UNITED STATES DEPARTMENT OF AGRICULTURE

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FOOD SAFETY AND INSPECTION SERVICE

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ANIMAL AND PLANT HEALTH INSPECTION SERVICE
AGRICULTURAL RESEARCH SERVICE

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PRE-HARVEST FOR CATTLE PUBLIC MEETING

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WEDNESDAY
NOVEMBER 9, 2011

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The Meeting was held in the Oklahoma City Memorial Conference Room, 4700 River Road, Riverdale, Maryland, at 8:30 a.m, Dr. David Goldman, Moderator, presiding.

PRESENT

DAVID GOLDMAN, Moderator, Assistant Administrator, Office of Public Health Science, FSIS
ELISABETH HAGEN, Under Secretary for Food Safety, USDA
TRACY BRUNNER, President, Cow Camp Feedyard, Inc.
JOHN BUTLER, CEO, Beef Marketing Group
DEAN DANILSON, Vice President, Food Safety and Quality Assurance, Tyson Fresh Meats, Inc.
GUY LONERAGAN, Professor of Food Safety and Public Health, Texas Tech University
GREGORY PARHAM, Administrator, APHIS
ADELA RAMOS, Chief of Staff, Office of Food Safety, USDA

BILL RISHEL, Owner, Rishel Angus
ROBERT TAUXE, Deputy Director, Division of
Foodborne, Waterborne, and
Environmental Diseases, CDC
MARY TORRENCE, National Program Leader, Food
Safety Agricultural Research Service

C-O-N-T-E-N-T-S

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

8:43 a.m.

DR. GOLDMAN: Good morning. I'd like to ask everybody to find a seat and ask for those who are on the outer ring, if you'd like to join a table, please do so.

Looks like most people are settled. Well, good morning. My name is David Goldman. I'm with the Food Safety and Inspection Service, one of the assistant administrators for the Office of Public Health Science. Our office does all of the regulatory lab testing of meat, poultry and processed egg products. We do the risk assessments and outbreak investigations, and I will be your moderator for this morning session.

And, first, I want to welcome all of you who come from near and far to join us today for a joint presentation of a pre-harvest issue that I think obviously has a lot of interest for those of you who have come in.

I also want to mention that we do have some foreign government officials here. We also want to welcome them to this meeting. We're glad to have you here, as well.

The first thing I'd like to do is to have you - make sure everyone has a packet, first of all. And I want to orient you to the packet just briefly to start out.

So, on the right side you should have an agenda. And I'll go through that in just a minute briefly.

On the left side, I want to call your attention to - actually, first on the right side behind the agenda is a list of the bios for the speakers.

On the left side, there are several papers there. The first is a paper that talks about pre-harvest food safety activities and initiatives at the Department of Agriculture. These are jointly-sponsored initiatives and activities between three mission areas represented by three agencies, the

Agricultural Research Service, the Animal and Plant Health Inspection Service, and the Food Safety and Inspection Service. So, you can look at that while you're here.

And in addition, there are some information papers from APHIS Center for Veterinary Biologics, and the FDA Center for Veterinary Medicine, which discussed in brief the regulatory process for approval of pre-harvest intervention. So, this is there for your reference.

I will say that we will have representatives from both of those organizations here during the day to answer any questions that might arise about approval of vaccines or biologics.

If you just look at the agenda briefly, in just a minute we will have the official welcome and opening remarks from our Under Secretary for Food Safety.

Our keynote speaker will be by Dr. Guy Loneragan, and he will set the stage for

the rest of the meeting.

Then, there will be a panel discussion from several industry representatives who have been, I'm going to say, pioneers in terms of implementing some innovative pre-harvest strategies. So, you'll hear from them.

And then the bulk of the meeting will be discussion in your table. So, if you'd like to move to a different table, why don't you do that now or at the break. And we may move you depending on the mix of people we have at the tables.

But the tables will be your small group settings for discussing three discussion questions that you'll see, and I won't go through those right now. We'll introduce them fully when we get to that part of the agenda.

And then we'll close up the meeting with Dr. Parham, who is the administrator of APHIS, and hope to get you out of here by 5:00 or so this afternoon.

So, let me start by saying that I want to go over the goals of this meeting. I've actually already had some people ask what the agencies expect from this meeting. So, I want to go over that with you.

We are looking for discussion about food safety improvement through identification and development of effective pre-harvest practices.

We are looking for creation of an increased focus on pre-harvest food safety, and the identification and development of incentives for producers and processors to adopt effective pre-harvest practices.

We are looking to increase producer engagement to emphasize their importance in the overall food safety system.

We're also interested in finding effective solutions through discrete projects, including demonstration products of new technologies and implementation of best practices.

So, those are the overall goals. We'll talk throughout the day about the outcomes of this meeting, but I'll just mention a couple here.

We expect to hear both in the panel discussions, as well as the report-outs from the discussion groups, many ideas about things that have worked or appear to work in a limited sense, in a research environment, or in a pilot sort of environment.

So, we may end up with a list of best practices, those things that really have been or promise to be effective in controlling pathogens at the pre-harvest level or stage.

The other thing is as with any meeting that's focused on things that are largely scientific, we may well and expect to identify some research gaps. And we hope to incorporate those into future research opportunities.

You'll notice that this meeting is co-sponsored by the Agricultural Research

Service and the Research, Education and Economics Mission Area. So, we will have interested representatives from both ARS and I think maybe NIFA as well, who will be here to listen to any research opportunities that may arise from our discussions.

So, again, thank you all for your interest in being here. We're pleased to see a full room.

Before I introduce Dr. Hagen, I just want to thank our pre-harvest folks from the agencies who have helped to arrange this. In particular, Drs. Joe Annelli and Pat Basu, who are the leaders from APHIS and FSIS respectively. And Dr. Mary Torrence is here from ARS representing that agency here.

And finally, I want to thank APHIS for hosting the meeting in their nice facility here, and Jerry Coursey and his staff for all the logistics. And you'll hear from Jerry in just a minute. He'll cover some of the ground rules and logistical issues.

Okay. Let me introduce Dr. Hagen. I'm very pleased and honored to introduce our Under Secretary for Food Safety who was sworn in August 20th, 2010.

It's sort of hard to imagine she's only been on duty for less than 18 months. Because I think in FSIS, we feel like we've done a lot under her leadership. So, we all appreciate that.

As the Under Secretary, she oversees the policies and programs of the Food Safety and Inspection Service, which is the Public Health Agency within USDA that ensures the meats - the nation's commercial meat, poultry and egg products are safe, wholesome and correctly labeled and packaged.

She joined the federal government in 2006. And in those years, has served in a number of leadership roles and advanced a science-based public health agenda at USDA.

Prior to her appointment as Under Secretary, she served as USDA's chief medical

officer advising FSIS and other mission areas within the Department on a range of human health issues such as food safety, nutrition and zoonotic diseases.

Before joining public service, Dr. Hagen taught and practiced medicine in both the private and academic sectors.

In addition to several hospital and university appointments, her experience includes research and publications in infectious diseases and providing medical care to under-served populations. Dr. Hagen holds an M.D. from Harvard Medical School and is board certified in infectious diseases.

Please join me in welcoming Dr. Hagen.

(Applause.)

UNDER SECRETARY HAGEN: Thank you all. I guess this is the part of the program where the soft lighting comes in for me.

(Laughter.)

UNDER SECRETARY HAGEN: I'm sorry,

I've got you all started late already. So, apologies. I've been on the road forever this morning, it seems like, but I am so happy to see everybody here this morning. This is a wonderful turnout and it exceeds our expectations.

Is this okay, or does it sound - so, thank you. Some of you come from a great distance. Some of you have come out of retirement. Bill James, recent retirement -

(Laughter.)

UNDER SECRETARY HAGEN: -- just to attend this morning's workshop with us. I really appreciate that.

So, I think many of you in the room have heard me talk over and over again about a true farm-to-table/farm-to-fork effort.

Anybody who works in food safety, anybody who works in food production is fond of those phrases, but they need to mean something.

And I think if we are going to have

an honest conversation, a real dialog about how we make food safer in this country, how we keep people safer from foodborne illness in this country, we have to talk about how foodborne illness occurs and where the risks really enter the system.

We are certainly not looking to go on the farm or to regulate on the farm at FSIS. I'll just say that again for the benefit of everybody here. We are not looking to go on the farm here at FSIS.

We just feel like we are the food safety agency within USDA. We are a major leader in the world of food safety regulation.

And, again, if we're really trying to tackle these big questions about how do we make food safer, we have an obligation to be looking everywhere along that continuum.

And we have, we think, an obligation and a role here to start sponsoring these very important conversations that you all are going to have and to pair up the right

people to get everybody talking about this and figuring out together where we're going to go.

So, on that farm-to-table continuum, we've done a lot of work on the table part in the last, whatever it is, 15 to 18 months.

I think we've placed a greater emphasis on consumer safety education than in most other previous administrations. I won't say any other, but I'll say most other previous administrations.

We're doing all the right things in terms of getting our messages out. We certainly started thinking about how do we push things out instead of requiring people to come in.

We're Tweeting a lot. Who's here? Bill, are you here? Someone is Tweeting right now, I'm sure. Bill Bagley or someone.

I don't know how to Tweet, but everybody is out there Tweeting for us. We have 270,000 followers, I think, on Twitter,

which is really amazing that that many people follow food safety information.

Obviously, we're on Facebook. We've come into the 21st century in terms of a lot of what we're doing in communications.

We, this year, announced a mobile app for Ask Karen. We've had this terrific service available on our website for a number of years, and now people can take Karen with them on their smartphones to ask food safety questions. And we've seen a tremendous amount of increased traffic to Ask Karen in the last couple of months.

And one of the most important things we've done is to partner with FDA and CDC on an Ad Council campaign called Food Safe Families, to really raise awareness at a national level about how serious foodborne illness is and to get people to really tune into the fact that one in six Americans get sick from food every year.

This is a real risk for people and

their families, but to also give them some concrete, actionable behaviors that they can move forward with.

So, hopefully some of you have seen our ads. We're on TV and we're starting to be on a regular print. So, we're doing a lot of the consumer, the table end of the farm-to-table continuum.

Obviously, we're always focused on production, the slaughter and processing part of the continuum. That's where our resources are. That's where our appropriation is. That's where we spend most of our time. But now we're starting to talk about what happens on the other end.

Again, we're not looking to do this through regulation. We're not looking to establish new jurisdiction. We just want to acknowledge the fact that everything that happens on the farm to animals that come in slaughterhouses, impacts -- directly impacts the amount of risk that has to be handled

throughout the rest of the system by packing houses, by processing operations, certainly by consumers.

So, that's what this is about. We've been talking about this at FSIS for a very long time. Certainly the folks at the Agricultural Research Service and in NIFA have been talking about this for a long time.

We actually have quite a significant research portfolio at USDA on pre-harvest food safety approaches. And the team at APHIS has been interested in this for decades.

So, this is really just about USDA sponsoring this conversation, having people get together and, as I said, figure out where we go in the future.

David already thanked some of the people that I wanted to thank. So, I appreciate that.

In addition, I really have to thank Adela Ramos in my office who has been leading

this effort from the very beginning. I managed to eke this out of her before she goes on maternity leave in a couple of weeks.

So, thank you for putting this together, and I'm really looking forward to what comes out of today. So, I'm going to just leave it at that. Thank you.

(Applause.)

DR. GOLDMAN: Thank you, Dr. Hagen.

And at this point, what I'd like to do is to ask Jerry Coursey to come up. Jerry, as I mentioned, has been instrumental in organizing and arranging everything in the room here. And he is going to cover the facility and ground rules for the meeting itself.

So, Jerry, thank you.

DR. COURSEY: Good morning, folks. Glad to have you all here. Again, my name is Jerry Coursey, and I'm with APHIS. And I want to also recognize two of my colleagues, Conrad Salinas and Anne Dunigan, who have been a big

help in working on this.

And we appreciate the hard work of the FSIS staff and ARS who have been working with both of you.

Okay. We've got a couple ground rules, suggested ground rules for the work at the table. Now, you've got a few copies on the table itself. I don't think they were in the packets. So, I'm going to walk through these pretty quickly and you can ask some questions.

But, basically, share your thoughts, ideas and suggestions throughout the day. That's a given.

Please respect each other's perspectives even if they're different. And, again, that's a given.

At the table groups, and most of your work is going to be done at the table groups, try to speak one at a time and give everyone a chance to speak, to weigh in.

Also, express your interests around

these key issues. Why are you so passionate or concerned about a particular issue? Make sure everybody understands that at the table group.

Members at the table group do not need to reach consensus. This isn't a consensus exercise. I think it's great and FSIS and ARS also agree to have robust discussion at the table groups.

What you'll also be doing at the end of a question, is writing up on the flip chart some of the key concepts, concerns, suggestions, recommendations that came out of the table group. Again, this is not a consensus base.

We need one member at each of the tables to act as a scribe and write up these key things. Also, we need one member to report out, and we'll go into that more when we get closer to that piece.

There are actually no formal breaks today, but we encourage you to take a break

when you need to. We are having a lunch period of about 45 minutes. You know where the cafeteria is nearby for water, juice, et cetera.

You'll also notice at the table, and I'll ask you to raise your hands, we have USDA staff at each of the ten tables right now. And could you raise your hands, staff people, both from FSIS and APHIS?

