basically give us the same. Most of us believed that intervention, having planned the X, but they have capacity to reduce certain

number of 0157 from this. And most of the time we don't have any problem. But when the incoming cattle load exceeds the capacity of the intervention, that's when we have the problem. So we're trying to bring the incoming load in line with the capacity of the intervention. So we don't need to go zero percent prevalence in hide, but we need to bring it down again for intervention to be able to eliminate 0157 and the risk. So this is a -- it's been a great project. We've worked with most members of the industry, almost all of them, actually, and Colorado State University and so, basically, with this project. So this is the basement for the startup lab, became our laboratory for a while. The folks at Excel have become very creative. They put these two barrels together to become an external unit. They will remove hides from the floor, fresh off the floor, direct into these barrels, and it will become an experimental unit. I'm going to talk to you about a -- one of the chemical compounds that's worked with -- worked with CPC. That's the same product now that Alice, I believe, mentioned is in front of -- has been in front of FDA for several years to get approval to use for poultry. But we worked with other chemicals. And some of these chemicals are proprietary for the company we work with, and I'm sure they will release them just as soon as they

are approved. But I'm going to tell you about CPC, but by all means, this is not the only one. There will be others that can do the same, but CPC happened to be very effective, and I'll show you. So this is the kind of experiment we will do. We will treat hide with CPC, basically using the same guideline, and you can see we can do in a packing plant in terms of dwell time and pressure, et cetera. And after that, we will sample the hides. And we saw the dramatic effect on enterobacteracae and ABC. So the first pile is CPC, for aerobic plate count from 8.8 raws per hundred square centimeters, dropping down to 3.5. Water, alone, is not effective, but some could argue that it's probably detrimental in terms of -- and making the bacteria available. And then the bactera from 6.6 raw, eliminate not detectable level. We're going to skip a few months' worth of research which did not work, but we decided to take the process into the plant, and that's what I also have to give our FSIS colleagues credit for helping us get approval for this, to do this in the plant in a speedy time. We, basically, treated. Because CPC is not approved, we treated cattle in the pen right before they go onto the floor. So we treated hides in the pen, and then we took them on the floor and collected data again. We did hides and carcasses. So this is ABC, and

for bactriaci about a 1-1/2 raw reduction for ABC, and about a 1 log reduction for bactriaci where they saw a tremendous effect on 0157:H7. On hides, reduce it from 56 percent to 33 percent. On carcasses, reduce it from 23 percent to 3 percent. Again, I want to emphasize we're trying to bring the incoming load in line with the capacity of the intervention. We don't need to go to zero to not to have any problem. So as we were doing all these experiments with meat on a regular basis, the industry partner updated what we do, and some of these companies have basically developed hide intervention facility, brand new facility. This happened to be Scott and Dodge City, where Excel had built a brand new, 7,000 square-foot facility for this process. And I'll just show you how they use it. And they use the chemicals that we developed. And I'll show you some data on those chemicals. But the bottom line is, it shows the effectiveness of focusing on hide. So this is with the cattle coming in. They are stunned before they go in the cabinet. They are, too, depending on the condition of the cattle, there are two to three employees that try to get as much they can get off by a reciprocating saw before they go into the cabinet. They go into the cabinet, and then there's basically two or three chemicals that are mixed and applied at different times.

They come out -- come out of the cabinet, and that's what they look like. And there's another three sets of employees that, basically, do the scraping and steam vacuum, and this is a time that I probably should stop and give Ken Master credit for -- this is the company in Omaha. The company and us work together to make the steam vacuum the way it is right now. So this is a Ken Master steam vacuum. This is what they look like, and this is what the carcasses look like after they come out. They are extremely clean. And when you talk to the employee, as I have, they love it too because they -- it makes their job a lot easier. We collected a lot of -- a lot of data. Basically, I'm sure you see the effectiveness already. Now this data set, with the chemicals that I'm using. This cabinet, which is not CPC, so this is hide before treatment. It was 60 percent. After it came out of the cabinet it dropped to 16 percent. This is the treatment, again, before it happened. Controlled hide was 88 percent, and carcasses after the hide removal was 16 percent versus 1 percent. Again, it shows dramatic effectiveness. Again, it's been a very good product. The project continues to be a good project. Our collaborators are -- I want to give credit to everyone that's been involved in the project. The National Cattle and Beef Association, and AMI,

obviously, Excel, Future Beef Company, Harris Ranch, I.V.P. Tyson, Swift & Company and Safe Food Corporation for providing CPC for these experiments. We now have a project, our other project, that it's in Washington somewhere. Supposed to be submitted, or has been submitted to FSIS to get approval to do an in-plant study on CPC. So I think it's a very exciting area of research. Another hurdle in the concept of market multi-hurdle system to help us ultimately eliminate 0157 from the red meat supply. These are our team, and all of them, they worked on the project, and I thank you for attention, and I'll leave you with that beautiful sunrise in a feed lot in Hayes Center, Nebraska. Thank you.

MR. DERFLER: Okay, one more talk and then we'll have some questions. Next up is Dr. Marlene Janes, who is going to talk about edible films with antimicrobial agents for control of food-borne agents. Dr. Janes is an Assistant Professor in the Department of Food Science at Louisiana State University Agriculture Center. She has taught food safety, food microbiology and industrial microbiology. She's been involved in a variety of research topics, including edible films that contain antimicrobial agents and bacterial phases used for control of food-borne pathogens in food products.

Dr. Janes.

DR. JANES: Well, first of all, concerning football, I think I have no gripes about our team. We were national champions this year, so unless you're from California. Well, today I want to talk to you about edible films and coatings and the use of antimicrobial agents inside these films and coatings to control food-borne pathogens. First of all, I'm going to talk to you about the various films that are available, and most of these films are used in film products. Then I'll talk to you about what research has been done, and the research that I've been doing and continuing to do. Films and coatings can be defined by two basic principles. First of all, they must be generally recognized as base. And what they're usually used for in the food industry is to inhibit migration of water, oxygen, aromas, carbon dioxide. They're also used of carriers of food ingredients, antimicrobial agents, flavors and antioxidants. Secondly, they must be composed of a film forming material. They must form a film around the food product. They can either be dipped, they can be sprayed on the surface, or also, we have preformed edible films. And these films look like Saran Wrap. I mean they're just -- and they're edible. And there are two types of films. Water soluble.

They're able to dissolve in water. Solvent soluble. You have to use a solvent such as ethanol or propylene glycol. One of the oldest films is lipids, beeswax. It's used to coat fruit. It prevents moisture loss. They've done a study with bell peppers coated with beeswax, and found that it permitted the attachment of E.coli 0157:H7 to the surface. One of the problems with the wax is is it there before oxygen barrier? It provides problems in some food products because of that. Next, resins. Shellac. It's used to coat roots too. It slows down respiration. It's a big moisture barrier. It can be incorporated with amino acids to inhibit benzomynic [ph] activity in some fruits, and they have a longer shelf life. Carbohydrex, alginates, calcium alginates. Several people have worked with alginates on meat products. Beef, lamb. I know Dr. Koohmaraie's group has worked with alginates to control pathogens. And they found this -- the alginates, itself, are inhibitory to the bacteria. You get about a log to a log and a half of reduction on the carcass of lambs and on beef fats. Carrageenan. It's used to coat beef products. It retains moisture, and a lot of people use it to add flavors, carrier flavors. And we know flavors, some flavors, also have antimicrobial properties. Now there hasn't been applied research yet

done on that with the carrageenan, but I know that a lot of research has been done with lipids and their antimicrobial activity. Pectin. Pectins are used a lot in foods, dried foods, because it limits the uptake of fat and it prevents migration of moisture. It's used on meats. A lot of meat products use pectins. Celluloses are good at moisture barrier. They are also good at preventing fat migration. They have pouches now. They are edible pouches where you can put food products in these pouches, like rice. You put the rice in the pouch, stick it in the boiling water, and the pouch melts. Protein. Collagen. Collagen is a film that's used in the meat casings. It is a poor moisture barrier, but it's really good, an oxygen barrier. The next one, corn and Zane. I've done a lot of work with Zane films. It forms a hard, glossy film. Right now it's used in candy, dried fruits, meds and pharmaceutical tablets. It slowly releases the medicine in the tablets, so it, when you take a slow-release tablet, pharmaceutical tablet, it goes in your stomach, then it slowly releases the medical agent. It's stable in high humidity, which, of course, Baton Rouge, Louisiana, our humidity is really high. It hits the hundreds. And we reach that. And it's also stable in meat. Proteins. Wheat. They've done studies on fruits

with this, and it reduced weight, firmness, and loss of the fruit. Whey. It provides a good barrier to oxygen, aroma and oil, and it's water soluble across a wide, huge range, which is important. Egg albumen. They've used it on meat products and found that it reduces lipid oxidation. Soy. It replaces egg albumen on food products. They found that it has the same properties as egg albumen. Now I'm going to talk to you about some research that's been done with antimicrobial agents in edible films. Natural antimicrobial agents. Sima-alginides [ph] with acidic acid and propiatic acid. Now kiacin [ph] films are not approved for use in food products right now. It's from shellfish. But it, itself, has antimicrobial properties. I've been work -- doing research on kiacin films, and we're finding that we get a log and a half to two log reduction with Listeria on red meat, chicken products, and they've shown that on processed meat products that it completely inhibits the growth of spoilage bacteria. Natural antimicrobial agents. Lysosine and soy protein film inhibit the growth of lactocils lycarim [ph]. Fatty acids, loric acid added to the same films containing EDTA reduced an eight logs per gram of Listeria monocytogenes do not affect the levels after 12 hours at four cc's. And that's quite a big reduction right

there. Now I think this was just done on the film itself, not on the food product. So it may be different on the food product. Organic acids and their salts. Acidic acid and kiacin on shrimp, coated on the surface of shrimp, in a mayonnaise -- and then placed in a mayonnaise-based inhibitive spoilage factor by four logs, compared to the control after four weeks. That's quite a long time. Four weeks. Four logs. And Niacin. Niacin is a protein produced by lisococtic lisids [ph], and it's mainly effective against ground pogic [ph] bacteria. And I note that it's approved for use in soft cheese products. It's also just recently been approved to be used in sauces for ready-to-eat meat products. Niacin added to calcium alginate coatings. This was done in Dr. Koohmaraie's research station by Dr. Cutter and Dr. Saragoosa, and they found that it produced spoilage bacteria, and they also did some work with Listeria monocytogenes, found to produce Listeria. Niacin added to calcium alginate films with 5.1 EDTA and 3 percent acetic acid produced Salmonella type bymrian [ph] on broiler drumsticks by 3.5 logs. After 72 hours at four -- and here we had to use EDTA because Niacin is not effective against ground pogic, but when you incorporate it to key liters, it will kill the gram negative bacteria. And niacin added to Zane film, this

first stage by Hoffman, they did it on the surface of the film and found that it reduced eight logs -- by eight logs. Reduced Listeria monocytogenes by eight logs. Niacin added to cellulose-based films coated on the surface of beef hotdogs, it reduced Listeria monocytogenes by 5.4 logs due to per gram per package after 24 hours of 433. A study that I made going into more detail now with niacin added to Zane film coated on pre-fixed chicken, I found it reduced Listeria monocytogenes to non-detectable levels from day zero to day 24. I mean at day 24 at 433. And this figure shows we started out with a 2.5 log per gram inoculate of Listeria monocytogenes. And this film is a Zane ethanol film, and we added -- national units per gram of niacin, and then we added 1 percent calcium propionates. And then we coated the surface. And this is a very thin coating. The chicken is very thinly coated. And then over time we see that our control rose up to around eight logs per gram. And we found the most effective treatment was the Zane ethanol with niacin and calcium propionate. It was at non-detectable levels through most of the experiment. The Zane ethanol with niacin also was very effective, and we found too that the Zane ethanol, itself, the film, itself, inhibited the growth. So the film, itself, added a significant reduction in

bacterial count. Now this is with the Zane propylene glycol film. And again, we started out with about 2-1/2 logs, and by the end of the experiment, it goes up to 8 logs safety per gram. And here we found the Zane propylene niacin calcium propionate was reduced to non-detectable levels with the Zane propylene with niacin. And what I think happens here is just kind of a synergistic effect, and also the film slowly releases the antimicrobial agents. And there's been work done with that that shows, over time, it's slowly released. And that's why our control, niacin by itself, reached the level of a control, Listeria monocytogenes. This shows a picture of the chicken patty coated with the edible film. You can't see the film. There's really no difference in appearance. There are several factors that influence the type of antimicrobial film coating. Factors inside the pH. pH is very important, especially when you're using niacin. Below 6, a pH of 6 or lower is more effective. Water activity. The lower the water activity, the better. The composition of the film, itself. We've done work that shows that the proteins, the more hydrophobic the film, the better activity we get with. A really critical point was the temperature needs to be maintained. Relative humidity. That influences the growth of bacteria. This study we did

just a surface probe. Surface hydro from 50 different films that we made. And we found that lycosin nitrate was more hydrophobic than soy protein and -- and then we tested the different films and we found that the more hydrophobic the more reduction we got in our counts. The more hydrophobic the film, the more active Listeria -- I mean nitrate barrier. So with greater understanding of film and coating process, edible coatings and films can be formulated for different food products. And I think that it could be a really good advantage for the business. And thank you.