Okay. The purpose of the staff sitting at the tables is to kind of track the conversation for the agencies. Your conversations won't be on the record. They're not taking names of who said what, but we're trying to understand the concerns, recommendations, the importance of the issues that we'll be discussing. So, they will be tracking that information.

What will be on the record, and we have a court transcriber here, is the report-outs from the group and any large group discussion that we have, either questions for

the panelists and the speakers, or more discussion on a particular issue. So, the transcriber will record that, and that will be on the record.

Also, at your table you'll see in the middle a salmon-colored sheet of paper. There are probably seven or eight. Those are for comments.

At this meeting, you can certainly write down a comment you have and this will be handed over to the three agencies. And at the end of the meeting, we'll talk about other options for comment after this meeting.

So, I've laid out a lot of things here. Any quick questions that folks have?

(No response.)

DR. COURSEY: All right. I'll make one last announcement for lunches. Again, if you'd like to order a box lunch, it will save you time. They're pretty good. We have to get our orders in at 9:30. So, the folks at the registration table are taking those.

Okay. Any other questions?

(No response.)

DR. COURSEY: All right. Thanks very much.

DR. GOLDMAN: Thank you, Jerry.

I also echo one point that Jerry made. There is a transcriber here and we intend to post the transcript. So, obviously we can't capture the table discussions and that's why you have note takers there, but certainly all the plenary session will be transcribed and we'll be able to post that for you.

Okay. Any questions for now? If not, then we will move to the presentation by Dr. Loneragan.

And as I mentioned at the outset, he will provide the keynote, sort of set the stage for the rest of today's discussions.

Dr. Guy Loneragan is a veterinary epidemiologist and Professor of Food Safety and Public Health at Texas Tech University.

He received his veterinary degree from the University of Sydney in Australia. He then pursued graduate training in population medicine and epidemiology at Colorado State University.

Dr. Loneragan is research focused and strives to fill data gaps to inform solutions for important societal needs.

His research activities include exploration of various opportunities to effect meaningful and impactful control of food safety pathogens in complex agri-food systems such as shiga toxin-producing E. coli, Salmonella and antimicrobial drug resistance in livestock production.

Dr. Loneragan also contributes to the epidemiological understanding of animal health and well-being in modern agricultural production systems.

In addition to his appointment at Texas Tech, he also serves as an Adjunct Professor at a number of universities,

including West Texas A&M, Kansas State University and Texas A&M University.

He's a member of the International Symposium of Veterinary Epidemiology and Economics, the Conference of Research Workers in Animal Diseases, the Association of Veterinary Epidemiology and Preventive Medicine, on the Executive Board there, the International Association of Food Protection, National Cattlemen's Beef Association, American Association of Bovine Practitioners and American Academy of Veterinary Consultants.

Please join me in welcoming Dr. Loneragan.

(Applause.)

DR. LONERAGAN: Thank you, Dr. Goldman, Dr. Hagen.

I appreciate this privilege and honor to come and share some information about pre-harvest intervention. It truly is an honor for me to be able to do this. I

appreciate the invitation from FSIS, APHIS, as well as ARS.

And before I begin, I'd like to preface my discussion with two points. And the first one is that most of the data that I will share with you is on E. coli 0157, and that's for a very good reason, because we've been focused on it for quite a period of time.

There is some information on Salmonella, certainly, as well as an eye on 0157 STEC. And I'll try and share that with you when I can.

And the second one is that my focus of the presentation is going to be on the beef supply chain. And what we're interested in this discussion is the relationship between pre-harvest, post-harvest and consumer exposure.

And so in that respect, it is the beef supply chain, but I think we need to be cognizant that one-third to a half of cases are attributable to exposure to beef. And so,

there's one-half to two-thirds of cases that are attributable to non-beef sources.

And so, as we think about these questions, we should keep that in mind that there are non-beef sources as well.

So, I would like to begin with what I think has been some tremendous progress. And so, if we look at where we were to where we are at the moment, I think we can safely conclude that there's been an incredible amount of progress, an incredible amount of good news in that if you look at an informed regulatory oversight, as well as industry adoption or development, really an adoption of HACCP plans, we now have improved even tremendous microbial process control within plants.

And as evidence for this, I think we can see a tremendous impact in a variety of metrics depending on which - where we want to look.

So, I've graphically tried to

present some of these improvements on the y axis of this graph of the human incidents. So, zero, one, two, three cases per hundred thousand in population.

Years on the x axis. This black line represents the Healthy People 2010 target. This is the 2020 target, and here is the incidents over time. And it's unmistakable that there has been downward trend.

Some of this downward trend is because of the way that FoodNet has collected and then expanded some of the population, but the CDC does estimate that the incidents of E. coli 0157 has decreased approximately 50 percent since the baseline year. So, tremendous improvement.

If we look at other metrics of success, the FSIS testing of raw ground beef samples in 2010 calendar year, approximately two-and-a-half positives per thousand tests and the year-to-date at least as of ten days

ago, it was less than one positive tests, 0.7 positive tests per thousand sampled. So, I think there is evidence of tremendous success.

A consequence of this is that I get to interact quite a lot with industry. I'm very privileged to be able to do that. And in my interaction, I see that there are many plants that are now excelling at microbial process control. So, this is a good thing.

The consequence of which, though, efforts now to improve, further improve, that microbial process control, will have smaller and smaller impacts in the plant. It's the law of diminishing returns.

And so, the question and why we're here at the moment, is to ask is can we do something pre-harvest that contributes to microbial process control within the plant? And I'll certainly try and provide you some data to help answer that.

But before I begin, I'm going to discuss a basic premise. I'm going to come

back to this premise several times throughout this presentation this morning.

And the premise is that impact, however we define it, is a function of both efficacy of what we do and the extent of adoption.

And by impact, we can define it at the population level, at the plant level. So, we can look at it at various levels.

Efficacy of an intervention - and here I'm using "intervention" very broadly. It can refer to a practice or a technology that we choose to adopt.

And then the extent of adoption is really the industry reach or the reach that we try and get industry to adopt it. So, keep this in mind.

I'm going to begin by talking about efficacy. And, again, most of the data that I will share with you is going to be related to E. coli 0157.

And as I go through here, I'm going

to present to you estimates of efficacy and oftentimes these will be reported as a percent reduction or so forth.

So, keep those in mind, because they become important later in the presentation.

And the third thing about discussing efficacy is there is a tremendous body of literature out there that describes this. And I can't go into the details of all of the literature. So, I'm going to skim it quite extensively. But if you have questions about the specifics of various studies, we can talk about that.

And so, intervention, loosely, could be practice, could be a technology. And, clearly, there's a natural desire to ask the question, and this has been asked quite a few times is, is there a management practice that we can either adopt or stop on the other hand, and that will change the incidence of 0157?

This is the way we originally began by evaluating this organism. And I must admit that to date, evaluation of management practice has largely, with a few minor exceptions, has largely been quite unsatisfactory.

I think if we now look at the accumulated knowledge of the ecology of E. coli 0157, I think we begin to - excuse me - begin to understand why in that it appears that the E. coli 0157 is co-evolved for life or to live within the ruminant gut, particularly with the bovine. And so, it's really a commensal organism.

And we see that a lot of Salmonella are behaving in a similar manner. And so, if it's a commensal organism, it becomes harder to control through management.

And if we look worldwide, we see a worldwide distribution of E. coli 0157. And so, this map on the right-hand side of the presentation is a map of Argentina with the

provinces.

Those numbers that may be hard to see from the back of the room, represent the incidents of hemolytic-uremic syndrome in children under five years old.

To put that in context, the incidence in the U.S. is somewhere between one and one-and-a-half cases per hundred thousand children under five. For the country it's about fifteen-fold higher than that in Argentina.

You look at some of these provinces, say La Pampa here, has an incidence almost 60 cases in children under five in that population. And this is a largely expensive grass-based production system. So, very different than the U.S. system.

And if you look elsewhere in the world, the UK and Scotland, you look at Ireland, Denmark, Sweden, they have very different production systems. They have a higher incidence than the U.S., and other

countries have a lower incidence.

So, it does appear to be a worldwide distribution of this organism across many production systems. So, that probably explains some of the futility that we've had looking at simple management factors.

I don't mean to imply that best practices based on management don't have their place. They do.

The Beef Industry Food Safety Council held an E. coli summit in 2003, and have held a Beef Safety Summit ever since, annually. And they as part of that, put together a best practice document for each of the sectors.

And the document that came out in 2003 or soon after is this one, and it was based on the premise that the four best practices they could recommend at that time were clean feed, clean water, appropriately drained and maintained environment, as well as relative freedom from pests such as biting

insects.

And these make good sense. And most of these are indoctrinated in state and national beef quality assurance programs and broadly adopted, but it was also acknowledged in this document that none of these by themselves would likely reduce the prevalence greatly, but they were viewed as prerequisites.

So, if we want to apply an intervention on an operation, we need to set the stage for that intervention to work. And so, that was why these were viewed as prerequisites for an intervention to work.

And certainly there are other examples, and you'll hear more about this in a moment. But in the Progressive Beef Program as part of the Beef Marketing Group, they have developed a - basically a pre-harvest operation manual that's based on SOPs and third-party evaluation, third-party audits, to evaluate and develop best practices for the

production of beef or raising cattle.

So, if we can set the stage then, the question becomes, well, what technological advances or innovations can we use that may impact efficacy? And here's where the industry is at the moment: Most, or has been for a long period of time, all of the interventions that are largely implemented have been in the slaughter/fab facilities. There are others though.

And what we're talking about now is this pre-harvest sector. And I'm going to talk about four particular technological platforms; vaccines, direct-fed microbials sometimes called probiotics, a product at terminal application, and the poster child for that one is sodium chlorate, and then talk about bacteriophage. And I'll do that in that order and talk about the efficacy.

So, there are multiple vaccine technologies that have been proposed. I'll talk about two of them, because they are

farthest along in the translation process, but there are others. There are others that have been proposed and there are news releases every once in a while about new vaccines. But the two - there's one produced by Epitopix/Pfizer Animal Health, and then the other one is produced by Bioniche Food Safety.

And I'll talk to the efficacy related to these two products as I can see them. And, again, I'm going to scan and provide you the highlights of multiple years of data of different study designs, different examples, different regimens, so we can talk about these in more detail as we go. But, really, the first one is based on a publication written by Dan Thompson. It was published a couple years ago. The study was actually done in 2007.

And this was a three-dose study where they - here is the timeline on the y axis. On the x axis I have E. coli 0157 prevalence. So, vaccinated on Day Zero, Day

21, and then again on Day 42. And then when we get to within a week of harvest, the researchers saw an 85 percent reduction in prevalence. But in that study, they also tried to quantify how much E. coli was in the fecal samples, and there was a 98 percent reduction in concentration.

So, in this study, which set the stage for it to get a conditional license, there was both a reduction in the number of animals that were positive, and in those that remained positive, there was a reduction in the concentration of bacteria in their shed.

So, this led to a variety of other commercially-initiated studies. And in 2010, there were two very large, very complex commercial studies. And the first one was a two-dose study. And they saw a 40 percent reduction in feces. In that study, there was no association on hide. But if you looked at the total number of beef trimming combos associated with a positive test, that was

significantly reduced.

And there was a second study in 2010, again a large commercial study involving vaccination of over 200,000 animals. And there was approximately a 65 percent reduction of prevalence of E. coli 0157 on the hides of animals as they entered the packing plant.

There were two studies in 2011. One is ongoing. But the completed study that was led by David Renter, who is here today, saw a 50 to 60 percent vaccine efficacy in the feces, as well as they looked at a measure of high-level shedders. And they saw that that high-level shedders was reduced approximately 75 percent.

So, again, an instance where the number of positive animals was reduced, as well as the concentration that was shed in those positive animals.

In terms of the non-0157 STEC, I think it's fair enough to say that the research is very nascent. We're just

beginning to understand this, but I think there's opportunities for hope.

So, to give you an example of that, this would be the fingerprint of the antigens in the Epitopix/Pfizer vaccine. This line represents the antigens here. One set of antigens called the siderophore receptor proteins, and here are the porin proteins, and here are six of the non-0157 STECs and you can see that there's a lot of similarity in the antigen.

So, this certainly doesn't result or doesn't indicate that there is field efficacy, but we certainly do see similarity in the antigens. We see cross-reactivity in vitro to antibodies to 0157. So, I think there is some hope or at least opportunity to look at this, and there is an ongoing study this year to do that.

There is similar technology, or the same technology, but antigens now from salmonella, that's actually fairly broadly

used in the dairy industry. And so, I'm sharing with you some information on salmonella. This is relatively few and far between, but there are some data that look encouraging.

This was a study that was done looking at cull dairy cows from nine different dairies, and we saw a tremendous variation in salmonella prevalence here on the y axis from dairy to dairy. And when we asked the question why, we were told to look at whether they use this vaccine or not.

And so, we broke the dairies out into those that used the vaccine and those that didn't, and there was approximately an 80 percent reduction in prevalence among the dairies that did use it relative to the dairies that did not. And certainly this study design is interesting, but it wasn't designed to look at this question.

So, we were encouraged. So, we went further and prospectively designed a

cohort study where we have 11 dairies that use the vaccine in a whole-herd approach, and 11 dairies that had never used the vaccine. And we look now at healthy dairy cows, because they become the source of the culled market dairy cows. And we saw a 40 percent reduction in salmonella prevalence among those herds that use this vaccine. So, certainly this technology appears to have promise beyond E. coli in looking at salmonella as well.