MR. DERFLER: Okay. Now we have an opportunity for questions. If people have questions, come -- just come on up to the microphone and we'll recognize you. You need to say your name. Well, I actually have a couple questions. Given the purpose of this meeting, I think it's important that we sort of follow through on the basic themes that we outlined at the beginning. So the first thing I'd ask each member of the panel is do you, based on your experience as a researcher, have any suggestions for FSIS as to how we can approve our new technology process? And I'll start with Dr. Rasmussen, please.

DR. RASMUSSEN: Well, my experience, I mean, we thought about this long and hard early on, how to

approach this technology. Do we go to the regulators? Because we wrestled over this idea of zero tolerance on fecal contamination, and you don't want to get in an issue of the Delaney Clause, where the more sensitive detection method you've got, that drives the regulations to a lower and lower level. And, in fact, some of the industry people we talked to were concerned about that initially, you know, that I'm not sure we want that in our plant right now because it tells us things -- if it tells us bad news. And so we chose to, you know, rather than talk to the regulators, initially, I guess, we chose to go to industry and present it to them and work with them. How do we -- how do we go forward with this and make it work? So I'm not sure I'm answering question very well, but that was our experience.

MR. DERFLER: Well, I guess the question is is there a way that you would feel -- is there anything that we could do, I mean, given some of the intrinsic problems that we can't do something about, but are there things that we could have done to make you more comfortable coming to this?

DR. RASMUSSEN: Well, perhaps. I mean we had some good discussions with Dan Englejohn, you know, so I guess access to the people at the top that really, you know, make the decisions on some of these things, and

that have the intricate knowledge of the rules and regulations, which we know nothing about, and knew nothing about at that time we got into that. So, you know, we had some good discussions with him. For example, at our ARS -- annual ARS/FSIS meeting. So those are always a good chance for interchange, where you can talk to these people that normally you don't, you don't get a chance to talk to and get to know. So that's useful.

DR. DERFLER: Thank you. Dr. Koohmaraie.

DR. KOOHMARAIE: Well, this doesn't quite apply to me. We consider FSIS to assist our agency, and I've been dealing with FSIS probably for at least 15 years, so I know where to go. But as an outreach program, I'd kind of love to see the standard operating procedure that Randy Huffman talked about here. Put that on the web. It can tell people where you need to go and how you can get there, because I have a feeling that would help greatly. In my case, for example, we're going to do a project tomorrow in support of BSE. The keynote talk is here. I called FSIS colleagues Friday morning at eight o'clock. By 8:30 I had what they'll have, and hopefully it's out this morning. Yesterday morning in terms -- we're going to do that initial relationship and indentation and actual later.

MR. DERFLER: Yes.

DR. KOOHMARAIE: So I know the source, but not everyone knows. So I think to make that transparent web base, you can tell people where to go, you know, for help.

MR. DERFLER: Okay. Dr. Janes.

DR. JANES: Well, I think my main concern, like in Louisiana, it's a small business. We have a lot of small companies in Louisiana. And they are not aware of the new technologies that are available to control Listeria on ready-to-eat products. And I feel so sad for these people because they call me and they don't know what to do. They're frustrated. And so I think we need a way of getting the new technologies to these smaller companies to help them, because I think, in the future, we'll see more of them going out of business.

DR. KOOHMARAIE: I really liked the comment that someone made this morning, Dr. Brahmen. On your web site, it lists only intervention technologies that are currently approved by FSIS with a link to direct that they could get more information. I think that will be very helpful.

MR. DERFLER: Okay, thank you. Any questions? Okay, then I have one more, and then I'll let you go. My other question is what's the applicability of your

work to small plants, and is there a way that you can, if it doesn't have applicability, or there's problems in the -- in getting it to -- transferred to small plants, are there -- are there ways that FSIS can assist in trying to enhance and facilitate that transfer?

DR. RASMUSSEN: Well, I guess, in our case, we were fortunate in that this technology was scalable and that you could make both large and small units and price them accordingly, so that -- and we had thought about that from the very beginning, that we could make small, handheld. Tom and I joked about using flashlight night-vision goggles to go inspect carcasses with, you know. But, you know, that was some of our early concepts of where this was going, you know. But it was always, at that point, going to be kind of individual operating kind of small applications. So...

MR. DERFLER: Are you getting any interest from small plants in the technology?

DR. RASMUSSEN: I'll transfer that question to Al. He would know better than I.

MR. GATZ: We're in discussions with a number of...

MR. DERFLER: Could you go to the microphone? I'm sorry. And could you identify yourself?

MR. GATZ: Currently, we're in discussions

with a number of companies, but most of them are larger at this point. We're going to model a smaller version, a design of the system's modular. So we can take one modular of the system, package it, and be more effective for a smaller producer.

MR. DERFLER: Okay. Could you just identify yourself?

MR. GATZ: Oh, I'm sorry. I'm Al Gatz from Emerge Interactive.

MR. DERFLER: Thank you. Dr. Koohmaraie.

DR. KOOHMARAIE: Actually, a number of years ago, as a result of a request by FSIS, we wrote a document that basically shows how small a process that can adopt the technology since it's cold water and -- acid. The technology that we work are readily adaptable to small companies. I see two of my colleagues from the University of Nebraska here. They work very effectively with small plants and do regular discussions with each other. So, with them, they can equip small companies. So most of these things can be readily transferable if they can afford them. So some of these things are too technical and how many carcasses they process, that they probably cannot afford the technology.

MR. DERFLER: Okay. Dr. Janes.

DR. JANES: I guess a lot of these small

companies don't have the money to test the new products on their products. And that's a big problem. They look to the university to help them a lot. They just don't have the money to test, make sure that the product, the new technology is reducing Listeria on the product, or E.coli on the product. So I think that's a big problem.

DR. KOOHMARAIE: Dr. Kelley knows how excited I am about the bolded text, and I'll go way out on a line and say I don't think we'll have any major re-calls any more because the company's doing such an effective job at the bottleneck. So it's a great cost to them, but they're doing it. So that means we're going to have a lot of small re-calls. Five hundred pound, a thousand pound here and there. That's because these small companies are not able to perform the tests. So anything we can do to subsidize them will help them to perform the tests, I think will greatly reduce the risk to humans. So the large plants are doing extremely effective, they're going on board. Those that are not going on -- that are not on board yet to building large cooling facilities to hold this product, and I have no doubt before we know it they will all be on board. And I can't think of anything that's more effective in eliminating the large re-calls that cause all of us headaches.

DR. RASMUSSEN: Yeah, sure. Absolutely. I noticed on the handout of my presentation, only half of it was out there. But I do have a master copy here. If anybody wants a copy of it, I'm going to leave it with the convener so that maybe a copy can be made for anyone that wants the whole, the whole thing.

MR. DERFLER: Thank you. Last chance for any questions of our panel. Okay, we'll reconvene at 1:30. Thank you. Thank you to the panel very much for your presentations. They were extremely helpful. Thank you.

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MR. DERFLER: Okay, we're going to get started. If there's anybody outside, can you ask them to come in now, please? We're going to start now with the second panel. This is on Detection and Decontamination Technology with Poultry. And the first talk will be about ARS imaging technologies for poultry inspection. And this morning there was a lot of talk about football, but I guess I get a chance to use a little baseball. We're going to have a pinch hitter that I get to announce. Instead of Dr. Wyndam, Dr. Bosoon Park is here. Dr. Bosoon Park is a research agriculture engineer with expertise in -- he's in the

Poultry Processing and Meat Quality Research Unit at the Russell Research Center in Atlanta, Georgia. Dr. Park was a research engineer at the Instrumentation and Sensing Laboratory of the Agriculture Research Service in Beltsville, Maryland, and his expertise includes imaging technology development for food processing automation, particularly for food safety and food quality. Dr. Park.

DR. PARK: Thank you for the introduction. And this is my great opportunity to share my research accomplishment, particularly imaging technology applied to food processing. And I want to get some feedback, because today's audience is so many people from our industry, so that is actually I'm going to share with you about my technology because its application is only poultry right now. However, there's a lot of potential to apply it in many other food processing areas. Before I start my presentation, I'm going to briefly introduce the areas of research accomplishment regarding the imaging technology. The actual areas that imaging technology is developed by two different units. Or, actually, one is just mentioned at the beginning of the moderator, and instrumentation in the sense of it, they're looking imaging technology to differentiate the wholesome versus unwholesome, including cadaver,

septacemia [ph], and something like that. And other thing we're working on and support your processing and quality research unit in Athens, Georgia. And we are working on the developing of some imaging to detect fecal and ingestive contamination poultry processing. Let me briefly introduce the research accomplishment conducted by ISL and Helsley [ph] Group, and the objective or maybe the poultry inspection research at ISL was to develop an automated system for online safety inspection or will encompass this in the small plant environment. And also they developed an antigen to detect individual disease such as cadavers, septacemia, tumors, something like that. And reason and defect. And then to integrate their system into an online system in the poultry plant. And also, they started dividing some differences in effectiveness. They usually have to work from that research a lot. So I'm going to share this information with you, and that's in slides. And all research accomplishment that they have done for us, the visual poultry inspection system. Actually, they have finished with the in-plant trial already, and they will then do research work to test performance of the visual, and control system in a chicken processing plant. And also they tested the robustness and the accuracy of the system in a commercial poultry

processing environment. And a group have done an in-plant trial in the Tyson plant in New Holland in Pennsylvania the past several months. I think for several years. And they have done a section measured more than I've heard it's more than 12 or 13,000 birds, and got the -- they had the result that they found. As you can see there, the result is varied with some kind of a central chicken. However, finally they got almost 97 percent accuracy to identify for some, versus -- and the second program that they accomplished was the dual camera system. Separate water system for set for the marta spectron [ph] for poultry cutter's inspection. Also, they have done an in-plant trial. The objective of this was originally to develop more -- from this processing system, and including development. Also they tested a dual camera system for online separation of wholesome and unwholesome carcasses. And this is a diagram that they developed. Actually, the system has two cameras. One has a 540 nanometer and the other one has 700 nanometer. They combine those two imaging equation together to identify the unwholesome and wholesome bird. And also, they have done the test in-plant trial, the same plant in Tyson in New Holland, Pennsylvania, and they got about a 94 percent to identify the wholesome bird. This is actually the real

time testing, not sample testing, okay? They about tested more than 6,000 birds, tested the performance of their system. However, and mobile is a lower accuracy like 87 percent at this moment. So they still continue to test this system in plant. The ISL group actually successfully built an automated poultry inspection system using two systems. One is a visual NIR spectroscopy system, and the other one is a multi-spectrum Indian [ph] system. So, actually, they test it in a commercial culture plan, I just mentioned, in New Holland, Pennsylvania. And they study, they actually show economically feasible. This thing is very good to apply to the poultry industry. Of course, they're still working on the increase the accuracy. And also, they have quite an already established between the areas, and -- to the commercial system. And this is a summary of the spectroscopy research. Also they just tried to develop system to separate the liver of unwholesome and the sets of chicken. So they have about a 90 percent accuracy to separate sets of chicken to look at the liver. An ISL group developed a color using system for identifying diseased chicken carcasses and the coloring technology is able to separate livers and the heart of a wholesome from a set cadaver and sets with accuracy. This range is about 87 percent too, up to 92 percent.