There is another vaccine. This one is produced by Bioniche Food Safety. This vaccine is sold and marketed in Canada as Econiche. It is fully licensed and available off the shelf in Canada. And Canada has label indication for vaccination of healthy cattle as an aid in the reduction of shedding for Escherichia coli 0157.

This is not yet conditionally or fully licensed in the U.S. yet. We hope that it will be soon. But this has been fairly thoroughly evaluated and there's a lot of peer

review literature that support it.

I realize this table is complex and I thank Dave Smith from the University of Nebraska for sharing it with me, but all the data are not that important in here, except each one of these rows represents a different peer reviewed publication.

So, the study was done a couple years typically before it was published, and you'll notice there are multiple publications represented here. And they looked at multiple different outcomes from feces, to terminal rectal mucosa, to environmental sampling, to hides and so forth. And the outcome measure that they reported here is odds ratio.

And what we do is we look for an odds ratio of less than one to show that the vaccine would have a protective affect. If it's greater than one, it would indicate that the vaccine actually did not do what it was hoping to do and actually made the situation worse. And the odds ratio is presented here

in this blue column. And if you look at these, every instance that they looked at, any sample type across all of the studies, every single odds ratio is less than one.

Sometimes these are not significant, but in many instances they are. And so, if you want to talk efficacy, the first odds ratio is 0.35. That would represent roughly a 65 percent reduction, or approximately a 65 percent vaccine efficacy in these cases. So, I think the data are quite compelling for the Bioniche vaccine as well.

So, there's a growing and compelling body of evidence, I believe, that these vaccines work as they claim, that is, as an aid in the control of E. coli 0157. There's some evidence of efficacy against salmonella in dairy operations. And there's ongoing effort to try and evaluate this with non-0157 STEC, but it's just too soon to understand whether that is working.

But I think one thing to take out

of this, and we'll go through some of the other products as we move forward, but time and time and time again every time we evaluate it, the gradient is usually in the right direction. Sometimes it's significant, sometimes it is not statistically significant, but there is a consistent gradient time and time again.

But we have to accept that that gradient is not perfect. It's not a complete reduction, but there is a consistent gradient from study to study. And in the evaluation through a recently published systematic review and meta-analysis, and this approach is perceived as providing the most compelling evidence of a cause and effect relationship, the authors concluded from their systematic review, that indeed vaccines do significantly reduce E. coli 0157.

So, to move down there and now look at another intervention technology, direct-fed microbials, probiotics they're commonly

referred to, one of them has been evaluated most thoroughly. And so, I'll talk to that one.

It has GRAS statues, so generally regarded as safe, for approval for use in cattle -- the bacteria do. As such, there is no label claim. So, the marketing of this is based on scientific evaluation. And what we've seen in this one, it's very strain specific. So, some of the probiotics work, and some of the probiotics don't work, so that's important. And the other one is there's a dose response.

We do see in effective strains, a dose response or an effect at lower doses, but we see a greater response at higher doses. And there's one product, as I said, Bovamine, that's produced by Nutrition Physiology.

And so, this is just a graphical way to represent the data that I showed you in the table beforehand. Where we look for odds ratio as less than one, we look for boxes to

the left of this red line. This red line represents no effect. Over here would be increased shedding. Over here would be decreased shedding.

So, this was a meta-analysis that was done several years ago. And if you look at this, you'll see all but one of these boxes lay to the left of it. And where these lines cross this red bar, it means in their individual study it may not have been statistically significant.

But if you look at them, it's hard to deny that all of these lay to the left. And if you produce an average across these studies, we find that the efficacy of this in feces is around 50 percent. And on hides, it's close to 40 percent.

So, again, another technology that I think there's a compelling body of evidence to say that this is relatively consistent. It works time and time again in the evaluations from different researchers, different research

groups and certainly over many years. But, again, it is imperfect.

And on the probiotic, there is some evidence for efficacy against salmonella and there's an ongoing study looking at 0157.

Now, if we keep moving down the supply chain, the terminal application would be sodium chlorate as a poster child product. We've talked about sodium chlorate for a long time. In the 2003 best practice document, we talked about sodium chlorate. This would have to be approved through FDA as a new animal drug.

And the reason this works is that all enterobacteriaceae, so E. coli, salmonella and others, are nitrate reductase positive. So, in an anaerobic environment, the nitrate reductase can reduce nitrate down to nitrite to produce energy for the bacteria to survive in an anaerobic environment where there is no oxygen.

The challenge for the bacteria is

that this enzyme will also reduce chlorate down to a toxic metabolite called chlorite. And they do that in the bacterial cell, and then it ultimately kills the cell. So, there's tremendous application for this.

The challenge is we're lacking field efficacy. Because this has to go through the FDA route, we don't have an authorization to use this in animals intended for human consumption. We haven't had this authorization. So, it becomes prohibitively expensive to try and do a field study. So, we have small-scale studies, but certainly everything appears to be encouraging to date.

So, this was a study that was published by Todd Callaway almost ten years ago now, in which animals who were challenged with E. coli 057. So, ten cells, a hundred cells - excuse me - a thousand, 10,000 up to a million.

And you can see the black bars represent those that will get sodium chlorate,

and they're all bouncing around similarly to the open symbols that are those of the controls.

On this vertical dashed line is when the animals were dosed with sodium chlorate. And you can see those that were treated dropped tremendously. This represents about a 99.9 percent reduction.

So, again, I think the opportunity is here. It requires FDA approval, and hopefully we can evaluate this in the field before too long.

Now, the last technology I want to talk about before we go into the next part of the segment is bacteriophage. And this is another form of biological control. There is a product available that is produced by Elanco Food Solutions and the field data are quite encouraging.

There's one study that was performed, a week-on/week-off study, where the bacteriophage were applied for a week, and

then water was applied for the following week, and so forth. And it did appear, in the data that Elanco provided, to reduce the amount of trim positive tests by about 55 to 60 percent.

So, again, there's some encouraging data to say that the bacteriophage can have an effect, albeit imperfect again.

And so, when we ask the question about non-0157 STEC, well, the existing cocktail they use has efficacy against some of them and they are actively expanding this platform to cover all of those non-0157 STEC.

So, I think it's only a matter of time before this technology is available to do 0157 and 69 0157 STEC.

And the other thing about this, this would be applied at the packing plant. So, as the animals are unloaded, they either run in single file or in groups through this misting that applies the bacteriophage to the animal. And there has been significant adoption of this technology, but it certainly

is limited to warmer month adoption.

So, if I can sum up the efficacy then of these interventions, I think there are a variety of different technological platforms that are available. That is good, because we have no two production systems that are absolutely identical. So, some technologies may be more adept to some production systems, whereas others might suit others much better.

The efficacy is consistent in that there is a gradient with these platforms to lower prevalence of E. coli 0157, some evidence against salmonella, but, nevertheless, that efficacy is imperfect. It's not complete removal. It's not a silver bullet. So, the question is, can these interventions have an impact?

And so, if I go back to the basic premise, then I want to talk about impact, because that leads into the third leg of the stool, of adoption.

And impact is a little bit harder

to evaluate, because where we stand in the system now, perspective of the system of the big supply chain, the impact that we want may vary. So, it may be a public health response, it may be a plant response or so forth.

And for a long time we've been living on a simple, yet logical and qualitative relationship, that groups of cattle carry some line of E. coli 0157 or other foodborne pathogens to the plant. The plant has a series of hurdles that for most of the time, most of the groups of cattle, most of the year effectively mitigates that load that comes to it.

And so, the working hypothesis, the qualitative hypothesis, is that at certain times, that pathogen load on those animals is greater, whether this is through the warmer months of the year or a particular group of animals, is greater. So, it comes into the plant and it overwhelms the series of interventions. And although it decreases it

quite dramatically, it may overflow and lead to contaminated beef product.

I certainly don't want this to happen. This is my family and the cattle that we raised at home. So, the question then becomes what is the purpose of these interventions? We know that they're imperfect. And so, the purpose would be that something happens pre-harvest to decrease this excessive load. And this could be a natural intervention moving from warmer months to cooler months of the year, or something that we purposely apply so that we can decrease this load sufficiently so that what enters that plant can be effectively mitigated by these interventions, these hurdles that the plant have designed and strategically implemented.

So, this relationship is, I said logical, it's qualitative, and it is supported by some empiric evidence. And one of those is from a study that I'll talk about.

On the x axis here, I've got month of the year. So, January through December. This horizontal, black line represents the average across the whole year.

So, if something is above the line, it represents an increase above the average. If something is below the line, it represents a decrease below the average.

I've added some color to it to help out a little bit, but this red line here represents the prevalence of E. coli 0157 in cattle.

And based on the available data, it looks like during the warmer months of the year the prevalence is almost double the yearly average. And during the cooler months, it's much less than the yearly average.

And then if we follow ground beef, which is -- excuse me -- the green line which is ground beef prevalence, we see that that following FSIS data, increases with the lairage phase behind cattle during the same

period of time. And then if we look at FoodNet human incidents, we see that that increases in relationship to each other.

So, this doesn't establish cause and effect, but it's a very temporal relationship and it's a very qualitative relationship, but it is empiric evidence that supports this relationship of prevalence in cattle, load in cattle, contamination of beef, and then exposure of the human population.

The challenge with this qualitative relationship is that we can't necessarily quantify an impact. We would like to know if we do something, does it change something meaningful? And if it does, to what extent is that impact expected?

And so, that is a limitation of the qualitative data, but more and more we're starting to see some quantitative relationships. So, there was a paper published by Jim Withee a couple of years ago, and Eric Ebel who is here who can talk about

it if you have questions on it, a paper out of Kansas State looking at pre-harvest to carcass contamination that found that pre-harvest was associated with carcass contamination and certainly talked of intervention efficacy.

And there was also an FSIS document that was released and published in 2004, which was a first attempt to look at this farm-to-fork relationship. But I want to talk more to a new, relatively recently developed that's yet to be published, quantitative model that is truly a farm-to-fork model.

And Dr. Scott Hurd and his group developed it. Dr. Hurd is here. So, he can answer some of the more specific questions related to it. But it looks at production, slaughter/fabrication and then consumption. And it evaluates the impact at various levels. So, it evaluates the expected impact on public health, the expected impact at the plant level. And Dr. Hurd evaluated or modeled three different scenarios.

We looked at imperfect, or he looked at -- excuse me -- at imperfect efficacy from 40 percent reduction, to 60 percent reduction, to 80 percent reduction. So, in the ballpark of those efficacy numbers that I presented from the interventions.

And then also a concentration reduction. So, 0.3 logs all the way up to one log reduction. Which is if we look at some of the efficacy data, may be somewhat conservative, but certainly appears to support or is supported by the data from evaluation of efficacy.

And to show the relationship of prevalence in concentration, the first slide is the number of human cases attributable to beef. So, these are straight from the CDC.

Here is the log reduction from zero log to almost one log. And then the proportional reduction. And you can see that with decreasing concentration, the number of human cases decreases. With decreasing

proportion of animals that are positive, the number of human cases also decrease.

But what I'd like to do is talk to a couple of these levels of impact that I borrowed, and I thank Dr. Hurd for these slides.

So, again, number of human illnesses attributed to beef from the CDC. This model includes imported beef that is assumed to be unvaccinated. So, the impact is somewhat diluted by the imported beef that's assumed to be unvaccinated.

The red line represents 40 percent efficacy. The black line 60 percent. And the green line 40 percent. And here is varying levels of adoption.

And so, if we go to a hundred percent adoption, there is somewhere in the neighborhood of 30 to 60 percent reduction in human illnesses attributed to beef expected based on this model.

But there's something, I think,

more important in this model, or at least just as important in this model.

If we focus at 40 percent adoption, and we move from 40 percent efficacy to 80 percent efficacy, that represents a nine percent reduction in human cases. So, again, just looking at 40 percent adoption going from low-level efficacy to high-level, nine percent reduction.

But if we move from 40 to 80 percent adoption in a poorly efficacious product, so 40 percent efficacy, 40 to 80 percent adoption, that represents almost a 20 percent reduction.

So, I think the take-home message from that discussion is that adoption is just as important, or maybe even more important, than focusing on efficacy alone.

So, there are other levels of impact. So, this might be a plant level impact. This is the probability of regulatory detection of E. coli 0157 in ground beef or

trim. Again, vaccine adoption on the x axis. The probability of detection with a regulatory test. And then the three levels of efficacy, 40, 60, 80. And, again, you'll see a stair step.

So, as the efficacy improves, we get greater response. But, again, as adoption increases, there is a greater response still. So, again, that similar message of adoption is just as or more important than efficacy, at least in this model.

And then the last one is the number of illnesses -- or the number of 10,000-pound lots of beef that result in illnesses per plant. So, for a typical plant, they might produce 16,000 or 10,000-pound lots. And based on the model, the number of lots that produce two illnesses with nothing is on the y axis here. And if we have a hundred percent adoption of 40 percent efficacy, 60 percent, 80 percent efficacy, basically you can see that the 80 percent or the hundred percent

level reduces that down or eliminates the number of times a lot results in two illnesses.

And this is described as an outbreak. Most of these outbreaks, two illnesses, will never be detected. So, this is background illnesses that are never detected as part of an outbreak.

But you can go along the x axis to number of lots, which is very rare, that will produced ten illnesses, is eventually eliminated in this model by any level of efficacy at a hundred percent adoption.

So, if we then ask the question now on opportunity to impact, this farm-to-fork model does allow us to quantify the expected impact of the intervention.