Still, they are working on this project to increase the accuracy of this information. And also, the coloring technology can't be used to classify E.coli use of -- for severe recent cases. However, color using is not working very well to meet all very unserial level reason. So this is a -- they're still working on their color using. And also the ISL proved that developing multi-spectrum Indian find disease in chicken carcasses, and also, they found -- find a different category of a heart. They just measure the heart from carcasses, including wholesome and cadaver, the septos. And also, they found the accuracy ranging from 84 percent up to 100 percent. And multi-spectrum Indian technology for the separate, no more -- with 91 percent, and also the -- that 86 percent separated those symptom. And this is actually a summary conducted by the ARS instrumentation sensing group in Beltsville, Maryland. So let me switch gears and talk about the research I am doing right now. It's Russell Research Center in Athens, Georgia. In essence, ARS, we have three areas culture research unit, and also in-house high scale processing facility just finished to make our -- underground. So this is very nice. I'm going to show this facility in my slides later on. And also we have two commercial processing plant in Athens, and also -- the University of Georgia

is a big benefit for us to develop all the market research like this. And also, we have a group of houses, and also we have a -- manufacturer associates, Stocanco [ph], is very close and we have the -- to develop the system together. I'm going to present all of the detail to develop what we -- all-night inspection of a poultry product. Actually, this is our imaging research team, and here's a -- AG engineer, and our smears and culture scientist. Here is William Wyndham Bob. It's our Acting Research Leader and myself. So we have four scientists working to develop imaging technologies together. Actually, though -- all this technology development work to reveal the imaging technology for detection of a surface contamination on poultry carcasses. We -- at this moment, just -- Dr. Washington mentioned it this morning. We just look at the feces. And also, it is done in the optimal step for recent data and in processing pre-treatment. This is very important task for us, because our goal is actually implemented in the plant. So basically, we have built a time limit that is only -- our goal is actually one -- at least 140 birds per minute. It's a very fast processing work. So still, we just keep in mind we have to implement the system in the plant, not just in the lab. Okay? And so objectives were developed at -- to

identify the site and the type of contamination. And also, we developed a real-time online detection system. Finally, we tried to implement this system in the processing plant. This morning, as many presenters mentioned about this fecal contamination regarding to have the program, so I just emphasize that they borrow one. After we developed this system, we could apply that this system was to find out a critical control point. So there's a -- critical control point for poultry processing is prior to the carcass entering the coolant ice water. Okay. Because we want to chill it, then. And we tried to create our system just to be for for chill tank, to make sure that zero tolerance. There's everything both -- every bird -- there should -- no feces on the bird, okay? So that's our main goal, is to try to implement it just before the chill tank. And because of this can, we have cross-contamination of the carcass into the chiller. We collected, after the three feces, from duodenum, Secom, and coli. Before I started this research, and I'm actually the engineer, I never saw the feces until I just started this project. I -- okay? But it's not true. Look at that. All the feces from different sources is different. Color-wise, just everything is different. So that is actually we started with. Initially, we have to find out the

characteristics. What kinds of feces have different characteristics? Okay? So there's the reason we just collected duodenum -- coli. As you can see, it's always different. And also, this color and everything is chemical component, it depends on the 100 variants chickens have. So after we also tested colon bile and grit with the soybean mixture, this most popular diet in United States, okay? And we just realized, even I think a way for processing chicken -- here. Sometimes you can see, sometimes you cannot. So it's a very difficult job is for the inspector. They look at the bird every two seconds. And it's very difficult to see inside, outside, the fecal contamination, okay? So there's the reason you develop a machine that can do it, right? What is FSIS solution? Maybe a process inspector can closer look at the bird to find out the fecal contamination. But this isn't an easy job, as you know that, right? So what is the industrial solution? Instead of inspection, they just lots and lots of water. So the -- said that they used the water from maybe six gallon up to the ten gallon. So increase the water consumption is about six -- more than 66 million -- 66 million per year. Okay? There's lots of -- also lots of water consumption. So what is our solution? Of course if we tried to develop real time system, because

this is -- thing is science-based, continues consistent and cost effective and safe. Okay? So this picture is our third generation prototype system. I am going to show them how does that system work a little later on. Okay? There are -- technology isn't available right now. We just try all the multi-spectrum imaging and the hydrospecter imaging. This is most advanced imaging technology now available. So let me introduce a little bit more detail of hydrospectrum imaging because I hope that somebody already heard of hydrospector imaging, but there's not many people familiar with, so I'm going to show the picture like that. So hydrospectrum technology started only 80s, even before that, for the primosensing [ph], like the first observation. Okay? So this is one example of the hydrospectral data, so-called Hi-Q [ph]. So this is actually the album, hydrospectrum imaging system collected at Moppet Field in California, okay? So normally, when they look at this picture, you usually see the surface. There's only one thing. This actually combines all the spectrum information together. So hydrospectrum camera can slices all of this information. It depends what the system used. You can make maybe 20, 200, even 500, 1,000, okay? They just record the resolution, how close it can slice the wave length. They're still called wave lengths, okay? So, basically,

the higher -- three manageable data fare, two spatial and the one spectrum. And, of course, the spectrum data in this case is highly redundant, so there's reason we need to print them to find out best quality image we need because we have to use the same equation to real-time. So is it impossible to use this bunch of data and and this data is now -- the size of data is more than 100 millibytes. Okay? So we cannot use that. So this is one example. And look at the -- this is a standard color chart. So it's a color surface. But then look at the hydrospectrum camera, this is the same. You can see it. Okay? Because you can see some color is different more than the other color, right? That is as the contrast between the different fecal matter such as duodenum or phirsis [ph] -- something like that. Okay? And I think I'll skip this. So that is actually the three that from -- generated from the chicken, okay? So this is ideal when we look at -- take a look at it. This is duodenum, recontaminate. Fecal, coli, increases in gesta. So when you look at the duodenum, this is spectrum, but just one pixel spectrum from the different wave lengths. If you look at the scan, the spectrum is changing. So -- can you see it, here? This is the 500, the 600. This is -- of states in my broken -- . So if some surface has fecal contaminating, this

-- is gone. So this is sometimes the idea. We just approach it, our -- okay? And this is hydrospectrum camera developed by the NASA Research Group, the Space Center and the ARS, they're together. So again, this is one example I will show you that calls for -- composites. And this is called composite. You can't see the -- the active, human eye can’t see like that. The duodenum, secol and Jessup. Knowing what kinds of contamination, the hydrospectrum image is played at a different way, like a different intensity, okay? So this is, I just recognized here, it’s a number, and you can see the -- changing, right? Okay. You feel how hydrospectrum camera works, right? And, after that, as I mentioned though, we have to reduce the number of data. So, finally, we found the key wave length, four wave lengths, okay? This is based on the principle component we prefer, the statistical level. And still the four wavelengths is too much. So we cannot handle the -- so we just approach the other way, like a bend ratio. It’s very simple imaging processing, our version. But as you can see, five or six fibers as 517 show the -- all the contamination here, right? It’s very distinctive, compared to others. Visually, we did not contaminate here. However, this is a natural contamination in the vented area. So we really tried to

look at this. Okay. Now, this is for the processing. Finally, the camera can detect right there because camera doesn't have any brain. Human can think, right? So we have to -- further processing to identify this. And this is another example, it's very exciting, we found. And some -- looks like contamination, but this is the blood crock. So we have only three different layer of fecal contamination -- secum, coli. However, look at this. This is a very exciting visual. And over, I think it's on the shaded area. You can now see the -- clearly, and we some contamination, here. The wing's shadowed, okay? So growth quality is not thin, like it disappeared, because problem is not contamination. And also here, some shade area, camera can see it, even -- you know cannot see. Right? So based on this -- we just varied our system. I just mentioned we have tested different scalding [ph] sample. hard scald and softer scald, and those three different diets. Corn, wheat, milo with the soybeans, because sometimes this system's working particular diet, sometimes not. So that is reason we have tested. And this, as I just already mentioned, I am going to skip this. And hydrospectrum consists of actually have the 97 percent contaminated detection. And -- however, it has the -- number of false positive. So we're still

working on the -- minimize or reduce the false positive to increase the accuracy. However, it's a 75 percent false positive for feather and boundary. So this is our other -- obstacle we have to solve, the background issues. And so what is next step? As I just mentioned, the real time multi-spectral imagining system developed. So this is actually the first prototype system, Nema IV [ph], because we have to put in all systems into the waterproof, okay? And multispectrum imaging system, we use is a common aperture camera. This is a very special design. One camera has three different detectors. So we just put in the three filters. The wave lengths are the same as we found from the hydrospectrum imaging research, such as 565 and the 517, okay? So after that, we just do a second prototype with a camera enclosure. In this case, the camera is enclosed. This is industrial standard. So again, for use with this enclosure, and then you can commercialize, okay? And, finally, we just developed industrial scanning -- and lighting. So this is ready for the in-plant trial. So I will get us some feedback, if folks just give me some idea which plant we can go. So that might be good for us. And -- all right. Let me briefly introduce how this real time common object camera works. And a camera -- as I mentioned, the camera has a three detector. And

when I look at the camera, collect the three images simultaneously. Okay, this is less than 5 milliseconds. So we just put in the three filter, 516, the 567, okay? And after that, the pro-am -- duration. And just, really, there's a background noise, okay? And then, finally, apply this ratio to identify fecal contamination spot only, okay? What is next? For the process, we can do many different application after that. After we found some fecal contamination spot, we can -- one application we're thinking about is maybe integrate some washer. We just wash that point only with this water, okay? So many other application might be think -- thought about. So accuracy of our real time multi-spectral imaging system, right now, is about 96.8 percent, okay? And also the speed, as I just mentioned, the speed is also most concerned that we have considered, right now to be -- can process 180, just about 251 millisecond. In other words, you can process a bird -- that's about 3 birds per second, okay? So there's a -- currently, the use -- the poultry processing industry has 140 birds per minute. So that is the number we can still -- we can cover under our system. And also we try to expedite -- actually, to increase the speed to 180 birds a minute. That is as a European standard, okay? And now we have -- our patent

issued last July for the system. So we have industry patina to develop this system together right now. And also we just apply this technology for the enteral contamination, because when I visit this industry, poultry industry, the people said is also the internal contamination is very important. It's about 1/3 -- it's is half of the -- but that's not in their visceral area. Fortunately, that is -- area. So we just have tested how this system is working for identifying the internal contamination, because as you can see, the background of the internal, these colors are different from surface, in the skin color. So we found a good result in this case. I'm going to show
you final visual. So we applied many different amenities, including some filtering methods. And finally some inner filter eliminate some false positive. And finally, we just found internal contamination. In this case, a secal contamination [ph]. Okay? And also, the resulting internal contamination is about 97 percent, based on the primary results. We're still working on test of this system. Let me show the system then. It's about two minutes. So you can understand how this system working. So first part on last slide is actually the 140 birds per minute, and the last scene is at 180 birds per minute. So you can see what is different,

okay? That's no foul-up. This is actually our lighting system, is the DC Telson Halogen [ph]. This is camera, which has the three detectors inside. Each light has 150 watts. This intensifies it. And this is our photoelectric sensor, that's ready for three birds a camera. And this is a fecal sample we collected from a commercial plant. Duodenum, secum, coli and ingesta [ph]. So our contamination problem's a little bit bigger than we expected. However, we also have a past study reduce the sizes less than 1 milligram. So this is just demo. The green light means clean bird. Red light means contaminated. And also, you can see the number of a contaminant, and also, you can see the chicken I.D. So this system can be integrated some control system in the industry already implemented, right? Okay, the last part is actually the 180 bird per minute. So this system was working both 140 and 180. In reality, we have tested a 220, but it's too fast. But still, the camera can detect it, all right? Okay, I think this is all I have presented today. Thank you for attention.

MR. DERFLER: Thank you, Dr. Park. Next we're going to hear a talk about rapid detection of bacteria using optical biosensor. The presentation will be by Dr. David Gottfried. Dr. Gottfried is a Senior Research

Scientist in Electro Optics at the Environmental Materials Laboratory at the Georgia Tech Research Institute. He began his research career in biophysics at the Albert Einstein College of Medicine in New York. Since moving to Georgia Tech in 1999, Dr. Gottfried has directed the microbial detection efforts of the obstacle sensor group. He is involved in the design of amino acids, coupled with cleaner optical wavelengths for rapid detection and quantification of environmental and food-borne pathogens. I'm glad I only have to read it. Dr. Gottfried.

DR. GOTTFRIED: Well, thank you for sticking around this long, and I appreciate the invitation to come and talk about our sensor work. This has actually been ongoing for about the last 10 to 12 years or so. And I would sort of -- in advance of what the questions might be for Mr. Derfler, what I would suggest is, since all of the speakers, as far as I can tell today, have been from either academia or government service, one of the roles that FSIS or USDA could play is to make the technology transfer from those research institutes to use in industry a little more -- I guess, a little less hurdles, or expedite that kind of transfer. Before I continue, I just want to acknowledge Georgia Tech Research Institute and particularly, the Food Processing

Technology Division, which has really been doing food processing, new technologies, and assisting industries in Georgia and in the U. S. with quite a bit of effort for the poultry industry for the last 18 to 20 years. And also, the State of Georgia, which has a program which has funded almost all of this research, called the Agricultural Technology Research Program, which funds bio sensor work, also robotics, information technology, and other imaging projects that have been of help to the Georgia poultry and other agricultural industries. The other point I want to make at the outset is that even though we're talking about food safety here today, and I think some of these technologies, and particularly, the technology I'm going to talk about now, have other applications. And one of those is currently, actually, quite a bit in the news, is agriterrorism. And since everybody else has talked about football, we actually recently have a collaboration that was started between Georgia Tech and Mike Doyle at the University of Georgia, my longtime football collaborator, shall we say. And to look at what the -- this is a FDA funded program to look for what's called nontraditional pathogens, which is kind of code speak for bio-terrorism agents and food matrices. And the last point I want to make before I go on is I've given presentations and

demos of this technology many times over the last five years that I've been working on it. And, particularly, when I talk to industry folks, if poultry industry folks, the first thing they want to say is either -- is how much does it cost, and where can I buy one. And I have to say, well, we're just a research institute. We don't manufacture it. So that goes back to sort of my first point, that we -- you really need to take it beyond the research stage and development stage to the industry stage. And, with that, I will sort have said my little piece there. Okay. This is kind of preaching to the converted here today, just talking a little bit about the motivation. This is something I borrowed from a recent publication. Just talking about detection togs, using various technologies. And again, I don't need to stress too much about this. Just that a lot of these technologies, particularly -- and Traditional Eliza, and even some PCR methodologies, all have an enrichment step in front of them before the technology. And so the term rapid methods is somewhat of a misnomer. And I know I'm not the first person to say this. And I don't know exactly what Stan's going to talk about next. But as far as I know, most or all of the commercially available "rapid methods" are only for the actual detection time, and not for the pre-enrichment time.