And so, all models contain some degree of uncertainty. As Scott Hurd will describe it, all models are wrong to some extent, but some models are useful. And so, this model that Dr. Hurd has put together is

built on the best available data. So, it is limited by the data that we have available, but certainly is useful and allows us to estimate the impact at various levels of efficacy and extent of adoption.

And so, if I can summarize this, then, because it leads into my final section of the presentation this morning, that a poorly efficacious intervention can still have an impact if broadly adopted. Whereas something that's perfect, a hundred percent efficacy, has no impact if it's left on the shelf.

So, that leads us into a discussion of adoption now. And so, I think leading into this discussion is an important question. And I think it's a question we need to ask ourselves based on the data that we're starting to share and discuss and think about. Should we collectively and individually, should we implement pre-harvest interventions?

And for some in the group, this may

be a rhetorical question, but I don't think it is a rhetorical question. I think it's something we need to collectively come together. Because at the bottom line, any systemic intervention that we design and implement is going to require a behavior change across a variety of sectors within the industry.

And it's not just a random behavior change. It's going to require a coordinated, purposeful and informed series of behavior changes. For example, we talk about incentivizing an adoption, an intervention. That would require a behavior change on the people who are going to adopt it, but also a behavior change on those who are incentivizing. They have to develop a program of incentivization.

So, it's a complex question. It's more than simply one sector driving it. One sector can't drive it. It has to be a collaborative approach across many sectors

that require behavior changes.

So, this question of should we implement it, is a question I don't know the answer to, but I think it's certainly something that we need to address and discuss.

And so, we talk about economic incentives and disincentives to adopt. I think it is important to focus on what are the economic drivers, but it has to be more than just the economics. And I want to give you two examples very briefly.

The first one talks about administering anti-microbials to chronically ill animals. And the authors, one of them who's here today, looked at what and why and how decisions are made to administer that anti-microbial to an animal that has been treated multiple times given that they know there are huge economic penalties from continually treating them.

And it basically came down that a series of social norms and perceived moral

obligations to others in the system, as well as the moral obligation to the animal in their care, was more important than the simple economic driver. So, that contributed to that behavior. So, their behavior or decisions to treat were based on more than simple economic drivers.

And another example I'd like to share is that - this was done in the UK. So, a very different system. A very different challenge. But I asked the question, two questions, how effective is an intervention, and how practical is it? And I found that one intervention was perceived to be the most effective, but it was one of the least practical for their system.

And so, I think that's an important consideration. And so, if we get down to behaviors, then, behaviors result from a complex suite of very personal, but also interpersonal values such as social norms, moral obligations and economics. And we need

to consider those if we want to do this.

And so, if we move forward, some suggestions then. I think we need to identify and test various scenarios in which producers -- if we answer that we want to proceed, in which producers perceive these interventions as effective, practical and implementable.

Ultimately, those who implement this, so behavior change at multiple levels, so it has to be collective, those who implement this has to perceive that it is implementable and practical.

And then the other one is they have to perceive that adoption of this behavior is advantageous at some level. So, that's going to require a tremendous stakeholder agreement. And I think it's going to be stakeholder agreement or engagement across the supply chain.

And I think the other thing we're going to have to do is provide and facilitate constructive and collaborate and positive

partnerships along the supply chain, because it's clear that one sector is going to have to bear the cost of it. And if there's value to be gained, then there has to be a partnership to do that.

And if I just quickly mention this paper by Jim Withee, he found that -- he looked at public healthcare settings as a benefit versus cost of the vaccine. And those are two tremendously separated variables. So, it's going to require some complex partnership.

And then the other one is we must remove barriers to adoption, or identify modifiable barriers to adoption. Certainly cost is a barrier to adoption, and it's not very modifiable. But we have to evaluate it, ask how we can get around it.

The practicality of various interventions is a barrier to adoption. But how someone frames the system or the situation that they're in may change the practicality.

And then there's an unintended consequence of the conditional license that one of the vaccines has, is that, while it's an important step in the approval process, has become a barrier to adoption in itself in that the default on a conditional license is a 60-day withdrawal, which is very problematic in production. Access is difficult in that it requires veterinary involvement. And the veterinarian has to be aware of it. So, it's a bit more challenging.

And the conditional license raises the question for the long-term access. Will this be available in two years, three years, four years, given that it's only conditionally licensed? And the questions that I get asked is, why is it conditionally licensed? There must be questions about the efficacy of this product.

So, I agree that conditional licenses are valuable in moving forward in the approval process, but they do create

significant, but modifiable, barriers to adoption.

And so, to evaluate that in another way, I think we need a clear, consistent and achievable process to approval.

So, if we look at the innovation pipeline to a translation to industry, certainly if there's a way to consistent, achievable process to get through the approval process to industry, the approval process itself can give some positive influence.

So, if it's been evaluated, regulated, approved, it gives some positive influence on adoption. Also gives positive feedback that, hey, we can develop the generation twos or to other innovators to produce a better product. And even partial adoption by the industry gives a positive feedback for further innovation.

My concern is that if we can't get into the approval process, or we can go through it partial way, but we can't get to

fully licensed or approved product, then this generates a tremendous negative feedback to the innovators, a negative influence as it currently is doing to industry in adoption, which again results in a negative feedback.

So, we get in a vicious cycle of negative feedback. And my real concern is that if we can't move through the approval process, we're basically going to empty the innovation partner because we're going to send the message to innovators that we can't get full approval. And I think that is problematic and it certainly is modifiable as we move forward.

And I'll start wrapping up. I think there are some challenges that we need to consider. And I realize that this is a political, hot title, politically very sensitive to some. But as I said, this approach, if we choose that we want to do this, is going to require very close, very tight business partnerships along the supply

chain. That's the only way I can see it happening.

So, if we make or if restrictions are placed on alternative marketing agreements in the beef supply chain, I say that is going to severely limit our ability to develop business partnerships to implement these food safety interventions.

So, we can have the best intention. But if we have developed those business relationships because alternative marketing regimens have been prohibited or restricted, I think that's going to be challenging.

Other challenges will be that if the U.S. decides to implement this, it certainly adds to the cost of production, and we're in a globally competitive environment. So, what do we do to the international markets? Do we require it of product coming in so they're not at a competitive advantage cost-wise and so forth? And I'm sure we can think of other unintended consequences as we

move forward.

So, the other one that we need to consider is the experience of Willmar Poultry. They're the group that developed the SRP salmonella vaccine and the SRP E. coli vaccine. And I heard some very impressive internal data based on the official Minnesota salmonella test.

On the y axis here, I have the percent of positive flocks. On the x axis, I have year eggs in 2001. The current data for the last couple of years is somewhere around two to five percent positive flocks. And this is in laying hen, turkey laying hens.

They developed this vaccine, implemented it over a two-year period across all of their flocks. And if you look at this, it's a stair step reduction. So, if they go up to here and said this reduction from 94 percent to 50 percent does not justify implementing this, the challenges of implementation, they could have done away with

this and the prevalence could have stayed at 50 percent, could have increased. Who knows really what happened.

But they stuck with this, and what you'll notice is every year it continued to decline. So, there was a cumulative effect observed in this poultry production system. Again, very different than cattle production, but a cumulative effect from 94 percent positive flocks now down to two to five percent positive flocks.

So, if I can sum up, I guess I'm going to leave this with a little bit of deja vu and also an opportunity to talk about progress.

This was an article, a news release that says APHIS to spearhead pre-harvest food safety. And so, this should sound very familiar. Approximately, 150 people representing food industries gathered at College Park, Maryland to talk about pre-harvest in a public meeting as such.

And if we think back to '94 and the response to the West Coast outbreak, there's been tremendous improvement. I shared with you some of the progress, the success from regulatory oversight, the implementation of HACCP plans, the development of in-plant interventions, now the innovation and development of pre-harvest interventions, but certainly we still have some similar needs that have transcended that time. And so, we still need productive collaborations that this called for.

And so, inside this it says the FSIS Pathogen Reduction Task Force has recommended a systems approach that we fully agree with, but they also recommend addressing consumer needs such as safe handling, greater interest in pre-harvest food safety, which is one of the goals of the meeting again this time, and integrated farm-to-table strategy for food safety.

So, some of the needs from 17 years

ago, are still the same. So, I think that is something to consider.

So, my last slide is that I'm very optimistic that we are in an era where we have effective interventions that are available or soon to be available. And while they are effective, they're consistently effective, they're imperfectly effective.

And I think we need to move away from this hope and this desire that we're going to find a silver bullet, because what we have is what we have. But they are consistent, and they appear to work.

The other thing I would ask is that we move away from focusing solely on efficacy. Because based on the best model that we have available to date, it appears that adoption is at least or sometimes even more important than efficacy in that we can adopt, broadly adopt, a fully efficacious product and it appears to have actually a quite substantial impact.

So, we get back to this question of

should we attempt to adopt interventions? And, again, I don't know the answer to that, but certainly it is complex and we need to discuss it. And if we do, it's going to need a very inclusive stakeholder-driven process to do that.

So, with that, again, many thanks to the agencies that invited me. It really is a tremendous privilege. And all of the people who provided data slides that I work with on a day-in/day-out basis, because they helped inform what I had to say today. Thank you very much.

(Applause.)

DR. GOLDMAN: Thank you very much, Dr. Loneragan. As usual, he's done his stellar job of both bringing us up to date on the science, as well as leaving us with many provocative questions. And you'll notice in your packet, where he ended up was really reflected in Question 3. So, we hope to encourage a lot of robust discussion about

Question 3 having to do with adoption.

So, we have a few minutes for some questions for Guy if you'd like. Please, just raise your hand. And I think we have microphones - yes, we do have microphones. So, if you raise your hands, we'll get a microphone to you and you can ask your question.

DR. COURSEY: When you ask a question, if you could stand and please state your name? Thanks.

MR. CUSTER: Hi. My name is Carl Custer, I am representing myself. Two key issues.

One was we've been focusing on the category of the slaughterhouses. One that I think that has been missed out, is that the pathogens coming from beef lots, dairies and other places, these pathogens can also be spread to the environment, to crops, to waterways, just out into the environment. So, there is variable interventions for people

there in the environment.

The second part about adoption, and this is something I wrote to Secretary Vilsack last August, and that it is my hope that one day we'll be able to paraphrase Section 602 in the Meat Inspection Act.

I hope that one day USDA would echo that and state food animals raised without pre-harvest interventions and bearing human pathogens can be sold at lower prices and compete unfairly with producers that implement pre-harvest interventions and whose animals do not bear human pathogens to the detriment to consumers and the public generally. That's it.

DR. RUZANTE: My name is Juliana Ruzante. I'm with the Pew Charitable Trusts. Guy, I thank you for your presentation. You mentioned some of the best practices and also some of the interventions. And I'd like to know if you think we right now have a good understanding of the risk factors at the farm

level, and also if you could comment on the availability and quality of prevalence data of not only 0157, but other pathogens at the farm level.

DR. LONERAGAN: I guess the question on the risk factors at farm level, there have been probably the most comprehensive -- there are some case study work, as well as USDA National Animal Health Monitoring System that evaluated a series of risk factors. And in the 2005 study, they found a series of risk factors, the 2009 study - or, excuse me. '95 and '99, they didn't find those same risk factors lined up. And I think what we're finding oftentimes is some of the risk factors we find in one study, just happen to be in that study. They are not true risk factors.

So, that gets at some of the management factors. And, again, I think that's been probably the most unrewarding part of this. We go to meetings and these never get published in peer reviewed meetings, but

they get presented in proceedings in abstract.

They talk about they put the animals on a concrete floor and wash the floors daily and wash the water trucks daily, and they don't seem - because what we're dealing with is a commensal of these cattle, they're evolved for life in the cattle, it seems to be regardless of the environment, usually regardless of the management factors. So, I think the risk factors are very limited at the moment.

DR. BLAIR: I'm Joe Blair with the HACCP Consulting Group.

The concern I have or the question I have relates to the food safety impacts of the compounds like probiotics and so forth. What does that have to do in terms of residue or how does that impact food safety just the fact that you are adding the material to the animal's diet?

DR. LONERAGAN: That's a very good question. If we go back to the probiotic,

that's basically a lactobacillus product that is in the environment everywhere. We consume it in yogurt everyday. The FDA has looked at these bacteria and said that they're generally regarded as safe. So, in that regard, I don't see a concern associated with that.

So, when FDA would look at a chemical, they would look at a withdrawal period based on human safety in the target animal. And then when CVB looks at - Center for Veterinary Biologics looks at vaccines, they establish a withdrawal period based on, again, human safety in the target animal. So, I think in terms of the technologies that we talked about today, the human safety component of that technology, per se, has largely been addressed.

I agree with you that we're adding things to the system, but I think the human side has been addressed or is being addressed.

DR. COURSEY: We have a question over here.

MR. VAQUER: Arnaldo Vaquer, Vaquer, Inc. You mentioned two interventions: the vaccines and the probiotics. Have you tried them both together and have you had a better result?

DR. LONERAGAN: So, the question was using more than one intervention at once, and our answer is we personally know that the person sitting at your table has evaluated two of them together. Certainly, it was at a lower dose probiotic. And I'll let him speak more to that in a moment. But if we look at the high dose, the very inhibitory product, and the vaccine, we haven't looked at those together.

DR. GOLDMAN: We'll take one more question and then we'll move to the panel.