What we're trying to do is develop a bio sensor that can go straight from sample to detection in under one hour. And the only way to do that is really through sensitivity. So this is the technology, the new technology part of it. I'm going to talk about detection using an optical wave guide. To get into that, you're probably familiar with what a fiber optic is. It is a high index of refraction material encased by a low index of refraction cladding, and this allows total internal reflection of light. That light bounces and is totally internally reflected. So this -- so fiber optics, of course, are used all the time as light guides for communications and various other applications. Essentially, what a point of wave guide is is, conceptually, if you slice this open and lay it flat, this is now a two-dimensional surface, where the sub strake here is your low index of refraction material, and the wave guiding material is a very thin layer of high index of refraction material. This is fabricated using conventional fabrication techniques that you would find in electronic chip processing. So plasma enhanced chemical vapor deposition and that kind of thing, and chemical etching. And what this two-dimensional surface allows is a number of things to enhance chemical detection. Chemical detection on a

fiber optic is limited to the little area down here at the distal end. With a two-dimensional surface, you've now got a much larger macroscopic area for interaction, either chemical or biological interaction. And also, again, because you can use fabrication techniques, you can put down optical or electronic components to fully integrate your device and make it much smaller than you would normally have in a laboratory analysis instrument. So how does this actually go about detecting something? Well, this is now that same not-to-scale wave-guide, looking at it from the side. As light is launched in, and we get light in through use of either butt coupling, which is just coming in from the end, or a prism, or in our case, a grading that's etched into the sub strake. As light comes in, it bounces, as I said, through this high index of refraction wave-guide material. Associated with that propagated light beam is an electric or magnetic field. And the tail -- actually this arrow is a little bit wrong. The tail of that field that sticks up into the cover layer or to the effervescent field. And that effervescent field interacts with anything that might be on the surface, and is very sensitive to changes in index of refraction. So I've drawn one particular application here where you might put a biorecognition element, which in this case

is, obviously, recognizable as an antibody. And if you have an antigen antibody interaction, you're going to change the index of refraction of that cover layer. And when I say the cover layer, I'm talking about a very thin layer, typically on the order of a half a micron thick. So you're going to have that interaction that's going to change the index of refraction, and we can detect that using another branch of physics called interferometry. And that's shown here, much as it's just a -- this is a single interferometer on one of these chips. Again, the light comes in. We have two beams. And I'll describe this a little more detail in a minute. A sensing channel, a reference channel. Those two beams come out. There's an optic that combines the two beams to generate interference pattern. Again, through microfabrication, we can now put multiple ones of these in the same chip. So you can now either put down antibodies to different pathogens, or you can put down different antibodies to the same pathogen if you want to increase your select -- or increase your selectivity and reduce your non-specific reactions. This is -- this describes how interferometry is actually performed. You have a light source, which in our case is a very small laser. The beam is split into two. This is the -- this is that wave-guide chip. And just

to -- I have one, a couple of these with me, just to show you how small that is. We're really talking about something that's on the order of a few inches or so. And if anyone's interested in seeing this, I can show them afterwards. You have two strips on this wave guide. One is a reference strip for giving out non-specific finding, and one is a test strip that has your antibody of interest or that you're looking for. The two beams come out, they're combined, they're blown up. And this generates this interference pattern which you see right here. And if you remember from your high school physics days, do you remember the two slit experiments, Young's interferometer. You take a beam of light, you shine it through two slits. You get that dark and light fringes. That's exactly what this is, except in our case it's not a Young's interferometer where you have two slits. This is some -- a configuration called the Mach Zender interferometer. With that image, using a very inexpensive two-dimensional rate detector, if you look at a single pixel of that detector, and you apply something that changes the index of refraction, what happens is this fringe pattern appears to shift. And I guess the best way to explain that, and I give this analogy all the time, is if you've got two runners that are known to run at

exactly the same speed, and they start off, you fire the starter's pistol, they start their race, and then you throw into the path of one of them, some, you know, molasses or wet sand, or whatever you want to use. There's going to be -- now, that runner is going to slow down for that period of time. And as soon as he passes that sand, he will regain his speed. But there's always going to be a time gap. When they get to the finish line, there's going to be this gap between the runner who did not have the obstacle and the runner who did have the obstacle. And that gap and that time is going to depend on how much of that stuff that the runner had to run through. And it's the same concept here. Depending on the index of refraction change, and your test strip, you're going to shift that interference pattern depending on the amount. So that's how you go from interference or from an index of refraction change to concentration of amount bound. So if you look at a single one of these pixels, as this interference pattern shifts eye. Unfortunately, I don't have a nice movie to show this. A single pixel, the intensity will go up and down, up and down as it sees light and dark, light and dark. And what we do is we take all of those pixels and we do a free transform on them to generate a total face shift. And this is the component that's directly

concentration dependent. Now this takes up about six feet of space on a bench top. And what we have done is shrink that all down into something that's about the size of a shoebox, a small shoebox. And this is the wave guide with a flow cell right on top. The laser is about a $15 item, comparable to what you would find in a CD player. And the CCD detector is literally ripped out of a web camera. So that's about $35. Total cost for this item is at least in the onesies and twosies, not the total manufactured or commercially production cost, is a few hundred dollars. So we're projecting this as a very inexpensive device. Here it is just packaged in a box. Right now it's run by a laptop computer. We don't concern Georgia Tech is full of engineers. We don't think it would be too difficult to take that computing technology and put that directly into the box, itself, so you have a free-standing device. And I'm a chemist, so I can say that. That seems easy to me. So here's some data. Initially this project was started to give, I said, for the Agricultural Technology and Research Program. And the main pathogen of concern at that time was Salmonella. So this just schematically shows antibodies on the surface binding whole Salmonella. And this -- and what I do point out is this is what's called a direct amino acid. That is we directly detect the

binding of the bug to the surface. There's no -- there's no said reporter, antibody or secondary antibody. There's no incubation steps. And so what you're seeing here is a real time accumulation of bacteria on the surface, and under the 30 or 40 minutes or so. And if you can't read the numbers, this is 5,000 up to 50 million cells per milliliter detection. And this -- so this shows now, again, for 20 or 25 minute time points, just a response curve to those concentrations of Salmonella. Just to illustrate reproducibility, we took a number of different wave guides and applied the antibodies and tested them for the same concentration, and just fit them to an arbitrary function. This just shows the equilibrium value and what it -- what turns out is, actually, we don't even have to wait for it to reach equilibrium. It turns out the rate at which it approaches equilibrium is also proportional to concentration, although it looks slightly greater error bars. Using antibodies, we can -- we have found a method for drying those wave guides once prepared, and storing them. This just shows some data for wave guides that were prepared and stored for only one week, although we anticipate we could probably do it a little bit longer. And I don't even remember which of these is the fresh wave guide and which is the

dried wave guide, just illustrating that we get roughly comparable results for the two. And again, now, this is to take it out of the laboratory slightly. This is actually poultry chiller water that was brought back to the lab, spiked with Salmonella, just to show that again. And partially this is because this is a surface method, where we're essentially not seeing the large, bulk index of refraction changes due to whatever stuff, and I use that term loosely, might be floating around in the chiller water. Just showing that we can detect Salmonella in that, in that matrix. This is results from really the last year or so, where we decided to, since we had such good results with Salmonella, to go on to something that turned out to be actually a little bit easier. It may be that because of the notorious stickiness of Salmonella, we were really tackling one of the harder problems first. Because when we went to Campylobacter, really what the first two -- first two antibodies that we chose, and these are commercially available antibodies -- we were immediately able to get down to 1,000 cells per milliliter detection level in under 30 minutes or so. And actually, that thousand cells per milliliter is actually less cells. We've recently starting using a closed loop system. This is now that whole wave-guide with a flow cell. These are

antibodies again, not to scale. And now if we use a -- just a pump, a peristaltic pump, we can get away with about a half a milliliter or less of sample volume. So that thousand cells per milliliter really translates to about 500 cells of bacterial cells that we're detecting. We've also done some recent experiments with surface regeneration. And people ask about this. Particularly people in -- when I go to sensor conferences, they want to know about surface regeneration because they want to know if you can use the same chip over and over again. And this demonstrates, I think, that we can for at least -- I mean we've only done up to three or four repeated uses. At higher ph we get good results. If we go to a slightly lower ph, of course, you can see it starts to be less effective. But I think that's actually less of an issue for the type of application we're talking about because you -- what you're doing is you're looking for -- I mean you're looking for a positive. If you get a presumptive positive, you're going to then send that sample off for confirmation testing anyway, and so you might want to save that, that sensor chip, because that actually has culturable bacteria on the surface. So just to summarize some of the features of this new technology, it's small, can be battery powered, and it's in a robust package that it is possible for -- can be

used in the processing plant. In fact, this is geared to be used within a processing plant. We have actually taken this out into the field, not for a food safety application, but for a ground water testing application. And it seems to have held up find. Response time is now in the order of minutes, so it certainly fits in the rapid method category. We can, as I showed you, we can have multiple analytic detection on the same chip. And we're in the process of evaluating that type of technology right now. It's a highly sensitive transducer, and a very -- and a flexible one. I'm only talking here about sort of antibody analytic binding. But it can be used for chemical detection. We put down polymer layers that might have a chemical selectivity all the time, and we can detect various chemicals or volatile organic chemicals in the environment. And this can be used both in air and in water. As I said, it's a direct labelist detection, the dry biosensor chips for storage and ease of use. And I think something that will help even further in that regard is we've also got an internal research program funded by Georgia Tech to evaluate the use of -- instead of using antibodies, which have a known sensitivity to room temperature and prolonged exposure to various -- to, you know, non-buffer conditions. We've started evaluating nucleic

acid-based binding elements. That is aptimers [ph]. If anybody's familiar with aptimer technology for biosensor detection. And, finally, I've just shown some results that we can regenerate the surface for multiple ongoing acids with the same chip. And I think that is the end of my presentation. Thank you.

MR. DERFLER: Next we'll hear from Dr. Stan Bailey, who is going to talk about rapid detection methods to support HACCP. Dr. Bailey is Lead Scientist and Research Microbiologist for the U. S. Department of Agriculture, Agriculture Research Service, where he's responsible for research directed toward monitoring, controlling, reducing and, ultimately, eliminating contamination of live poultry by human interred pathogens. During his career, Dr. Bailey has authored or co-authored 480 scientific publications in the area of food microbiology, concentrating on controlling Salmonella in food poultry production and processing. Salmonella methodology, Listeria methodology, and rapid methods of identification. Dr. Bailey is a Fellow of the American Academy of Microbiology and has served as an expert consultant for the Foreign Agricultural Organization and International Life Sciences Institute. In 2003 he was named the outstanding research scientist for the USDA ARS. Dr. Bailey.

DR. BAILEY: Hey, I'm technology inspired. I thank you, and I want to thank FSIS for inviting me. Let me start by saying my talk is a little different than the last few seen because I'm not going to be talking about something I developed. I was asked to talk about microbiological methods and how they may fit into technology. I was specifically asked, in my original contact, to talk about with small plants. And I asked to change the title because I'm not really going to focus on that per se, although I'm going to have a component where we will talk about that. To start with, as I had to develop this talk, which is a little different than other talks I've given, I got to thinking, what do we mean by HACCP in terms of micro methods? There's the obvious pathogen detection. But I thought it would be best to break it up into three components. And that would be microbiological methods to support sanitation or the -- showing that you had good sanitation. Methods to measure process control. And, finally, methods to identify pathogens in products. There are some points as we go through all these slides that I'd like us all to consider. And one is the large plant versus small plant. Certainly, small plants have real challenges. Primarily, as was pointed out earlier, they're monetary. They don't have -- most small plants

won’t have a microbiologist. They -- many of them would be very challenged to do a lot of the technological advances we’re talking about in terms of monetary means. But there’s another component that I want to just think about. Because depending on supplier contracts and other things, some large plants may not have the testing volume that some small plants may need because you have different things that is driving what is going to determine what methods you need to run. So those things we need to think about. Another thing that we may want to think about is a single-plant company versus a multiple-plant company. In a single-plant company, everything is in house. Either you’ll have a microbiologist or, hopefully, a consultant, or some mechanism. You can work with a county extension agent, or an extension agent from the university to help you interpret your data. Whereas a multiple-plant company will have corporate microbiologists. And they’ll want to be looking at trends and way things are done in different plants so that they can evaluate how well one plant’s working versus another. Those kind of things will help determine, many times, the types of technologies you want to run. Another component that we’re talking about with methods is are we doing this strictly in support of HACCP? And I’ll use the term

regulatory HACCP, which has one connotation, versus pure HACCP, in my mind anyhow, versus good manufacturing practices, which many things we need to do from a microbiological sampling and testing point of view with good manufacturing practices, may not be directly applicable to HACCP. And by that, I mean things like setting up baselines so that you know what's happening in your plant at different places all the time, so that if you want to make a technological change, you could have a good basis for determining if that change is worthwhile and worth the money you're spending. And then, of course, large companies, many times, have in-house labs. But even they are sometimes they use contract labs. But, in many instances, the small plants, and as we work to help them, they probably won't be setting up their own in-house labs, and they're going to have to learn how to work with contract labs. And so what may be applicable in a small lab that you set up may not be the same as the methods that would be used in a contract lab supporting a small lab. So those are just all things we need to think about. I'm going to start with my standard disclaimer here, and I thought this was particularly important with the talk I'm giving, because I'm going to be using a lot of methods that I'm going to use as examples. I'm going to read

this because I want everybody to understand. Methods and instrumentation highlighted in this presentation are used as examples of existing or potential technologies and are not endorsed or certified by the USDA ARS or FSIS, nor suggested at the exclusion of other technologies or methods not discussed. Now all of my friends in industry who make methods, I don't want -- that clears it. I don't want anybody mad at me because I didn't pick their method as an example. So I'll start with microbiological support for sanitation testing. Obviously, if we go to the old gold standard for sanitation testing, we would all think back to the Rodac [ph] plate. Just a plate with a little auger shown where you would do a contact surface. You would stick it in the incubator and grow it to see if you had any bacteria growing. So that's kind of the old gold standard that we would be working against. Moving from that technology into something that's somewhat similar, and I'll talk more about petri film later on, and I'll give you a slide showing how it works. But we take a petri film plate, which most of the industry people in this lab are familiar with now, a little dehydrated piece of paper with some media on it that you put your sample on. And once you rehydrate those, you can use those as a technology to simulate what goes on in a

Rodac plate. Another thing that you've seen a movement to in recent years is away from direct microbiological testing, and that's to look for proteins or carbohydrates that might be on equipment surfaces. And so there is technologies that we can do there. And one of those is Charm Scientific has a very clean carbohydrate/protein test strip. So it's a test strip type product that you can use to measure, not a direct microbiological test for sanitation, but you can measure whether you have protein and carbohydrates present. And I guess in the sanitation check area, in terms of rapid methodology and technology, the area that most of us have seen the most work presented and worked with over the recent years is ATP technology. And I'll use the lightening, which I think is a bio-control product, and a slide set here to show you some of the technological things you can do with this. You can use, in terms of this instrument, you can -- you can not only measure ATP, but you can use it for ph and temperature probes. All of this working together. You can store the data in your instrument. You can download it. It can be accessible by a central computer for a microbiologist. So you can set up a standard testing program to do that. The ATP sampling is good for both surfaces and liquids. You can do product testing where you can run a

background chemical through it which will separate out biological or microorganism ATP from non-microorganism ATP so you can differentiate the two. So that's one way that you can use ATP technology. Another thing, with this particular instrument we're talking about, it has a really good software package which allows you to download all this stuff, have it readily at your hands for an in-plant evaluation or trend analysis at the end of the week or end of the month. Or it can be accessible by corporate microbiologists who want to compare between plants. They also have a program which allows you to compare product lines, to compare surface types, and all kinds of things. So that's a particular advantage. That's enough about that product. And I just threw this slide up just to show you that -- and I didn't go and do an exhaustive search. That it has an ATP analysis. There's cells. There's just numerous companies that have that. And the example that I've heard people talk about through the years is sometimes with these ATP programs for sanitation checks, you don't get a particularly great correlation for the amount of bacteria are there. But it seems to have a pretty amazing effect. If you take your night crew in with you that was doing your cleaning, and you walk around with an ATP swab, and you swab it, and you stick it in your

instrument, and it lights up saying you've got too much there. It's an immediate feedback thing. So it almost, in many instances, on the sanitation side, has almost more of a psychological effect on the people doing the sanitation than it does on a direct hide correlation with a bacterial count or anything. So many companies that I know who use this technology have used it for that reason almost as much as for how well it works from a direct microbiological point of view. So now I'll move into process control. And there's many, many ways we can measure process control from a microbiological point of view. We could measure total counts or inter bacteria counts, but I think the thing that many people do most is probably measuring generic E.coli, or at least in the meat industry, poultry industry, that I work mostly with. And I guess our gold standard up there is obviously petri film. And that's what most people tend to use. And, certainly, is -- we'll talk about -- we can talk about just running generic E.coli, or you can do culti-forms of E.coli off the same plate, depending on the media that you have there. And how petri film works, that technology was initiated approximately 20 years ago, and they've made an awful lot of money from it. But it was really a highly innovative process that basically took paper or film,

which 3-M is good at making, and they impregnated dehydrated media onto that film so that when you put your sample on it, it rehydrated it, and you had a growth media. And then you just count, depending on the type of media you put there, then you have -- you can count different colony types. You can do a total plate count, and some you can do coliforms or E.coli. And so as we talk about technology, that's clearly one that has been highly successful. There are other things that have come along which offer some opportunities for some alternative ways to do it, and maybe give you a little different way of looking at things. And one of them is a -- which is a quite interesting technology. It's not based on your old traditional microbiology where you count your colonies. But, in this case, you, depending upon the type of media you put in your vial, you look for color changes. And what you're doing is you're reading that color change over time. And you're reading, in this case, you'll actually be reading the little part down at the very bottom of the vial. And you read this product every six minutes. Part of that didn't translate. Oh, there it comes, slowly. But you can use different types of media, depending on what you're looking for. And then in each case, the instrument will be reading it. There's something else,

I guess, will pop up there, the actual instrument. That it reads it every six minutes. And based on the rate or time that you get for that color change, you can do a correlation back to your initial starting point. You can do that with meat, you can do that for swabs of equipment surfaces and the like. And so there's pretty good correlations developed depending on the quality of the media you're using, and the initial starting point, and how long it takes you to get your break points and your curves. And you can use this. Oh, these weren't my slides. I didn't realize they moved in. But you can use this kind of data for trend analysis. You can compare your detection times, your positive locations over time. They have a particularly nice software program for this. In terms of relating it to HACCP, you can have a cutoff level of whatever you want. And, based on -- you run it each day, or every other day, or how often you run it. You see where your data points. And so it's really easy to get good trend analysis. And I find that to be extremely helpful when we're running baseline data or we're running things. The biggest trouble we can get into as food microbiologists is to do snapshots of what's going on, because when you do you can be misled. You can be misled in a positive manner or you can be misled in a negative manner on the quality

of what you've got going. What you really need is trend analysis over time because we have a lot of natural variation. And only by understanding that trend analysis can we evaluate new technologies and see how well they might work. And, again, this is just another way that using the same software, you can take the same data. You can break it out by month or by season or by all kinds of things and get histograms and look at your trend analysis. So now let's move into what most of us, probably, from a HACCP comparison point of view would talk about, and that is pathogen detection. I didn't have a slide in here for this, I just realized a while ago when I was looking at it. But, I mean, some of this stuff didn't translate very well. The first movement, as I recall, from going to meetings and being involved with workshops, teaching micro -- rapid methods for foods, would have been in the mid eighties, I think it was, '83, '84, '85, '86, somewhere in there, when we first started having the Eliza technology. And those were basically 48-hour tests at that time, counting the testing technology. The next wave that came along was PCR technology. And then we started working with improved sensitivity and better enrichment media, and we moved those all through 24 hours. And then -- and then somewhere in there, the Vidas technology, which took the

Eliza technology and automated it, came along. This was probably around 90-ish, ’90, ’91, ’92. And so the Vidas technology was one that, to me, was a good example of what technology can do, because if somebody who has worked with companies developing methods and media, and as somebody who used to be a -- the secretary for the AOAC Rapid Microbiological Methods Committee for years, everybody always said, you can’t introduce new technology, new micro methods, into the industry until they are AOAC approved. And as a general rule, that’s been a pretty good guiding light. But where technology can circumvent, that is when Vidas came out, which was basically taking and automating the Eliza process, within a matter of six months to a year, fully, 50 percent of the industry who were using rapid methods, had switched over to Vidas because it was giving them something they needed. At that point, they had not gotten through the AOAC process. They subsequently did. But even before they did, people found the technology to be so useful that they went ahead and implemented it even before it got through AOAC. The next generation that we see in the terms of automation of technology for pathogen detection would be the automation of PCR. Now PCR technology had been around a long time, but it was not getting much general commercial use or use in the

meat industry until the Dupont company had a division called Qualicon, which when Qualicon developed and automated the bacs, the PCR technology, then it -- you started seeing this product be widespread, and certainly a significant portion of companies that are using rapid methods for pathogen detection now have switched over to this technology. And the common thing here with what happened with Vidas is it's an automated process. All of our laboratories are being asked to do more with less. With less people. But, at the same time, being given more samples to run. And so technologies that are being effective on the pathogen side are, clearly, ones that are having more and more automation. This is going to give -- show us how it works, but I'm going to skip it. There we go. You -- so you prepare the DNA. All -- this is all that's involved. Well, PCR technology. I'm not a molecular biologist. And so I think I would serve as a good example. It was kind of like a black box to those of us who aren't molecular biologists. And people in most laboratories. You know, they hear PCR. They say, I can't implement a high technology like that because I don't know how. Well, what they've done is they, if they -- they made it simple. All you have to do is prepare your DNA, you amplify the DNA, and then you put it in the instrument and you walk away. And you

come back with the answer. And I won't go into all the technology of how it works but, basically, you're just detecting a light change, which from a melting curve of what's going on with the DNA. And then, for those of us who are real simple, it's a nice system because it tells you green if it knows -- no positive there, or red if you have a positive for the pathogen you're looking at. Another area that we -- we won't spend any time talking about today, an example of is automated hopping. And it was referred to earlier. As many times, depending on what we're doing with our data, it's not enough to know if you have a pathogen present. You need to know where that pathogen came from. So you need a little more information than just is it Salmonella, or maybe even just is it Salmonella, or is it Listeria monocytogenes? You need to be able to genetically profile that pathogen or that isolate so that you could compare it to where it may have come from in the process. If you have a Listeria monocytogenes problem on your final product, you want to know that it's there, but more importantly, you want to know where it came from so you can put an end to that and not have the issues that you're dealing with. And so there are -- is certainly one technology. And there's a number of others that have been developed and are very good at giving you genetic profiles which

allow you to compare isolates. And so you can say, what was on the final product? Was it what was on the raw product? Was it something that's in a drain? So where did it come from? Certainly, there are other types of products. Bio-Control Company has the one, two test. I particularly wanted to show this because, as we talk about small companies, if they're trying to do things in house, this is a technology that is an AOAC approved technology. It's not really for companies that are doing large numbers of samples. It doesn't lend itself to that, in my estimation. But it is a very good process for running a small number of samples. And you, basically, would drop your sample in here, and you have your antibody here. And where they meet, they form a little precipitant line. And it's something that's fairly simple and straight forward for smaller laboratories. And then another big trend we've seen in commercially available pathogen detection tests, and a number of companies have them, is your lateral flow devices. And again, you grow your enrichment media, has a sensitivity of approximately 10 to 5, which will give you an overnight enrichment, should do that for you. You drop it in. It goes to the ladder float, where it hits your antibody that's imbedded in the sample. You'll get a precipitant line that you can read. And

then there's a number of different types of enzyme amino acids. I'm not going to spend a great deal of time on those because each of these company things are just examples of a large number of those that are available. Now, a fairly unique and interesting technology is called a simplite [ph]. And that's one that depending on the types of media you use, where you can look for different types of color changes, it could be for total counts or culti-forms or or even Campylobacter, is you put media in and, basically, it's an MPN technique that's in one plate. So you have a formula for the number of the little vial -- little holes that turn positive, versus the total number there. And it -- and there's an MPN type analysis you can do that will tell you the initial number that you started with. And again, different companies have different OI's and different lateral flow techniques. And I thought I would end by just -- there's no right answer to this question, but it's just something for you to think about as we talk about all these technologies. And it's a tradeoff that companies and people who are making these instruments and assay have to think about. And that's what is the cost of pathogens? Well, I can give you -- I could have given you a whole 30-minute talk on the cost of pathogen testing because there's so many

considerations. But let's just boil this down to the actual assay, itself, not all the things about time you're saving and storage you can save by doing things rapidly and all that. Just on the actual running it, itself, it's highly variable depending on your fixed costs, the number of laboratory support personnel that you're already paying, and the fixed cost of overhead and things like that. But just the analyses, themselves, the media. Conventional media, generally, for most of the top technologies we're going to run, it's going to cost you a dollar to say $4 per test, depending on what you're running. Most of them are 48-hour assays, which are now -- which used to be the high-tech stuff, which are now the old-line stuff, run you from two -- two dollars and a half, to maybe up to $5, mostly in the lower end of that right now. Most of the 24-hour assays that are available, and there's quite a few of them now, run in the neighborhood of $3 to three dollars and a half, up to maybe $10 in some instances. Biosensors and other new technologies that are coming along, we don't know. But, certainly, they'll be higher. And the reason I -- the thing I want you to think about as we end on this, on this thought, is what is it worth to you, as a company, to pay? What are you doing with the data? Is it something you're holding

product with and you won't ship it until you know your results? Then paying twice as much for an assay would probably, certainly, be worth it. Is it something you're doing for a baseline data that you just want for historical reference? Then it may be hard to justify a more expensive cost if it's just something that you're using for trend analysis. So those -- so there's no right or wrong answer to this question. But it's things that, as we are developing technologies, and as we're buying technologies, we just have to think about all of those things. And, certainly, there's a lot of other factors too. If it's done for regulatory purposes, is it a -- a collaborated or approved method? And there's all kind of other things we could talk about if we had time. But those are just some of the factors we need to think about. And I believe that's all I got. Thank you very much.