MR. ROACH: Yes, I'm Steve Roach with Food Animal Concerns Trust. And my first statement is a comment. I agree that there doesn't seem to be farm management practices that have affected 0157, but I think you will

see that cattle from feedlots have much lower levels of salmonella and decreases over the production period. And I think there is also evidence that campylobacter is highly inconsistent. So, it's not specifically that all pathogens go against farm management practices. Clearly, there are some differences there.

But another comment I'd like to make, I really appreciate -- coming as an anthropologist who's married to an agriculture economist. I really appreciate your statements that your real barriers are not the technological ones but it's how we get, that is the systems, to actually adopt these practices. So, I greatly appreciate that, but I would like to hear your thoughts on what I said about salmonella in particular.

DR. LONERAGAN: Very sorry, I used up a lot more time in my presentation than I thought.

So, salmonella is an interesting

organism because it spans the spectrum of pathogenicity. So, some like salmonella Newport, salmonella typhimurium are very pathogenic. So, if animals are negative to salmonella typhimurium and they go into an environment whether that be a pasture setting or a feedlot or dairy setting and salmonella Newport is there, they are going to get infected with it. So, in that sense, I agree.

But at the other end of the spectrum, salmonella - there are many types or serotypes that behave like commensals. And so, when we looked at -- in a limited sense, I agree with you. But in a limited sense of cattle as they come off extensive pasture settings entering a feedlot. On entering, they're commonly populated with these commensal salmonellas.

So, in that sense, the management would depend on whether we're looking at the pathogenic strains, which, again, I agree with you, we have very good management strategies

to look at pathogenic salmonella and they should be implemented, but in terms of the commensal strains, they appear to behave like 0157 in that they're robust to a lot of these management -- but that's a very good point. Thank you.

DR. COURSEY: Dr. Goldman, just a quick question.

DR. GOLDMAN: Yes.

DR. COURSEY: Will Dr. Loneragan's presentation be posted on the FSIS website?

DR. LONERAGAN: It is available already.

DR. COURSEY: Okay. Thank you.

DR. GOLDMAN: Thanks again to Dr. Loneragan.

(Applause.)

DR. GOLDMAN: And as was mentioned at the beginning, there are no breaks scheduled. So, please avail yourself when necessary.

We're going to move to the industry

panel, and I want to introduce Dr. Mary Torrence who will lead the introduction and the panel discussion as well.

Dr. Torrence is one of the two National Program Leaders for Food Safety at the USDA's Agricultural Research Service, in the Office of National Programs. ARS is the intramural research arm of USDA. And she provides leadership and strategic direction for the research conducted in the food safety program. Currently, the program includes over ten research centers and 190 scientists. This research supports the mission of USDA, as well as other federal and industry stakeholders.

Previously, she was at USDA's Cooperative State Research Education and Extension Service now known as NIFA, for ten years where she was the National Program Leader for Food Safety and Epidemiology there.

While at CSREES, she initiated and ran the Epidemiologic Approaches for Food Safety granting program, which provided some

of the first large grants in pre-harvest food safety, anti-microbial resistance and other epidemiologic studies. She provided leadership on food safety and epidemiologic issues to universities and on national committees.

Dr. Torrence has her Doctor of Veterinary Medicine from the Ohio State University, and a Ph.D. in public health and epidemiology from Virginia Tech. She is board certified by the American College of Veterinary Preventive Medicine and a member of the American College of Epidemiology. And in 2010, she received the Distinguished Alumnus Award from the College of Veterinary Medicine at Ohio State University. She is an author and co-editor of two books. And is Editor in Chief for Zoonoses and Public Health.

And we welcome Dr. Torrence to lead the industry discussion in which we hope we'll hear some more of the best practices that are used in the food-producing industry.

So, Dr. Torrence, thank you.

DR. TORRENCE: Thank you. I think really the only reason I was asked to moderate this is I'm well-known for cutting people off if they go past their time.

(Laughter.)

DR. TORRENCE: I think if I'm understanding right, we're going to bring the panelists up to the table with the mics. And some of our industry panelists also have presentations. And I do have a pretty good watch.

I'm really excited about the representatives we have here for industry. They represent a wide range of producers and some real insight, I think, into the potential for pre-harvest food safety.

(Off-record comments.)

DR. TORRENCE: Okay. As the panelists are assembling here in the front of the room, I'll read their bios.

Bill Rishel owns Rishel Angus,

which is ten miles south of North Platte, Nebraska, with his wife Barbara. He received his B.S. and Masters in animal science from Penn State University. Bill is the 2011 President of Nebraska Cattlemen and has served on the Cattlemen's Beef Board from 2000 to 2006. He has received numerous awards from the cattle industry, including the 2007 Record Stockman U.S. Livestock Industry Leader of the Year, the 2006 Nebraska Angus Association Producer of the Year, and 2005 Beef Improvement Federation Seedstock Producer of the Year.

Rishel Angus has been an ongoing purebred Angus operation since the purchase of its first registered Angus female in 1966, and has kept performance records on its herd since then. Rishel was one of the first breeders to make a commitment to identify the carcass merit of its cattle because of the belief that its program's real focus should be acceptance of the product by the consumer. Because of

this effort, many of the leading individuals for carcass merit in the Angus breed carry the Rishel Angus prefix.

Tracy Brunner is president of Cow Camp, Incorporated, a family-owned agribusiness enterprise at Ramona, Kansas. Beef Cattle are the focus of the fourth-generation family-owned farming and beef production business.

Cow Camp Beef is an umbrella organization of several related entities, all aligned with the goal to produce higher-value beef. Cow Camp Ranch is a producer of beef cattle genetics and seedstock, supplying ranchers and cattlemen throughout the nation with premier replacement bulls and females.

Cow Camp Feedyard markets roughly 15,000 head per year. Cow Camp is also integrated into the processing of their product, owning most of their own cattle production through beef processing via value-based marketing. They are also involved in

beef processing via U.S. Premium Beef stock ownership. At Cow Camp Beef, the focus is on quality with a mission to supply other producers with tools needed for an improved beef business.

Tracy is active in the national Beef Industry representation and governance, in 2009 serving as the Chairman of the Policy Division of the National Cattlemen's Beef Association. Past service includes many years on the NCBA Board of Directors, as well on the Executive Committee. He is past Chairman of the New Product and Culinary Initiatives Committee of the NCBA, and currently a member of the Beef Quality Enhancement committee. Tracy is a graduate of Kansas State University with both a Bachelors' and Masters. A Bachelor's in animal science and a Masters in agribusiness.

His wife and daughter are also graduates of Kansas State University, and his son is now a student there. Tracy sees the

key to any successful business as customer satisfaction. Their everyday work is helping other producers make the move from cattle producer to beef producer.

John Butler is the Chief Executive Officer of the Beef Marketing Group, a producer cooperative consisting of 15 cattle feeding and growing operations located in the states of Kansas and Nebraska.

The cooperative formed in 1987, harvests 500,000 cattle annually and has been focusing on consistently producing value-added beef and beef products that meet customer demands.

The group has developed a number of initiatives that have provided end-users differentiated value-added products. These include securing a USDA Quality Systems Assessment certification for source and age verification, a verified Food Safety, Animal Care and Sustainability program. And under the guidance of the BMG, each of these

programs uniquely aligns the entire beef supply chain.

John has worked with value-added programs for the last 15 years. And prior to this, served as President and CEO of Ranchers Renaissance, a beef marketing alliance that was instrumental in the development of branded beef programs for the second and third largest retail markets in the United States: Kroger and Safeway.

And finally, Dr. Dean Danilson is the Vice President of Food Safety and Quality Assurance at Tyson Foods. His current responsibilities include developing, implementing and sustaining quality assurance and quality control, HACCP and GMP programs that involve food safety, product quality and product specifications.

He is responsible for Food Safety and Quality Assurance programs for Beef, Pork, Case Ready, Custom Manufacture and Distribution and Warehouse business units.

He's a liaison with USDA and FDA on regulatory issues. And a liaison with industry, trade groups, universities, suppliers and customers on technical issues. And so, what we will do is have each industry panelist provide their five to eight-minute presentation. Hold questions until the very end. Okay.

MR. RISHEL: Thank you very much. My name is Bill Rishel, and my wife and I have an Angus cattle operation in North Platte, Nebraska.

(Off-record comment.)

MR. RISHEL: We raised three daughters, and of course they're all married now. I'm getting up there in years to where maybe you're supposed to be a little wiser, and a little smarter. But we learn as we go along that learning is a continuum process, and particularly true in our industry.

We had a challenge getting in here late yesterday. Spent all day at the University of Nebraska with the Beef Industry

Scholar Program and the seniors in that class. I wish all of you would have had the opportunity to see those kids and the program they put together about the industry and the challenges and how they're going to face the future. Our industry is in great hands.

One of the things that I'm concerned about here today is making it all the way through the afternoon. The challenge of getting in late and then almost missing a flight due to weather and getting in and having not too many hours of sleep -- I'm very proud of the fact that we produce a great product in our industry that's high in heme iron and zinc and essential B vitamins and the power of protein.

And I looked at the menu when I got here, and there wasn't any beef on the menu. And I'm just afraid I might not be able to make it through the afternoon.

(Laughter.)

MR. RISHEL: At any rate, I'm

charged with the fact of explaining the production system in our operation. And I have to share with you that it would be a huge mistake for me to talk about just my operation. Because at the cow-calf level, it is a tremendously variable business.

It varies for many great reasons. There's the great variation across the country in the types of operations, and that's due to several things. Most importantly, environmental differences due to weather. Certainly, seasons of the year.

We also deal with geographical differences. We go from sea level, to high mountain country, to the great plans, to high desert, just to name a few.

Some of the things that are more consistent in what we have in the cow-calf segment of this industry, is that our main business is taking a bovine individual and managing that -- that individual, managing that bovine, that cow, by utilizing grass

that's available to us and trying to turn all of that into a profit.

In most cases, that grass is razed and these cows are run in locations where that land is of little or no value for any other purpose.

The slides that are going to be up here today are few. I won't even be talking about them. I would appreciate it if you just read those as they're up there, but I wanted you to see some of the things that we deal with. We talk about variation. That's variation.

The other thing is that I need to mention the consistency of the cow-calf industry is that we're primarily family-owned operations. They may have a corporate name or a corporate structure, but they are family owned and they've been that way for generations.

Yes, the operations are getting larger for the most part over time, and that's

simply due to economic efficiencies of scale.

The national average for cow herds in this country, and this may be a shocker to some of you in this room, perhaps not, is right around 40 cows.

You hear about the larger cow operations in the country and, yes, they're out there, but the national average is about 40 cows.

That's important to understand to get your arms around this huge variation when you're talking about programs like you're discussing here today.

The other thing that's very, very consistent in the cow-calf industry is the fact that all of these operations, or nearly all of them, are backed by years of experience with basic animal husbandry practices. And I think that's important to understand.

Today, there's more sound science than any time in the prior history of this industry. And I've been around it for a long

time, and these gentlemen up here have as well, and we just continue to see more and more improvements at a faster and faster pace.

In that respect, we're not much different than anyone else in any other industry.

This leads to far greater performance and production in what we do. That's very, very important because it is about profitability. And it's about profitability in an industry at the cow-calf segment where we're utilizing grass to raise that calf that goes into that system that we're talking about.

And we're doing that in what has been historically a very low-income margin business. You need to understand that.

How in the world do these people sustain these low-margin businesses? Lots of family labor. Experience in how they utilize and preserve the natural resources that we have and care for.

We use the resources, but we also have to make sure they're sustainable for future generations.

We understand the particular environment. And, again, it comes back to good animal husbandry practices that all of us either learned at the farmer ranch level, or we got it at some higher lever of education.

It is a foregone conclusion that if we're going to keep healthy cattle, it's clean water, it's great nutrition. Those vary a little bit from environment and weather, we talked about. We try to reduce stress.

We think we are the original animal welfarists. And that just goes without saying that if we don't do that properly, we're not going to be very successful.

Good health protocol, obviously vaccination programs are part of everything we do.

So, those animal husbandry practices are important and I'm going to close

with a couple of comments I'd like to make.

I think it's very, very important for me to state that the vast majority of the producers in the cow-calf segment of this business are or do have some form of higher level of education.

I think you would be amazed and surprised that even in my generation, the number of individuals who have at least an undergraduate degree or more based on animal science and animal husbandry practices.

And certainly I can attest to the fact that the young folks coming back into these operations, are brighter and way beyond anything we could have ever hoped to have accomplished.

The other thing is that the folks in the cow-calf sector in this business are very proficient at what they do in applying management practices, and especially those practices that improve our business and improve our ability to deliver a healthy, safe

product to the public.

There are two things that have to happen. I think Guy touched on these. Those management practices have to be cost effective. And they have to be management friendly. Thank you very much.

(Applause.)

DR. TORRENCE: Thank you very much. Our next speaker is Mr. Tracy Brunner, President of Cow Camp.

MR. BRUNNER: Well, good morning. I've known Bill quite a while and I like everything about him, except following him on a program. Bill, that was very good.

MR. RISHEL: Thank you.

MR. BRUNNER: My name is Tracy Brunner. I'm from Ramona, Kansas. Along with my family, we operate a diversified ranching and beef production and marketing business.

Our headquarters are in central Kansas, but we have producer partners that extend throughout the United States.

We are somewhat typical of the majority of cattlemen in that our livelihood is not only our heritage, but also our future.

I'm honored to be asked to take part in this panel discussion as a producer representative. As a baseline for my thoughts, please note nothing is more important to family farm and ranch sustainability and success than the safety of the food we produce.