MR. DERFLER: Are there questions? Questions from anybody in the audience? I'm tempted to ask mine, but I'm not going to, because we should be on break now. So let's be back in 15 minutes, at about three o'clock. Thank you.

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[Recess]

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DR. SHARAR: I think most of you who are in the food industry are familiar now with Listeria final rule. So I'm just going to go through it in terms of the new technology and existing technology being used to comply to the rule, and also for the sanitation procedure. The Listeria rule was published in the Federal Register on June 6, 2003, and with an implementation date of October 6, 2003. It's called an -- because the approaches to control Listeria monocytogenes is novel and as compared to our proposed rule which we published in 2001. Therefore, we are accepting comments up to December 8, 2004, at which time we're going to review and evaluate the requirements of the rule. Together with the publication, the rule we have issued complies guidelines which can be -- which is on the web site of FSIS, and these guidelines for establishments in complying with the rule, especially small and very small establishments. Aside from the guidelines, FSIS held five workshops in five locations in the United States before implementation of the rule. This is in order to present the requirements of the rule and to answer comments and questions from the public during those workshops. We also issued a directive, 10,240.4, which is -- which are instructions the inspection personnel in the inspection -- in the

enforcement of the rule. The Listeria rule, which is food control of Listeria monocytogenes in ready-to-eat meat and poultry products, can be found in the Code of Federal Register 9, Title 9, Section 430. It was issued in order to control, reduce or eliminate food-borne illnesses due to Listeria monocytogenes. In the last three to five years we have had two food-borne outbreaks linked to Listeria monocytogenes due to the consumption of ready-to-eat deli and hotdog products. As you all know, Listeria monocytogenes is an environmental pathogen and can be found on farms, in animals, and also in the food processing environment. So ready-to-eat meat and poultry products which receive lethality treatment, and which are exposed to the environment after the lethality treatment, can have cross contamination from the equipment that might have some Listeria monocytogenes. Therefore, the Listeria rule covers all ready-to-eat meat and poultry products that are exposed to the environment or the post-lethality environment. Establishments are required to control Listeria monocytogenes in ready-to-eat meat and poultry products that are post lethality exposed using any one of the three alternatives that we have in the rule. Alternative one requires establishments to control Listeria monocytogenes using post-lethality treatment

and antimicrobial agents and processes. Alternative two requires establishment to control Listeria monocytogenes using either a post-lethality treatment or an antimicrobial agent or process. Whereas alternative three requires establishments to control Listeria monocytogenes using sanitation procedures. After the publication of the rule, FSIS received questions and comments concerning requirements of the rule. Since the rule covers ready-to-eat meat and poultry products that are post-lethality exposed, a lot of questions were concerning differentiation between ready-to-eat and not ready-to-eat products, and also whether -- how do -- how to determine whether products are post-lethality exposed or not. We have also questions concerning the post-lethality treatments and antimicrobial agents that they can use for red meat products. And we have questions on labeling, and also on deli and hotdog products. In terms of sanitation we have questions concerning food contact surface testing, as when to -- when they have to test for it and how to test for it, and also on hold-and-test provisions of the Listeria rule. I will not be going through all this, all these kind of challenges. I'll be just touching on the post-lethality treatments and antimicrobial agents and processes which have relevance to this meeting, which is the New Technology

meeting, and also on the sanitation measures using food contact surface testing and hold-and-test procedures. The rule defines a post-lethality treatment, as a lethality treatment that is applied or affected after the post-lethality exposure. It is applied to the final packaging or sealed package of product, and it is applied in order to reduce or eliminate the level of pathogens resulting from post-lethality exposure. Here's a list of some post-lethality treatments that can be used by establishments or are being used by establishments right now. Steam or hot water pasteurization is an existing technology to decontaminate carcasses after de-hiding or before chilling. But it's new application is in ready-to-eat meat and poultry products that are sliced and packaged or hotdogs also that are repackaged. High pressure processing is a relatively new technology for fruits, fruit juices and meat and poultry products and vegetables also in order to retain the texture, flavor and color of the product. This new application is in ready-to-eat meat and poultry product that are sliced, and also in hotdogs. Ultraviolet treatment is an existing technology used to decontaminate laboratory benches and equipment, but now this new application is in ready-to-eat meat and poultry products. Radiant

heating uses infrared heat in order to decontaminate whole muscle products like ham after it's removed from this packaging, its cooking bag, and before packaging. Also in treatment is also an existing technology used in the processing of meat and poultry for water treatment, and now it's also being used for ready-to-eat meat and poultry products. Acidified sodium chloride is also an existing technology that's being used in the processing or decontamination of meat and poultry products, and now it is being used also for ready-to-eat meat and poultry products. An antimicrobial agent as defined by the rule is one that reduces or eliminates Listeria monocytogenes and other pathogens, or suppresses or limits the growth of Listeria monocytogenes throughout the shelf life of the product. An antimicrobial process is an operation that suppresses or limits growth of the -- of Listeria monocytogenes or other pathogens in the product throughout its shelf life. Here is a list also of some antimicrobial agents and processes that can be used by establishments, or that establishments are using right now. Sodium lactate, potassium lactate and sodium acetate are sorts of acids that had been used before in the decontamination of meat and poultry products. They were found to be able to limit or suppress Listeria monocytogenes in poultry products and in poultry and

meat products, and they are found to be more effective if they are added to the formulation. They can be used singly or in combination. Freezing is an antimicrobial process that has been used for a long time. During freezing, the growth of microorganism is stopped and, therefore, the metabolic processes stop and that's how it acts as an antimicrobial process. Growth inhibitor is fairly new. Cellulose casings are used for hotdogs or frankfurters. These are coated with niacin and during -- during the heat treatment or the cooking part of hotdogs, the niacin is transferred to the product, to the surface of the product, and so it becomes an antimicrobial agent during processing, and also during the storage of hotdog products. Zane-filled coatings have been discussed by Dr. Janes earlier. These are -- these are also used as antigrowth inhibitor packaging. The rule did not include or specify the minimum levels that are expected for the lethality treatment and antimicrobial agents that would be affected. However, the compliance guidelines have included these expected minimum levels of effectiveness of post-lethality treatment on antimicrobial agents and processes. It ranges from greater than two log reduction of LM to less than one log reduction of LM. And it's tied into the frequency of testing, of verification testing by FSIS,

and also legal claims. The rule also did not include the expected minimum levels of effectiveness of antimicrobial agents in process, but the compliance guidelines include these levels. It ranges from less than one allowed increase of LM to greater than two log allowed increase of LM. Food contact surface testing is required by -- by the rule for products in Alternatives two that use antimicrobial agents or processes, and products in Alternative three, to verify that sanitation controls are effective against Listeria monocytogenes contamination. The rule defines food contact surface as any surface in contact with the product in the post-lethality processing environment, peeling, slicing, repackaging and other operations. Examples of food contact surfaces are surfaces of the slicer, peeler, conveyor belts, work tables that are in contact with the product. The rule specifies that food contact surface testing must be included in the sanitation program in order to ensure that surfaces are sanitary and free from LM indicators. The establishment must include the frequency of testing, whether it’s once a month, twice a month or twice a year. It should include the explanation of why frequency is sufficient to be effective -- to effectively control Listeria monocytogenes or its indicators, such as Listeria

species. This will depend on the kind of product, the volume of production, and the sanitation problem that establishments has. It should identify the size and location of testing sites, and that's self-explanatory, and identify the conditions under which establishment will implement a hold-and-test procedure following a positive test of a food contact surface for Listeria monocytogenes or Listeria species. For deli and hotdog products in Alternative three, the rule requires that after a positive Listeria monocytogenes or Listeria species, on a food contact surface, establishment must take corrective actions and verify that the corrective actions are effective by conducting follow-up testing. Now if the follow-up testing shows positive LM or Listeria species or Listeria-like organisms, it must hold lots of product that may have been contaminated by contact with the food contact surface until the problem is corrected. In order to release the product that may have been contaminated, establishment must test the product with a sampling method and frequency that would provide a level of statistical confidence that ensures the product is not adulterated. If the food contact surface testing is positive for Listeria monocytogenes, the products in contact with the food contact surface are considered adulterated. So the implicated product

can either be destroyed or reworked with a process that's destructive of Listeria monocytogenes. The rule did not specify expected minimal frequency of establishment verification testing of food contact surfaces, but compliance guidelines included these guides. For Alternative one, it indicates the food contact surface testing frequency for the different alternatives. And for Alternative three, for non-deli and no-hotdog products and for deli and hotdog products. We have other future challenges that we're -- we are looking into. These are review and evaluation of the rule after the 18-month period. Listeria monocytogenes at retail, and the final rule that will result from the review and evaluation. Thank you.

MR. DERFLER: Thank you, Dr. Sharar. Now what we want to do is focus back on small and very small plants. And we're going to have a talk by Dr. Dennis Burson on Listeria interventions in small and -- small meat and poultry plants. Dr. Burson conducts cooperative extension programs on food safety and HACCP with special emphasis for small and very small meat and poultry processors here at the University of Nebraska in Lincoln. He also conducts educational programs for livestock producers and processors, emphasizing the improvement of the quality, consistency and value of

meat and pork products. Dr. Burson has recently received the Distinguished Extension Industry Award from the American Meat Science Association, the Achievement Award from the Nebraska Association of Meat Processors, and the Distinguished Extension Specialist Award from the University of Nebraska Cooperative Extension Service. We were here for a meeting of foreign particles about a year ago, maybe a little bit more than that. Dr. Burson was good enough to speak then, and we were really impressed by his talk, so we're really happy to have him here. Again, Dr. Burson.

DR. BURSON: Okay, Power Point's great. I can remember when we used to do these things with 35 millimeter slides, and you had to have your presentation down weeks and weeks in advance, and mine was finished last night about 4:30 or five o'clock, and so -- I want to speak to you about Listeria interventions, and not so much to focus on what it is that might be new and exciting, and all the science and all the reports that might be behind some of the Listeria interventions. But in focusing on the small meat processor and trying to decide what it is that we think needs to be done in order to help these operations and to bring them along with the rest of the industry, so to speak, in terms of the kinds of things that are going on in control of

Listeria. Now, and so before I get started into places where we think we ought to go, I thought maybe we'd spend just a little bit of time thinking about, well, who are these people, and we can go from the small operations, which have some size in terms of a volume output. But then you can also go clear down to the very, very small operations. And many times we will find that in these cases we have the owner is the operator of the facility. They are also the person that does all the decisions about research and development, so to speak, in the small plant. They're also the sanitarian in the plant. And so you might be talking to the same person when you're looking at these operations. And I put this big picture up. And if any of you are in Omaha, here, you may recognize this as Ken Stoitsich [ph], with Stoitsich House of Sausage over here in town. And you'll say, well that's not an inspected facility, and so why are you working with them? Yet some of these guys are under the -- I'm also concerned about some of these people that fall under what we might call retail exempt or custom exempt. And maybe we ought to be worried, too, about some of the retail operations in terms of deli in retail. But these are the kind of people that we're doing a lot of focus for, and as well as trying to reach the small and the large operations in

some of our programs at the university. So what's unique about some of these guys? Well, when we go to talk to them and work with them in terms of their products, one of the things that we'll find out is that many of them want to produce a very high-quality product that has a niche or that's something very distinct and different than what you might find from going to the pegboard in your local retail store. And so they want to develop a market where they can have a place, top rate. And this happens to be, it doesn't show up as well up there as it does on my computer screen, but it's basically a cooked pork roast that has apricots seeded throughout it kind of in a ribbon mixture. And so it's very unique type of products. And some of the times we find these things, and these people will produce them maybe only once a year, maybe during the special holiday time when they do it. But these are the kinds of things that they're looking at doing. The other thing that we find is that we can go into some of these shops and, basically, they have the processing area as well as the retail sales located right in their shop. And some of them also operate the custom products that would go home to a customer. But you'll find retail counters like this. And the thing that, as I was going through pictures, that caught my eye, is that we tend to think

about things that we use to control Listeria, and we think about a vacuum-packaged product, and not all of them are vacuum packaged. And so they have some things that just sit out into the storefront. And the other thing that I take out of this picture is that these guys produce a lot of different products. And, in fact, a while back we did a survey. We asked them how many different types of labels or products would you produce in your facility. And at one point in time, and this was a few years back, they said there were 39 different products that they would produce. And so -- but some of them were very low volume. In fact, one of them reported that they produced a product, and the biggest batch that they produced was 30 pounds in a year. And so some of these operations have unique things in terms of looking at controls for Listeria, especially if you think about products. They're worried about quality. And so anything that we're going to do in terms of post lethality or antimicrobials also has to address quality issues with these guys because that's how they're building their business. Then the other thing is that some of it's very low quality, or low quantity, and so then it has to be something that is easy for them to apply in their operation. The other thing, as we go out of the metropolitan areas and we get into the rural

areas, many of the operations include slaughter and processing of fresh meat, and some of it as a custom slaughter basis. And so in the same facility they'll be doing both the fresh meat as well as ready-to-eat products. And because of their small size, they usually look for a low investment in the processing equipment; however, I would say that we've seen people that have taken an aggressive business approach, have decided that they can trade off some labor for processing equipment, and will buy into some equipment basically on that schematic that they can produce more with less labor, which becomes more and more difficult for them to get a hold of. As we said, the owner and the operator usually has direct oversight of the operation, including the sanitation. Packaging and preparation of ready-to-eat meat products is not a 24-hour operation for them, or not even a two work shift operation for them. It might be once a week for some operations. But, at the very most, they usually apply a few hours each day. And so then you start to think about sanitation, and how do they manage that, and make sure that care and checking, and if you have an infrequent operation like this, how do you make sure that you're following up? So there is a possibility, however, if you get these people educated, that maybe sanitation could be conducted

before packaging. And another thing that we talked about, freezing, is a possible post lethality treatment. Many of their customers in the custom exempt, that's why they used to get their products. And it's only recently here that many of these guys have bought into the small pouch or bag-packaging, vacuum packagers that they've been able to sell fresh meat products, or to provide fresh meat products that were not frozen, or the ready-to-eat products that were not frozen. So what are some of the challenges for these guys? And this was pointed out in some of our workshops that FSIS went through in October and November. But it's since they have a low investment in equipment, many times they use the same equipment for both operations, whether it's fresh meat, whether it's ready-to-eat meat products. And so you might have a slicer that's used to prepare -- to cut the raw jerky meat for preparation, but also the same slicer goes back and cooks the ready-to-eat meat. And so you can see that you've got a concern there in terms of spreading Listeria. Many of them are in a one-room operation. And whether that room is refrigerated or not might depend upon how cold it is outside. But this -- this particular operation, one room was focused primarily on the production of ready-to-eat products. But again, some of these operations, the one room also

provides the beef carcass fabrication or the cutting of retail meat cuts and fresh meat operations as well. This is a picture in our facility. And when we talked about the Listeria rule, and went through and thought about it a little bit, one of the things that you can -- need to educate the small processors about or think about, how cross contamination, or how things could occur. And this hallway, although it looks nice and clean right now, it's also a common hallway that fresh meat or ready-to-eat meat can go up and down, and traffic in that hallway. And not only that, since we're in a university system, we have a hallway here where some people think this is their way out of the building. And they'll come through this hallway and on their way out to their car and in from -- in the morning. And so taking and educating the small processor, and thinking about these things, and how is it you can manage in order to help avoid Listeria contamination is one of things that we have to go about. Most operations, since they're one room, do not have a separate packaging room. And those that do, I think with the rule, we've started to look at it and say, well, we need to make sure that you have the super clean part of the packaging room before you get started in your operations, and that you need to monitor traffic in and out of those areas, and

make sure that the packaging room is clean. And so, in the small operation, if they have the luxury of having a separate packaging room, I'm not sure they've thought about those things yet, and so we spent time with them talking about that. Some even have a challenge of whether they have separation for cooked meat versus raw meat storage. Hopefully, by now, most of them show a separation in that and have those kinds of things in place. And even with that, because many facilities are cramped with space, and in this particular picture you see that it also applies for equipment storage, as well as for the cooked meat storage. And so those are all things that we think are challenges. Many of the vacuum machines that do get used in smaller operations are the pouches, rather than using a roll stock machine, and so, in my view, you've got more chance of handling and more chance of cross contamination. So what are we focused on then? And I think that the thing that we've tried to do is try to look at the education towards these processors, and say that we think that this is a problem that you want to address. You know that you have to if you're under the meat inspection, to try and address some of these things. And one of the areas we spent time on in the past is the cleaning and sanitation. And one of the things that we have done with the rule that

has come in is one, we try to educate the small processors on the Listeria rule, try to understand where Listeria may be found, and where you have to make sure that you clean and sanitize. Make sure that the company has established proper cleaning and sanitation schedules for their processes. And then, in order to do that step where you do the testing and the validation, we were -- we've wrestled with that and what it -- should be done in a small operation. And, for the most part, we've recommended to the very small operations that the Alternative three is where they start at, and that they use the testing program that's identified in the USDA Listeria Guidelines. And so whether that's a good measure of looking at their sanitation or not, we don't know, but it's something that certainly allows them to comply. And with that, we think that part of our efforts should be that we need to provide the workshops, and we need to provide the efforts to help bring them along. We'd like to reflect a little bit on some of these operations as we've worked with them in the past, in that I've had, when I first started my job, we had some workshops that would bring these people in in terms of just making products and manufacturing products. And that's really what they enjoy doing, is the manufacture and making items. And so people would come in, and

you'd work with them, and you'd think, these guys, how do they -- they don't even know anything about what it is in terms of the meat products, as well as sanitation. And, eventually, after a few years of coming and working with us, and a few years of being in the business, why then they start to understand some of this stuff, and are really trying to make the right efforts. I don't think these people out there try to ignore this. It's just that many times they don't know and don't understand. And so we think that providing workshops that focus toward their audience that they will come to, and if you get them in and start to educate them, and have one-on-one contact with them, why then we can make a lot of progress and improve the situation. Part of the educational process that's happened with Listeria for the small processors, this is a table right out of a publication put together by Penn State University, and went out to the web site on FSIS and picked that up. And so you can educate about, well, how frequently should you clean and sanitize some of those areas. This is a -- you've seen this before already, but this is where we are at in terms of talking with small processors. Most of them would say, if you're in the very small operation, at this point in time, we want you to look at Alternative two. That means that you need to

provide some Listeria species sampling one time a month per line in your operation. And so that's what most of them have adopted at this point. But we would like to take it beyond that. And, certainly, one of the things we found is that if I talk about the very small operations, we go a little bit larger, is that their needs probably are a little bit more than looking at microbial testing for verification of their program more than once a month. And so Dr. Tipper Etti [ph] and myself, we've put -- looked at putting together a publication. And it's not fully published yet, but we've got a pretty good -- Dr. Etti has a pretty good draft on it. I'll give him most of the credit. But the publication was intended to give more of a complete package to Listeria monitoring than what we could find in other resources that we had out there. And so some of the things that we discuss are places in the plant or areas in the plant where they want to sample, and the techniques for sampling. Because, many times, these processors have no background on, in terms of micro sampling at all. And so we provide some description of different techniques, the frequency that they should sample, and responses and correction. And not only that, provide a chart that they can use that would work for data analysis in their facility as well. And so,

hopefully, we get that thing published and out there to use in the very near future. But, for example, in the document, we give a description of environmental sampling techniques such as sponge, or swab, or scraping, or rinse sampling, and air sampling, and so on, and some -- also some product sampling techniques. And that was something that we didn't find in other publications that could be useful in trying to test for Listeria. Now, we also make a recommendation on what kinds of sampling in terms of the environment on non-contact surfaces, as well as contact surfaces. And, as you can see, there could be quite an extensive bit of sampling here. And some of the processors that are into more of a volume of production of a specific product, but still kind of are, basically, in that small category, maybe ought to look at upping their level of testing. And this is where we're coming out with this recommendation here. But even with that, why then we have heard back where some people think that, well, the cost is getting too much, and there's too much sampling involved. And so once we've established that, why then we think the next true step that we really need to take them into is look at antimicrobials for Listeria control in the small plants. And, hopefully, this is something that we can start within this next year. And a number

of other extension people have already provided some information to small plants about it. But to use some of these common antimicrobials, and I'm sorry if I don't here but this is the ones I thought of when I put my presentation together. But sodium lactates or potassium lactates or diacetate, sodium diacetate, and combinations of those. And to put them in at the use levels where we can look at that one log or less type of growth of Listeria during the storage period. And so there are some modeling programs out there that will give us some help and some guidance in terms of the extension specialist, but this is something that's probably going to have to happen with our help and giving them guidance on what to do in their formulations, and it's not going to happen simply by the -- by themselves. We also think that there's a need to include other microbials, and one of them that we're going to look at is buffered sodium citrate, or maybe other antimicrobials that are natural, and look at those in combinations with each other and what are the effects they produce on quality will be a big question, especially for the small processors. And so we think that there's other areas that can be promoted with them. And part of the reason that we want to go into these other things is that if you go into a small meat

processing plant and their spices are already in a bag, they're provided to them by the company that put the spice mix together, and so can we work with them, or else through the spice companies, and also include some of these other ingredients, and make it work for them? What makes them unique? As I said, they usually purchase their non-meat ingredients from a regional supplier. Many times it's -- these ingredients will be at a higher price than what the large companies can buy them at, certainly. They -- and like I said, they'll purchase unit packs of 400-pound batch size, and that's how they get their ingredients. And that's also how they do much of their formulation. One hundred pounds of meat, one pack of ingredients. And this has also raised concern because sometimes when we've back calculated for them, and the CSO's out there know this too, is that we don't come up with the right number. And so we need -- they need some help in terms of those. I think there's a concern about, within these small plants, that they have their old-time formulation, and so if we go to add some other ingredients, what does that do to that old-time formulation? What is needed beyond the research? As I said before, I think the excellent way to get to these people is to do workshops. And the way to implement change in their operation is to

get them to come in and look at products, and taste products, and make products, and then they're willing to make the change. The other part that goes with that is if we're available and provide one-on-one consultation with them, why then they can feel comfortable about what it is that they're doing and make changes in their products. This change also, I think, needs to occur in what I called custom exempt and retail exempt processors that we have here in the state. And it's maybe the only way that we will make that kind of change, is to provide some of this assistance and some of these workshops in order to get them to come along with us. Post-lethality control may be out there, and I think we're going to hear more about that in the next presentation. But there are a few things that can be used, and maybe there's one or two that, again, that I have left off here. But small processors are probably not going to invest in a lot of high-dollar equipment, and so if lethality stepped -- post-lethality control step takes a new piece of equipment, they will probably be hesitant to do that. There may be some things that can be done with hot water treatments after the meat has been packaged, the ready-to-eat meat has been packaged, and there's some research now coming out where I think Penn State has conducted some, and Steve, you may have

conducted some as well where you've looked at using hot water as a treatment on a vacuum package and getting a two-log reduction with that. And so -- and then one of the advantages, if they are in operations where they still freeze their ready-to-eat meat products, why then that's a treatment that they can use. So I'd say that the small meat processors, they have unique challenges for Listeria control, and that cleaning and sanitation will, at this point, be the most common method that many of them will use. And, along with that, the validation testing that goes with it. But where we would like to move these operations is to include the use of antimicrobials. And they provide an excellent opportunity. And then, eventually, if we can figure out some systems that will work for post-lethality interventions, why then we would include those as well. But, from our standpoint at Nebraska, we'll probably end up using -- putting quite a bit of emphasis on the antimicrobials in the next year or two. So that ends my slide show. I appreciate the opportunity to be here.

MR. DERFLER: Thank you, Dr. Burson. The last presentation is going to continue on the small plant theme. It will be by Dr. Steven Ingram, and he's going to talk about taking a new look at meat processing, validation of old and not-so-old technology. Dr. Ingram

is the Food Safety Extension Specialist at the University of Wisconsin, Madison, along with the Meat Extension Specialist, Dennis Buege. He assists small and very small processors with HACCP implementation and related subjects. Dr. Ingram.