We constantly evaluate and work to improve the way we raise, finish and deliver our live beef to our processing partners.

I will openly admit I'm lacking some of the technical education that's represented here, and especially out there in the audience today.

I can tell you that in addition to a large career in ranching and feeding cattle, I have had extensive opportunity to be involved with producer organizations in sponsoring and evaluating research

interventions for foodborne pathogens such as 0157 and others.

Personally, our most extensive ranch and feeding experience has been with feed and water and facility sanitation, direct-fed microbials, and some experience with direct-fed seaweed derivative products.

Additionally, through participation with other producers and managing Beef Check-Off investments, we've been close up in the discovery and have even seen firsthand the widespread adaptation of processor applied interventions such as pre-harvest hide sprays, whole animal hide wash, carcass steam cabinets and hand-held steam vacuums.

I can vividly recall a revelation that crowded hotbox coolers where touching carcasses, were found to promote pathogen growth and negate even the best harvest line intervention success.

Beef is increasingly safer. I will not quote the statistics, most of you are

familiar with them, but I will loudly and vigorously applaud the entire beef processing sector for rising to the occasion and providing consumers with an ever increasing safer beef product.

I will summarize what I believe effective pre-harvest constraints that we face are this: First of all, pathogens live in organic matter of soil, water, on fruits and vegetables, and even within the body of healthy animals.

Furthermore, most are transmitted by things like casual contact, wind, dust, birds and other wild animals.

The economics of statistically lowering the incidents in naturally-occurring pathogens in the outdoor production system that we have today is, at best, limiting, and at worst, impossible.

Secondly, the efficacy of known current interventions falls in the range of 50 percent. From the limited independent

research that does exist, and even using technology owner's data, there is medium to low correlation between use of interventions before transport to packing, and significantly lower pathogen counts after the processor's first line of interventions.

Third, shedding of pathogens by unidentifiable animals during moving to weighing and shipment areas, during transport and after delivery to processing plants, causes cross-contamination on hides and is the primary source of pathogen loads at harvest.

What we do know is that shedding seems to be the highest in hot weather, and is possibly aggravated by some popular combinations of feedstuffs.

But we also know that it can be lowered by some management practices, but they are commercially impractical. And for the most part, shedding is still a mysterious phenomena to the modern North American beef production system.

In the play-to-win game against naturally-occurring pathogens such as 0157, eliminate the shedder-spreader, control pathogen and win the game. I believe if we can identify the shedder, we can get to first base.

No one wants our beef a hundred percent safe more than the producer. No one's heart and conscience cries louder when either foodborne illness or worse is reported.

And research shows that even a recall alone costs producers money through a lowering of the demand occurring for our beef.

For further progress in dealing with an elimination of foodborne pathogen danger in our beef, I would offer the following suggestions:

First, allow even only partially effective interventions to be marketed, thereby encouraging further investment in the next generation of technology that will be even more effective.

But we must avoid fostering some false security through strong regulation that demands accuracy in label and marketing claims.

Second, USDA must maintain its primary responsibility of food safety by focusing on production outcomes, consumer food products.

And third, our industry, ourselves must continue to refrain from technology marketings or food brand promotion of foods by disparagement that says my food is safer than your food.

No one wins in a game of competition that suggests distrust. All foods in our category will find lower confidence and demand.

Finally, we need further investment in pre-harvest interventions with these criteria:

First, genetic research for identification of animals possessing and

perpetuating the shedding phenomenon.

Second, research that can identify better management practices, or, if you will, critical control points for the voluntary application of pre-harvest interventions that really do lower the pathogen load on animals at harvest.

And third, adaptation techniques that use the above-gained knowledge and others still yet to be discovered understanding for the development of more widely adapted beef safety interventions. Given viable interventions, the industry will sort and select the most effective.

And in closing, I'd like to leave you with one final thought. Given what we know today, the processing plant is by far the most effective place in the value chain for major pathogen interventions.

Make no mistake the cost of those interventions is always eventually passed back to producers in the form of lower prices. So,

it's not a question of who pays, but the larger question of where and how can we best meet our food safety goals. Thank you very much.

(Applause.)

DR. TORRENCE: Thank you so much. Our next speaker is Dr. Dean Danilson.

DR. DANILSON: Thank you and I'm going to try to get in under that eight minute window. Guy, very nice opening talk and left a lot of things for us to talk about. I think if you were an insurance salesman, I couldn't resist it buying from you.

(Laughter.)

DR. DANILSON: Okay. Who's got the clicker? You're going to click, all right. Go ahead.

So, I'm going to try to rattle through some information here perhaps to give some of my perspective on per-harvest as it sits in my eyes and being with it over the many years of the evolvement of the issue and

where we sit today, but it is an hourglass. It is a funnel.

Fresh farm and the feedlot, there's a big, wide world out there. It funnels down through transport and into the packing house where we have the opportunity to do several things to those carcasses of the meats that I think that we have demonstrated some effectiveness over the years and then it goes back out into the big, broad world where there's billions and billions served. And that there were cooking methods or lack thereof or different people perspectives, different health conditions that we have to be aware of.

So, in slaughter plant, my perspective to you all is from a pre-harvest standpoint. I basically see four areas of focus. And, actually, the first one would be more of a best practice.

Lairage sanitation. In our operations you're out there washing up every

group of cattle. It means very clean system. It's not piled up in little piles. It's not pest-ridden areas. So, lairage sanitation is a best practice not only for the eyes, not to become an eyesore, but offers control with sanitation. Hopefully, it has some implication or benefit in the prevention or spreading, allowing the pathogens to spread and dwell.

Cattle washing, we've all practiced cattle washing over the years in various stages. Out in the yards, maybe even some of them coming off the trucks to knock off some of the heavier load of debris that's on those cattle.

And then a couple of newer ones in the last few years would be the bacteriophage-hide application and the hide-wash post-stun, which I'm going to give you a little detail on.

Go ahead. We use the bacteriophage at the slaughter plant at the points close to

immediately before slaughter.

Just a little bit through how we apply this. We initiated this in 2010 in all of our beef plants that have supplies of covering spray under the live cattle as they arrive in the plant.

We apply it during the warm months only, April to September. We have two different application systems depending upon the plant.

One is a single shower you see at the bottom where the cattle walk through. Took a lot of design and function development, engineering development to set these systems up so the cattle pass through it, move through it. And they do nice things. Do that nicely.

Then we have the shower system, a larger pen where we have showerheads over the top and the cattle mingle and rub get wetted down.

We try to get a two-hour minimum dwell time before actual slaughter to give

that bacteriophage, that E. coli 0157-specific bacteriophage time to do as much as it possibly can do.

We also try to keep the cattle hides wet as long as possible after phage treatment. So, they go back into a pen. We turn those sprinklers on in the pen to keep them wet.

It's a contact sport. These little rascals can swim. We want to keep them wet. They don't jump. They swim. And so, we try to keep them wet.

Other STECs, the company I think as was said earlier, that has the only hide application out there working on enhancements to phage product containing the additional facets to try to target several of the other non-0157s. We anticipate some of that coming available in 2012.

A point on the phage and I'll show you some information and data here. Okay. The packing plant, slaughter plant is the only

place the hide application can be used because of its current approval.

I believe it has greater application in other areas in the pipeline, the movement of cattle, the management of cattle out in the systems particularly as we -- they do have the additional pathogen areas.

It took us about ten years to get this application approved. I hope the next approval doesn't take another ten years. And the way it's going, it might.

Next. Hide wash post-stun, very quickly, is before the hide is removed. These systems are in many plants. Not all, but many as they're needed. Particularly in the northern sector we see most of them. High-volume caustic water. Oftentimes recirculate water, very high pH on those hides to wash off dirt, debris, loose hair, light mud, tags.

Our elevation has shown a 25 to 30 percent reduction potential in 0157:H7 as we measured on the pre-evisceration carcass.

Next slide, please. This is some information that we collected for ourselves as we look at the application of bacteriophage and whether it provided benefit or not to us.

These data lines would be variety meats positive, presumptive positive data that we collect in all of our facilities on head meat, cheek meat, weasands and hearts.

And as we looked in 2010, the black line, would be the implementation data with phage in that summer period between two gray lines. The blue line would be the 2009, the year before implementation. Red lines are 2007 and the `08 and `09 lines.

So, as we look on the left of the green verticals, we see basically no difference between a potential presumptive positive activity in those cooler months.

We get into the warmer months, however, we saw a substantial shift in this variety meat presumptive positive activity. In this time period for this particular

pattern across the plants, basically nothing else changed. No significance in the process.

And so, it's very difficult to prove these things whether they really, really work or not. And this is essentially how we demonstrated to ourselves that we think we're getting value from it.

So, we believe that -- oh, back one. Back one. We believe that in 2010, we saw about 30 percent reduction in presumptive positive activity versus 2009.

Next slide, please. In 2010, now the red line, or 2011, we continued use of the phage through this year. We continue with the lower, reduced levels that we saw in 2009, 2008 for these variety meat offal products.

And so, again, we have some hide washes that come into play in that time period, but the phage also, we believe, is contributing to this.

Next slide, please. Continuing on through now, that's kind of the slide, the one

I want to go back and talk about pre-harvest as we look at it and think about it or as I look at it and think about it.

Next slide, please. Going back to the ranch, pre-harvest and best practices and interventions must be found in reducing incoming pathogen loads to levels that the plant interventions can effectively deal with it primarily in the warm weather season.

Next slide, please. This is actual fecal tests. Rectal swabs from the rectums of cattle that were slaughtered. This is from one plant over the past 12 months where we have been measuring many different feedlots. Over 20 different feedlots on an ongoing, continuous basis each month as they're presented in for slaughter, we have a sampling program.

Here's what we're dealing -- click one more time, please. Go back. Clearly as we talk about cool season effect and warm season effect, October through March, this

would be October of last year through March of this year. And then April of this year through September of this year.

The numbers that you see, that's the days -- the blue line is the percent of days that had positive E. coli, presumptive E. coli. That's the eae genetic material that's in what we measure.

The number of days of the positive for this material -- actually, this is stx and eae from the feces of the cattle presented into the slaughter plant.

The red line would be the percent positive test across the different feedlots that were tested.

So, clearly this April through September season we're seeing levels coming at us into our plant. And 60, 70, 80, 90 percent of the time we know it's coming at us.

Next slide, please. Interesting to note now, this will be the same data from the last slide. This interlaid is the variety

meats data that I showed you from the presumptive positives from the previous slide with bacteriophage with the 2010-2011 average.

Very interesting how they track with each other. They fit with each other. And as it deals with our perception of what we -- or our practices of what we have to -- interventions, what works, what doesn't work and when the game is on.

Next slide, please. Here comes the trims data interlaid. This is actually the trimming state of presumptive positives interlaid upon variety meats, interlaid upon what's presenting into this packing plant during this exact same time frame.

Very similar pattern, but you can see the reductions that are occurring at each step of the process.

And then of course this tested material, unlike Guy, your slide where you showed that going directly to the consumer, well, there's a whole lot of meat taken out of

the system before that arrow ever gets to the consumer. And that meat is taken out of the system. And that leads us to a lot of the things that we've seen over the years.

Next slide, please. So, looking at the levels of incoming pathogen levels coming in to me at my packing plants, I'm dealing with these two levels.

Next slide, please. The warm season I've got pathogens, E. coli 0157, coming to me probably a hundred percent of the time. This says on the average, 60 percent of the time. Cool season, less than 30 percent of the time on the right-hand axis.

Next slide, please. If we're going to -- are to perform pre-harvest perspective, the mission to look at is that at least 50 percent reduction is needed to reduce 0157, incoming 0157:H7 loads to bring that load down to that wintertime level of incidents occurring.

If we can do that, we will continue

to drive illnesses lower associated with the pathogens, associated with beef.

Next slide please. So, if you're a beef slaughterer, pathogens are coming into the plant every day on and in the cattle between April and October.

Next. Current slaughter plant interventions and systems are capable and effective of control of pathogens when not overwhelmed by incoming loads.

Current incoming summer pathogen load must be reduced 50 percent or more in order for slaughter plant systems to be most effective.

Pre-harvest strategies on the front side as we look at what we can do if we have a plant or an area or a region or a bunch of feedlots that are -- or in the summertime management areas, what's out there?

Guy talked about most of them. Feed, the biologicals, water management, manure waste management, transport stress,

super shedders.

Next slide, please. We have the USDA pre-harvest guideline and management intervention options in 2010.

Next slide, please. But I would submit that there, to my knowledge, there is nothing that I'm aware of either in best practices or interventions that are affective and available to the farmer-feeder industry today for reducing 0157 or pathogen load of live cattle.

It's very disappointing that almost the exact same dialogue or words of verbiage in 1994, has been said in this meeting and we really aren't any farther than we were in 1994. That's disappointing and that's frustration.

Next slide, please. I'm about done. Like we heard, some products are hindered. Where are we? Why have we not progressed? What can we do?

Some products are hindered by

delayed or reluctance FDA/FSIS approvals. Chlorate, vaccines, phage, feedlot, bromine-water systems, it takes way too long to get them approved, to get them in place.

Some products are in very preliminary research in development phases. Many are impractical. Even if they're in guidelines or in best practices, they just don't flat -- they flat don't work as professed in those research publications, best practices and guidance.

The new P-STECs will confuse and complicate pre-harvest efforts of the past ten years. We now have a bigger envelope to deal with.

Salmonella initiatives will further complicate the situation on the pre-harvest area that will make things more difficult to get to an end result.