DR. INGRAM: Okay. Well, we've heard a lot about new technology today, and I guess what I'd like to start off by saying is that whether the technology is old or new, it needs to be validated to be proven effective. What I'm going to talk about is the service we offer at the University of Wisconsin, Madison, where we do lab scale validation studies to assist very small plants in these validation efforts. I want to just set the stage a little bit. Dennis did a nice job showing you the unique concerns in a small and very small operation. In Wisconsin we have approximately 300 very small processors. Most of them are state inspected. And although they sincerely want to make safe products, they lack a lot of the resources and expertise to do any kind of validation work. So we try to provide that for them. We offer validation services to really try to answer two questions. The first is, basically, are the critical limits I have in my HACCP plan adequate? In many cases, you know, where they can't follow Appendix "A" or Appendix "B," they are groping, or they're

choosing numbers that they've traditionally used, but they don't know if they're really scientifically valid. And, of course, as the emphasis in HACCP regulation has gone towards validation, they're really in a pickle. The second question they have where validation studies might be useful for them is I've got a deviation. Is my product safe? What can I do? And we focus mainly on the first of these questions. But we get a lot of information from these studies, and in some cases, have been able to help them with the second question as well. Dennis mentioned some of the niche products that these plants make. Validation work is very, very crucially -- or very much needed for these traditional products. Many of them, as he mentioned, are made not very often, small amounts. But the operator will tell you they have a long history of apparent safety. Now, the regulators in the crowd will kind of grimace at that. You know, everybody says, well I've never had a problem. I've been making it for 40 years. In many cases, they may be accurate in their perception, okay? But there doesn't appear to be a problem, but there's no validation of that. Also, several of these products may not have your typical, critical control points. They may not really be cooked. They may not have chilling or a stabilization as a CCP. So they have different types of

CCP's, and there's not a lot of data out there. Another headache that I have in trying to do these studies is that there may be a traditional product made by 40 or 50 different plants in Wisconsin, and each processor has a slightly different twist to it. Different type of smokehouse, different spice mix, different casing, what have you. And, of course, they need our help. Well, for the last little bit over a year, we've been operating de facto as a center for validation studies. And I'd like to just give credit to the people involved in this. Dr. Dennis Buege is our Meat Extension Specialist. And he's the one who's the expert in processing. Basically, interacts with plants and comes up or identifies the needs for studies that we need to do. And also, in a way, is my reality check. You know, he'll stop me and say, hey, wait, they don't do that. In the real world, you need to do this. Joe Losinski [ph] is a Master's Graduate student who finished up about a year ago, who runs the lab, does all the hard work, and also supervises a whole crew of under grads who, in essence, get an apprenticeship in applied food microbiology. And then I try to keep the whole thing running. We are very grateful. We've gotten some USDA funding from the Small and Very Small Plant Program that allows us to offer these validation studies as

subsidized studies. What we do, roughly, is for every $2500 of expenses, we bill the plant $500. Sometimes, when a plant is on the big end of small, we charge more. Sometimes we charge less. But thank you, USDA, for that. We were set up. We have a biosafety level two laboratory. We also have a facility known as the biotron, which is a controlled environmental facility so we can put racks of product in and imitate a cooler, a smoker, to some extent, drying chambers, and so on, all with actual pathogens. And that, of course, is one of the major hang-ups with validation studies, is you can't walk into a plant and spike the meat with pathogen. And surrogates are often lacking. So what will happen is, typically, we start with a product or a process from one or two plants, and we do a study. We try to post the results on the web. The web site's under development right now. If we think the results are appropriate and the processor who made the request is agreeable, we will write an article and submit it for publication. We've got a few of those working their way through the pipeline now. Ideally, we'd like to provide results that any plant making a particular product can use. Now, that's not always possible, again, because of these little twists and tweaks that people have in their processing. We do recognize that whatever we do

probably will not be quite enough to completely validate what's happening at the plant, so we are going to be encouraging the plants to get their own data. Things like time/temperature profiles, product composition, perhaps some indicator micro counts that they can use for verification. And, of course, the trick is when we do a study based on one or two people's process, we have to identify the key parameters that we might be able to recommend critical limits for to others. In the future, it would be nice if we could get some predicting models for some of these types of products, particularly, the low-temperature dried products. Okay. Well, what I'm going to now do is very, hopefully, quickly work through some case studies of old and not-so-old technology that we've tried to validate. And what you see in the picture here is a rack of cold-smoked, dry-cured pork loin. This was the first project we did. This rack is over at our controlled environmental chamber. This is a traditional product. It's been made for several decades in our area. Involves certified pork, so it's been frozen prior to processing. It's dry cured in logs. Several layers of meat stacked up in logs after they've been dipped in [MISSING WORD] and they're stored there for five days at 50 degrees Fahrenheit. Then they're hung up, as you see here, wheeled into a smokehouse,

which is very rudimentary. It's, basically, a slatted floor. The wood goes under the slats. It's lit. The door is closed. Okay. That's the technology level we're talking about here. And there are, you know, recording thermometers, but there's not a whole lot of control other than dampers, how much draft and so on are going on. So the product gets two cold smoking cycles over a two-plus-day period. The hottest the smokehouse ever gets is 136. So those of you who have Appendix "A" memorized are probably already getting nervous. Okay. The lowest it tends to get is about 120. Okay. And we've got quite a range there. Now, when the product comes out, it's got, on the surface, it's fairly dry. The water activity is down between .91 and .93, fairly salty. Now what we had to do was validate the lethality of this entire process because it's not really a cooked product. Okay. So we duplicated the process. This is almost the entire batch that you see here. So it's in a small batch. We did that in our lab incubator. We can't actually smoke the product at the biotron facility, so we dipped half of the meat in liquid smoke, and then had non-liquid-smoke treated controls. We found actually, in this process, the liquid smoke had virtually no effect on pathogens. And then we imitated the temperatures of the smoking in a controlled

environmental chamber. So, basically, it's what microbiologists would call a spike-and-count study with a lot of twists. What we found in this particular product or process, they did get more than a five log reduction in Salmonella, and more than a three log reduction in Listeria. Now, that's not the seven logs that's in Appendix "A," but it's a pork product. The plant is currently working with this and doing additional raw material and finished product testing. And so far, things are going well. Another kind of interesting example of old technology, and this relates to the Listeria reg. This is a small plant, not a very small plant, but a small plant. It has a whole muscle, hot smoked beef product. Very -- a lot of smoke deposited on the surface of the product. And their question to me was, well, will our hot smoking and formulation serve as an antimicrobial agent against LM? So what we did in this case, instead of making a batch of product ourselves, we simply got several lots worth of product, or samples from several lots worth of product from the company, removed small surface sections, inoculated them, vacuum packed them and refrigerated them. And then enumerated the organisms at various points. So, in this case, we miniaturized things. And in this particular product, and this is

certainly one I would not try to generalize to all smoked beef, they actually did get a 2.4 log reduction in LM counts during the expected shelf life, which was 11 weeks. So they can actually claim that the process and the formulation are adequate. They can call it an Alternative 2 in this Listeria reg. Okay, how many of you have ever had this product? One or two out there. The joke that my colleague, Dennis, uses is that all the headcheese customers are dying. And it's not because of food safety, it's because they're 80 years old or more. This is a niche product. It involves chunks of meat given a very, very severe heat treatment, the addition of vinegar, and then that congeals upon cooling in metal pans. They slice it, vacuum package it, and out it goes. A fairly long shelf life. Again, the question this niche company had for me is can we call the process and the formulation of headcheese an antimicrobial agent? Just as we did with the smoked beef, we got several logs, cut small pieces, inoculated, vacuum packed and so on. And, yes, in deed, headcheese is safe, okay? Within eight days, there's almost a three log reduction in LM. And after a month, it was over 5 logs. So that's a safe product, folks. We're going to be working on three stalwart Wisconsin products coming up here, looking at how well LM survives on products.

We're going to look at beef jerky, summer sausage and beef sticks. And these are things that are pretty much any of these small plants will make around the state. Now, if we move into the somewhat newer technology, and it's been alluded to a few times already today, the whole idea of post-packaging pasteurization. This is a project we worked on last summer. A processor actually in California was at a convention or something, and got the request to us. They had a dried-beef product, intact muscle, dried-beef product that had never been cooked. And they wanted to see if they could vacuum pack it, put it in hot water, and ensure safety. So it's a little different than the LM post-lethality treatment because it's never -- hasn't been cooked first. There's a lot of other products, of course, where small processors might try to get that post-lethality treatment, get the two log LM kill. Now, when I started on this, I thought it was a no-brainer. You know, what could be simpler? Put the Listeria on, seal it in a vacuum bag, dunk it in a hot water kettle, and do the plating, and there aren't going to be any survivors. Well, I learned that that's far from the truth. There's a lot of variables, the least of which will be water temperature, and size of the meat, how tightly the vacuum packaging material adheres to the

product. If you get any little air, or voids, that's insulation. So we did a lot of trials with this. Finally figured out how to do it for this processor, and managed to get, for his product, a five log kill of Salmonella and of Listeria with a 3-1/2 minute treatment, 195 degree water. Now, it was right on the edge of 3-1/3 minutes of really changing, you know, noticeably changing the organalectic properties of the product. Now, we're going to -- we've been humbled, and we're going to try to do this a little more systematically within the coming months. So we're going to work on ring bologna, summer sausage, pre-cooked pork chops and pre-cooked brats. Try to come up with some recommendations for plants as well. And, again, that's another project funded by the Small Plant -- Small and Very Small Plant Program with USDA. Another not-so-old technology we've looked at and, again, folks have talked about it already, is sodium lactate. This was a one-plant project. We worked on ham and turkey slices, cured products that had fairly long shelf lives. And the company was putting sodium lactate in, and they wanted to verify that it was an antimicrobial agent. And we found that with these particular products, it worked extremely well. We got, virtually, no growth through 60 days. So that was a success story for the

plant. Well, to conclude. What have I learned from all this? Well, first of all, it's a lot of fun. You learn an incredible amount working on these unusual products. Definitely, if you do these lab studies well and plan them out, you can provide a lot of useful information that these small and very small processors can use. Also, I've learned that many of these traditional processes are quite safe. We just have to get data to prove it. I'm definitely aware that the processors are going to need further help. I just can't hand them the study and say, go at it, here's the validation, go do it. Finally, there's lots more work to do. So thank you very much.

MR. DERFLER: Any questions from the audience for the three speakers that you just heard from? First of all, I've got to make a plug. The USDA is, the Small and Very Small Plant, is FSIS and the Small and Very Small Plant coordinator is Mary Cutshall, who's sitting out at the table outside. So there's that. I just have one question for Dr. Burson and Dr. Inghram. And that is, given what we're trying to do with respect to small plants, and trying to get new technology to them, do you have any advice for us, based on your experience with it? And I was told before, there hasn't been a reason for it. Can you speak close to the microphone so we can

get it? Thank you.

DR. BURSON: Okay, does this come through okay? All right. Thank you. I think, from the things that I've seen, is that, with these people, you need to get to them personally. And that the efforts that we've done in terms of the workshops that they might come in where -- and, to be honest with you, just a sanitation workshop doesn't turn these people on. But if you make product, and then in the process of making product, you also talk about sanitation, you might get some information to them. But you'll never get them to come, to just say, well we want to tell you about your sanitation program or cleaning program. I probably shouldn't say never. But that doesn't attract as many people as if they get a hands-on workshop type of experience. And so the efforts that you can do to do that, and as well as the one-on-one type of assistance. And that's hard to do because it's very intensive and takes a lot of people and time to do that. But that seems to be the places where you start to make a difference. And, particularly in terms of trying to put what we think in terms of getting to the Category 2 and putting more antimicrobials into their ready-to-eat meat products. We may end up talking also with the suppliers of ingredients to these small companies, and making sure

that they understand where it is that they want to go. And, in some conversations with those already, they have expressed concerns about giving out the technical advice. You know, they can get the ingredients, but many times the small companies will come to them and say, well how much do I add? What is it that I do to use this ingredient? And they're a bit hesitant when we're dealing with something like Listeria control, to give out that kind of advice. And so between ourselves or some other consulting authorities, why they need some help there as well. I think -- I'm probably taking too much time here, Steve. The last point that I'd like to make is that some of these studies, even though he pointed out that you can have lots of little variations, need to be accepted as validation studies that show what these guys are doing, because I don't think we can afford to do what Steve's doing, and validate everybody's individual product in everybody's plant. And so when a plant site's a study someplace, and it's not quite exactly what it is, but it's pretty close, there ought to be room for a judgment someplace in terms of compliance as to whether they have information that really validates what they're doing.

DR. INGRAM: Yeah, if I could add to that. There's really a couple of things Dennis alluded to at

the end there. One of them is that you've got to translate this information. They'll be innovative in product development, but when it comes to something like this, what I hear is, look, Steve, just tell me what I need to do, okay? Give me the variables. You know, do I need to buy a recording thermometer? What is it I have to do? So you've got to translate it down to not quite cookbook, but getting that way. Then the other thing is, and this is probably the number one complaint that meat processors that I deal with have, is if I do this and Inspector "A" likes it, I don't want Inspector "B" or the CSO to come in and tell me it's no good. That's probably the number one frustration in the small plant. Well, maybe labor is number one. But it's right up there. Is changing interpretations between regulatory people. The guard changes, and all of a sudden, I can't do what I've been doing.

MR. DERFLER: Thank you very much. Any other questions for anyone? At this point I'd like to introduce Dr. Garry McKee again, the Administrator, for closing remarks.

DR. McKEE: Thank you, Phil. Well, we've certainly had, I think, a very successful day today. I want to thank everybody for attending, and I think the turnout has been great. I particularly enjoy these

kinds of public meetings in that the science, and many times, in most cases, doesn't have an opinion. So that for where we're sitting, sometimes that's a plus. So it's our intention that the information that you've received here will encourage all of us to look for all new and different ways to further develop and incorporate effective new technologies and procedures to enhance food safety. I urge you to contact our New Technology staff with your questions and your ideas as well. We are here to facilitate the use of innovative procedures that, in deed, can help improve public health. We must work together if we want to achieve our food safety goals. I think the focus that we need to think about is that, with our combined efforts, the future of food safety is bright indeed. And the conference, I think, has went very smooth, and I'd certainly like to thank our organizers, particularly Mary Cutshall, Sally Fernandez, Gay Gart, Mary Harris and Martha Workman, for their efforts in making this meeting a very good success. So, with that, I thank our speakers, and I thank the audience for your attentiveness, and we appreciate your ideas as they come forth. Thank you very much.

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IN RE: THE STATE OF FOOD SAFETY TECHNOLOGIES TO ENHANCE PUBLIC HEALTH

HELD AT: OMAHA, NEBRASKA

DATE: JANUARY 13, 2004

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