Cost benefit will be the principle driving factor for adoption of live animal pre-harvest interventions if or when they

become available.

I say $15 a head. It may be 25 to $30 a head of cost in that farm-to-fork continuum on that live side. If we had a $25 per head cost, that's with vaccines, that's with chlorate, that's with bacteriophages, that's with probiotics, you're probably close to 20, 25 bucks a head.

Multiply that out times 60 million cattle out there. We're going to get pretty close to a billion dollars of cost to the industry. What is the cost benefit?

Next slide, please. Live pre-harvest, the only effective and consistent pre-harvest intervention today is mother nature.

Next slide, please. The last ten years have been a great success story for improved safety. And I ask will pre-harvest strategies take us to the next level? It's not going to be tomorrow. Thank you.

(Applause.)

DR. TORRENCE: Thank you. And our last panelist is Mr. John Butler.

MR. BUTLER: I'm going to go ahead and take the liberty of coming up here because I'm so short that if I don't stand up here, you all won't even see me.

So, I appreciate the opportunity to come here today. I want to thank Dr. Hagen and Adela for inviting us to be a part of the panel. I'm humbled to be on a panel with such esteemed colleagues as has already presented.

So, according to my watch, I'm already in negative territory. So, I'll try to move this right along.

I want to talk just a little bit about our company, the Beef Marketing Group, we've already been introduced and what it represents.

We can use the next slide, please. Just briefly, we are a cattle feeding cooperative located in Kansas and Nebraska primarily.

We have been involved in interventions, pre-harvest interventions in the arenas of food safety, animal care and handling and sustainability for a number of years.

And I just want to - I'll share with you in just a minute a program that we've got in place as an example in our company, and in another major feeding company in the northwest, that has implemented these standard operating procedures to address these very important issues.

We, like these gentlemen up here, are very committed to producing a safe and wholesome supply of beef for our consumer. Maybe unique about our company is that we tend to be very focused on the consumer.

We've been involved in a number of end-user meetings and dialogs with processors, as well as us representing the live side as many of the things that we can do on the live side can affect brands and branded beef

programs. And certainly in the area of food safety, we think there's opportunity. And certainly Dr. Loneragan did a really good job talking about some of those opportunities that are there.

We have operations in Kansas and Nebraska which makes it sort of interesting for us, because we have different geography challenges and environmental challenges.

Certainly as it relates to food safety and certainly the pathogens that we're talking about here this morning. Where in Nebraska you've got humid conditions, in Kansas we've got maybe a little drier condition. It has an impact on that pathogen.

We can go to the next slide. Enough about my company. What I want to talk a little bit about is a program that we have initiated, we've had in place since 1987. We call it Progressive Beef.

And basically, its vision is to implement best management practices, verified

best management practices supported by standard operating procedures in all of our operations that drive these rigorous criteria to ensure consumers a safe, wholesome beef product.

I mean, that's a big vision, that's a big statement, but that's what this initiative is about.

The next slide, please. So, what is it? It basically sits on three pillars. I've talked about the three pillars of food safety. I'll explain what we do in that arena, animal care and sustainability.

And I brought with me -- this is a handbook that is in all of our operations. And there's 26 standard operating procedures here. We put these together with the advice and counsel of an advisory committee, which we believe are perhaps representative of the leading meat scientists, the leading animal care individuals, and certainly individuals that can provide us guidance in the area of

food safety.

Again, we're cattle producers, but we're trying to be very innovative and we're trying to be on the cutting edge in each of these areas to provide a verified system. And that may be something that is scary to some, but we're very committed to it and have some experience with some programs dealing with age and source verification, we've been involved in cattle that go to Europe, we've been involved in cattle that go to Asia.

All of these have got to have verified documentation and supporting materials behind them. And this program, Progressive Beef, is no exception to that.

So, what it adds, we believe it adds confidence to the supply chain that we're involved in, because we are very involved from the cow-calf level through the feeding and growing phase and finishing phase and all the way up to the harvesting of the animal.

So, we feel like we have a very

important responsibility, but we also feel there's a very important opportunity there, too, to help our colleagues, like Dean, in major packing processing operations, do a better job addressing these very critical issues.

Let's go to the next slide. I will mention that this program, one of the questions was, what are the most important issues in the program relative to food safety?

And in our feed mills, for example, we've got acid-based system in each one of our feed mills that goes through the feedstuff as they arrive, the management of those feedstuffs, how they're actually delivered to the cow.

So, it's a very thorough process based on standard operating -- or supported by standard operating procedures, but it's a HACCP-based concept.

We put a lot of emphasis on education and training. That hasn't really

been mentioned here this morning. And I think as we look at these interventions, all of us, myself included, we cannot -- we cannot underestimate the need for education as we look for individuals, our employees, for example, here on the left-hand slide here, that are involved in day-to-day operations and interactions with the animals, because they're very key and they can be very helpful in mitigating issues like food safety.

But this program, I mentioned the food safety -- excuse me, the HACCP-based system in the feed mill. And as has been mentioned here today, we are also working with this E. coli vaccine and seeing very positive results and are excited about it.

As we look at this HACCP-based program, we've always been challenged by how do we move the needle?

Dean brought it up here, and so did Dr. Loneragan, about benchmarking performance from where we were to where we want to be, and

can we move the needle? Can we show an efficacious difference?

And we believe these interventions like this vaccine is going to give us the chance to really do that so that this system, this program, is not based on warm and fuzzy just because it's the right thing to do, but, in fact, we've got data that shows that we're able to, as I say, move the needle.

Last slide, please. We were asked to sort of make some comments on what we think are challenges. I kind of turned -- or, excuse me, the wording was what do you think are the strengths and weaknesses?

And with my marketing hat on, I sort of changed those words around and I used the words opportunities and challenges.

So, I think as a strength of where we need to be, we really have to maintain that consumer confidence. And we, as an industry, we, as a value chain, as a supply chain from beginning to end, have a responsibility there

and I think that's an opportunity.

I look at this, our commitment to this program that I shared with you, it's really going to hopefully ensure the opportunity for us to stay in business.

We've got to be sustainable. And with these types of challenges coming out as we believe that this is one token of assurance that we can do that we will be here tomorrow, we will be here five years from now, and we can continue to be a valued supplier to an organization like Tyson.

There is the element of doing my part. And I know cattlemen are sort of known for this. Sort of like motherhood and apple pie, right? We want to do the right thing, and certainly we do. But at the end of the day, it's got to be economical, as Tracy said.

It has to be something that we can do and it doesn't drive us out of business from an economic standpoint.

Perhaps some of the challenges, who

pays for it? And I think one of my colleagues mentioned that everything is sort of filtered downhill to the producer, right?

I don't necessarily absolutely accept that philosophy. I think if we work together as a value chain from the cow-calf all the way to the meat case, there's an opportunity for shared responsibility and shared cost savings, and opportunity to maintain our place in the protein marketplace and perhaps even grow.

Compliance and verification, I think that maybe is a little bit of a challenge we need to consider. These technologies if we're going to use them, then we've got to be able to validate, in fact, we are using them, that they are in place.

And I think some of them, for example, are very easy to validate. Some are not so easy. I think that's a challenge.

And then implementation, I think Dr. Loneragan did a really good job about

explaining the rule of adaptation. That's key.

We can stand here and think about it. And unless somebody gets out there and starts using these technologies and figures out a way that we can see the importance of it from beginning to end, it's going to be an ongoing challenge. It's almost like a chicken-or-the-egg scenario.

So, those are my comments. Again, thank you, Dr. Hagen, for letting me be here today. Appreciate it.

(Applause.)

DR. TORRENCE: Thank you. Those were incredibly insightful perspectives from our industry panelists.

We'll take some questions.

DR. BRASHEARS: Hi. I'm Mindy Brashears from Texas Tech University, and I just want to make, really, a point of clarification, I guess, to Dean's comments about the efficacy of interventions.

And when we publish the reduction of pathogens in our using of pre-harvest or any intervention, we obviously publish the confirmed positives. And I just want to clarify in your presentation, you were looking at reductions of presumptive positives.

And so, if, as a scientist, maybe it would be --

DR. DANILSON: I think those were -- they were eae/stx-positive on the --

DR. BRASHEARS: Right, right, but were they confirmed to be 0157 --

DR. DANILSON: They were - well, eae and stx. And we get a 90 percent confirmation rate on those.

DR. BRASHEARS: Right. So, when we publish these data, we have to confirm that there are 0157 both genotypically and through our serological testing and those things.

So, anyway, if we look only at presumptives in the eae/stx, we would have a much greater than 50 percent reduction. So,

we don't publish that, because in a peer review journal they're not going to allow us to do that.

So, I just want to make that clarification that if we went back and published the efficacy of the interventions, it would be closer to probably 70 to 80 percent of a reduction based on the presumptives.

So, I just wanted to make that point. Thank you.

DR. DANILSON: Okay. Thank you.

DR. COURSEY: Other questions?

DR. TORRENCE: We've heard a lot of discussion and we've heard mention of the last ten years in pre-harvest interventions and what people are doing. So, where do we go from here?

Do we review the last ten years, or do we take -- make strategic decisions on research or measuring outcomes or looking at specific barriers?

Or do we write up the transcript of this meeting and then have another piece in the literature 11 years from now?

Any thoughts?

MR. McCULLOUGH: Brenden McCullough, National Beef.

One of the things that was said by Guy and, Dean, you touched on it, was the approvals to use some of the technology that might be beneficial to us.

Does anybody on the panel have any following comments about what the Agency can do to help promote and move forward on some of these technologies?

UNDER SECRETARY HAGEN: I think in one of your slides you mentioned FSIS/FDA pending approval, and I'm not aware that FSIS holds approval authority for any of the technologies that we're talking about.

And, in fact, one of the -- something that we hope will be the focus of our meeting today is the discussion around

vaccine approvals, because it's tricky.

We've got FDA's Center for Veterinary Medicine that handles most of what goes into and allowed to go into live animals. And then we have the Center for Veterinary Biologics at APHIS that actually has vaccine approval, but APHIS is inherently an animal health-oriented entity and not food safety.

So, for a long time there's been this issue about when you're looking at vaccine efficacy, we're not looking at a vaccine that makes animals more healthy, we're looking at a vaccine that's supposed to prevent human illness. And so, there has been some debate about what an appropriate efficacy rate is.

I just -- I wanted to point out that I don't believe there's anything awaiting FSIS approval at this point.

DR. DANILSON: Thank you, Dr. Hagen.

You're probably right. Nothing is waiting immediately on the table. That was a

broader reference to past history and other issues, and not just the vaccines. Like, you know, there was labeling issues. Carcass irradiation is an intervention that we haven't been able to get to the point of becoming an application.

The bacteriophage that we use, that was a joint effort of FDA-FSIS back in that era many years ago where we got the 7120 -- first, it was GRAS. Then you had to go 7120, applied usages. And then you get what ties into the labeling.

But the company now has if we ask to go back further into the feedlot area, into the transport area or spraying those cattle and working on an environmental system, they can't do that because they don't have the label.

It was more of a general comment dealing with, I mean, we work through these things and these guys work through them, you deal with the EPA, you deal with the FDA. We

bring them in and we have the FSIS issues and it's very difficult at times, and frustrating at times.

DR. TORRENCE: We have a question in the back.

MALE PARTICIPANT: Yes, thank you.

Boy, you just struck, really, a chord of fear that just rippled through my entire body when you said are we going to be no further along in ten years than we are now, than we were ten years ago?

And I think it's become very, very apparent that over the past ten years, I really have to applaud the processing industry for a lot of terrific innovation.

And that was really put on them because it was something that suddenly we -- that was being more, I guess, transparency, for lack of a better term, of just being able to identify. And we were looking for, testing for, and identifying pathogens to the food supply and had practices in place where if the

product had been diverted.

So, there was an incentive to do that, to do those things, to put in place interventions that require -- affect the safety of the processed product. And I encourage us to keep moving forward with additional technologies.

That said, however, you heard it loudly and clearly, and have been hearing it loudly and clearly, that something has to be done to manage the incoming microbial loads on the live animals.

And one of the things that we have seen is that there has to be some sort of a reason for animal producers to decrease those microbial loads.

And what we've got here is a vicious circle that we heard in the first presentation that you will not have technology innovations, unless there's a reason for them.

We've seen that in testing methodologies for 0157. We're going to see

tremendous growth in innovation technologies for non-0157 STECs now that they've been declared adulterant.

So, we really need to have some sort of -- and this is maybe where FSIS can help move this process along, and that is to do some microbial testing on incoming animals, that animals found positive have to be diverted.

So, there are some creative ways here that we can start challenging the producers to come up with these better technologies and better ways of getting the animals cleaner for slaughter.

But I sure as heck hope we're not here ten years down the line and say we're no further along in these technologies than we were, just because we haven't done anything to incentivize -- I didn't say that correctly -- the industry to producers to move forward.

DR. TORRENCE: Thank you. Any comments on that? Go ahead, Guy.

DR. LONERAGAN: Thanks.

Do you mind if we just go back for a brief moment to answer the question that you raised and if I can expand on that discussion?

I did want to talk about the licensing of these vaccines. It's an important question and I don't know if the efficacy is enough.

It's a very, very hard question. But I think there's an opportunity, because I don't necessarily believe that that should be a holdup.

I think the agency or the regulatory body could actually let the others envision. So that we can agree with the regulatory agency on study design and show significant efficacy. Now, let's not worry about how much efficacy we need for approval. Let's put it out there and let the industry worry about that.

DR. TORRENCE: I think I'm going to have to move us along. Any other final

comments?

MR. BUTLER: I have one.

DR. TORRENCE: Sure.

MR. BUTLER: As a producer, I would use caution in commenting about segregating cattle. I can't manage something I can't measure. So, don't expect me to.

This pathogen is a wiggly worm, you know. And I think as producers, we will do everything we can with the technologies and the interventions that are available.

I promise you that's what we're here to do is to produce a safe and wholesome food supply for our consumer.

But if you start thinking that we can - when cattle arrive at our packing plant and you're going to segregate them and maybe penalize me on something I can't measure, I think we need to really think about that long and hard and really look harder at these interventions that are available and what are the best management practices, if they are,

that we can put in place and the standards that we can put in place to do the very best job that we can, right?

And allow Dean and his crew to if we reduce that - he said if we reduce it by 50 percent, which I think is in the realm of possibility, right? I'm not a scientist. I'm a cattleman, but I think that's in the realm of possibility. Then, his interventions will work a hundred percent of the time.

And our objective is zero tolerance, right? It is. Believe me, it is. So, I just wanted to make a statement there, because I'm a little concerned about the innuendo there.

DR. TORRENCE: Great. And I think we'll have a lot more discussion after that.

Thank you again to the panel and, please, let's thank everyone for their presentations.

(Applause.)

DR. GOLDMAN: Great. Again, thank

you to the panel.

We're going to move now to the table discussions. And before we start, I'd like to invite anyone who is registered for a meeting, non-USDA staff, to come to the table where you can participate in these discussions.

I see several meeting registrants who are sitting on the outside. So, you're welcome to come to the tables where there's an empty seat.

So, right now we're going to focus on the first question. And I'm not going to read all this. I'll just read the first question, and then we'll tell you a bit about the guidance questions. Let me give you a minute to find your seat.

Okay. If I could have your attention while you're finding your seat, what we'd like each table to do over the next 35 to 40 minutes or so is to take the first question, which is what factors influence the

shedding of salmonella and E. coli 0157 and other Shiga toxin-producing E. coli?

For each of the questions, and for this one as well, you will see six additional questions which should serve to guide the discussion.

We're not asking each table to actually answer these questions, but rather use these questions to guide the discussion maybe to help you focus on one aspect or the other in the questions themselves.

And then at the end, we will have several of the tables report out. We're not going to invite every table to report out, because there are too many tables and it would take too long.

We're going to invite several of the tables to report out on their key findings so that your note taker or your scribe and your reporter should highlight two or three of the key findings on your discussion for the report which will occur in about 40 minutes.

So, any questions about the process? Jerry?

DR. COURSEY: Folks, could I have your attention, please? Real quickly, let me suggest if you have conversations you want to take out of the room, you can go in the back of the room and they are right next door.

We want to get the table groups going. So, you're going to be working for about 40 minutes right now on Question Number 1. And we're going to have a report-out in about 20 minutes from the first three tables.

We will get to all the tables eventually. It's important in your table group, to have your recommendations, questions, concerns on the flip chart, because that's for the record. So, for all ten tables, please do that.

All right. If you have questions for us, please raise your hand and we'll get to you and try to answer your questions.

I also suggest if you haven't done

this already, that you introduce yourselves to each other at the table. We have some new members. You might not know everybody.

So, take about five minutes just to go around and introduce yourselves, where you're from, et cetera, who you are.

We'll give you a five-minute warning before we're going to do report-outs, and you can get your material. Okay. Please let us know if you have any questions. Thanks.

(Whereupon, the proceedings went off the record at 11:11 a.m. for a table discussion, and went back on the record at 11:49 a.m.)

DR. COURSEY: All right. Thank you. Okay. The process here, let me just go through the process again, folks. We've got ten table groups here, and we can't do ten report-outs on each issue.

I do want you to mark on your flip charts, I see you already have, what table you

are and what question it is. So, that's for the record.

So, for this first issue we're going to go with Tables 1, 2 and 3, all right? We'll have the records, have the flip charts with the other seven tables.

So, let's go with Table 1.

MS. GREEN: Hi. My name is Teresa Green. I'm from the National Consumers League.

And we actually ended up with a table of - without any industry or science experts on it. So, we kind of had a discussion about these questions and realized that we were here to kind of learn the answers from the rest of you all, but let me share with you kind of what we talked about.

We were really curious as to what studies had been done to identify shedders, what are the methods of identifying what qualifies as a high shedder.

We talked about the idea that risk

assessment models could really help define impact of high shedders and also how you can define them.

We talked about some potential barriers for managing high shedders in turnaround time. So, the diagnostic test can actually be a barrier as far as adoption goes.

And then as far as the level of shedding, again we thought that quantitative modeling assuming current processing and interventions could be helpful.

So, that's sort of what we talked about.

DR. COURSEY: Okay. Thank you.

Any quick questions for Table 1 here for clarification?

(No response.)

DR. COURSEY: All right. Table 2.

DR. SCOTT: Okay. Thank you. I am Morgan Scott, Kansas State University. I guess everybody is -

DR. COURSEY: Yes, why don't you

move down a little. And thank you.

DR. SCOTT: Okay. So, we had a few scientists that work heavily in this area. And so, we relied heavily on particularly Mindy Brashears to help us identify gaps and barriers.

And because the discussion is on both salmonella and E. coli 0157:H7, it actually provided for some mini contrasts. And we know that there are some variations based on geography, climate, seasonality, studies on diet and other factors both with the regular diets and things that might be added to diets.

One of the contrasts that we noted early on was that there are distinct within North America geographical differences particularly for salmonella prevalence, but that we don't necessarily see it for E. coli 0157:H7. And those contrasts actually may provide some interesting opportunities for uncovering some of the differences that we

might see.

Certainly, we identified that seasonality appeared to be important, but maybe we haven't quite figured out what is it that seasonality has to do with levels of E. coli or salmonella.

One might think that temperature, humidity, moisture would be an obvious answer, but there has been some work, also, concerning vectors such as flies, or also birds, starlings and so on. And those seasonalities may vary as well as those pathogens.

So, the second area that we are interested in was the super or high shedder phenomenon. And there was some discussion amongst the group as to what is this?

One side believes that maybe it's a phenomenon by which some animals will never become high shedders. Most people in our group agreed that high shedders wasn't a lifelong phenomenon. That some animals shed at a high level for a certain period of time,

and then they might return to normal.

But if we look at a cross-section, maybe five percent of animals might be considered high shedders. Maybe in excess of 10 to the 4 bacteria per gram. And we're talking mostly E. coli 0157:H7 here. We didn't consider salmonella much.

Some others said that while some animals will never become shedders, maybe we'll have to look for the factors that make them so.

The more skeptical amongst us said, well, it's probably more of a probabilistic population factor and this may just be the tail of the distribution.

So, there was some controversy about the whole concept, but most agreed that if you could identify high shedders at the point that it mattered such as when they were going to go to slaughter, if you could have a rapid diagnostic test, you could apply it to all the animals, you could identify those high

levels that work from the group. And key statements suggested that the presence of a high shedder on a truck going to slaughter or in lairage actually influences the probability of higher carcass contamination. So, that would be a good thing to actually be able to utilize that information.

And as to the level of shedding that could overwhelm an establishment's intervention measures, we didn't have a number. But as was pointed out by one of the individuals at the table, some combination of reduction of load with reduction of prevalence on the farm totally does represent a tipping point in which the processing plants can actually deal with that level of shedding.

No clear answer on confinement versus free-range rearing. As Guy Loneragan pointed out, obviously the density of animals does impact the dynamics of the spread of the organism within that pen and within that environment. We don't deny that.

But as to whether at any point in time such as going to slaughter that influences the level of E. coli 0157, we weren't clear on that.

And the same thing applied to the class of cattle. Whether the cattle were cull dairy cattle or from pet beef or veal, we weren't convinced that that alone would tell you anything about the level of risk.

But certainly the site of the operation could affect it in the way that a single super shedder could affect the risk of slaughter from transportation going from farm, to farm, to farm to assemble a whole truckload in a small-farm dairy shed versus a single truck being filled by cull dairy cattle at a single dairy farm. A large operation could affect this whole dynamic.

Did I miss anything? So, that's what we got.

DR. COURSEY: Okay. Thanks very much. Again, any questions for Table 2 on

clarifications? Any questions?

(No response.)

DR. COURSEY: Okay. I turn to Table 3. We disbanded and got together with other groups, which is fine. So, let's go to Table 4.

DR. MOREIRA: Thank you. So, my name is Fred Moreira. And we have already been mentioned especially by that table over there.

I think that there's two points that we talked about especially when it relates to the super shedder or high shedders.

The folks here on this table are somewhat unconvinced that super shedders or identification of super shedders should be one of the aims of research.

We've got two reasons. First, that it is non-infection problem. It is a colonization problem. So, it's more whether it was in a spread or also due to the fact that again those super shedders, they can be

super shedders today, normal shedders the other day.

And there was concern as well if we can identify those few animals in a large group, what so we do with them? So, that was one of the concerns.

And, more or less, we agree on everything else that you said in terms of vectors, seasonality, geography, probably playing a role. You talk about change, but there is no interest at this point. So, it seems that there are plenty of gaps that have been - that have yet to be defined in terms of those factors that include shedding of E. coli.

MR. BUTLER: Okay. So, the only other thing that I would add is that we felt like perhaps a logical approach would be to look at this from a system versus sort of identifying a silver bullet. So, the live side all the way through the entire food chain, value chain, has got a responsibility.

DR. COURSEY: Okay. Anything else? Again, let's check and see. Any questions for Table 4?

(No response.)

DR. COURSEY: All right. Okay. Thanks for the first round of report-outs. We're going to take a lunch break now. Let me give you the time frame here.

Lunch is from 12:00 to 12:45. The box lunches are in the back room. And our staff back there will help you get your lunch. If you didn't buy a lunch back there, you can use the cafeteria, which is down this hall to the left.

We're going to get back together for a presentation at 12:45. So, please be back in your table seats at 12:45. Thank you.

(Whereupon, the proceedings went off the record at 11:58 a.m. for a lunch recess, and resumed at 12:47 p.m.)

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

12:47 p.m.

DR. GOLDMAN: I'd ask everybody to begin taking your seats. We're going to start in a couple of minutes.

All right. Good afternoon. We're going to start our afternoon session. I'd ask everyone to please take your seats.

I'm going to introduce Adela Ramos who will take over as the moderator for the afternoon and take us through the next two table discussions, as well as to introduce our next speaker from the CDC.

Dr. Adela Ramos is the Chief of Staff to the Under Secretary for Food Safety at the U.S. Department of Agriculture. And prior to coming to USDA in 2009, she worked for Senator Tom Harkin on the Senate Committee on Agriculture, Nutrition and Forestry where she covered food safety, agricultural research, animal and plant health, and biotechnology issues.

From 2004 to 2005, Dr. Ramos served on the Senate Ag Committee as a congressional science fellow sponsored by the American Society for Microbiology and the American Association for the Advancement of Science, or AAAS.

She has a Ph.D. in Microbiology from Cornell University, and a Bachelor of

Science in Biology from Duke University.

Adela.

DR. RAMOS: Thank you for the introduction. Welcome to the afternoon portion of our public meeting.

It sounds like the table discussions have been productive, and interesting as well.

Just a reminder if you have conversations, take them out to the back room over there. And then after Dr. Tauxe's talk, we're going to have two more questions. So, we'll break up into small groups.

And then I just wanted to point out that at 3:15, we have about an hour scheduled to discuss any remaining topics.

So, if you can think of things that come up in your table, discussions that you want to cover more extensively during that hour, please let me know and we'll share that with the larger group.

So, with that I'll introduce Dr.

Robert Tauxe.

Dr. Tauxe is the Deputy Director of the Division of Foodborne, Waterborne and Environmental Diseases at the CDC. The division monitors these infections in the United States, investigates outbreaks and develops strategies to reduce their burden.

Dr. Tauxe received his medical degree from Vanderbilt in 1980, and a Masters in Public Health from Yale. He is board certified in internal medicine, trained at CDC in the Epidemic Intelligence Service, and joined the CDC as a staff epidemiologist in 1985.

Dr. Tauxe's research includes epidemiology of bacterial enteric diseases, bacterial genetic exchange, resistance to anti-microbial agents and new applications of epidemiologic methods.

Dr. Tauxe.

(Applause.)

DR. TAUXE: Well, thank you very

much. It's a pleasure and an honor to be here today. Thank you, Dr. Ramos, and FSIS for the invitation to come here and join you.

I am an interloper. I'll be very clear. I have no agricultural expertise whatsoever. Training has been in human medicine, but I've been fascinated by this arena for many years and have learned some things from many of the assembled people in this room and others. And I have a great deal of respect for what we can do together.

I'm going to talk about some of these general issues from the perspective of public health. Foodborne disease continues to be an important problem - let's see. Will this set?

Okay. Foodborne disease is an important problem. The infections that come from contaminated foods cause a lot of illness.

We estimated very recently, published at the beginning of this year, that

one out of six Americans, that's 48 million people, get sick every year. 3,000 of them die from infections from food.

There are about a thousand outbreaks that are investigated every year and reported. Most of them by local and state health departments.

Salmonella alone has been estimated to cause $2.8 billion in healthcare-related costs. And preventing a single fatal case of E. coli 0157 infection, considering in addition to not dying of E. coli 0157, which is a substantial benefit in itself, would save an estimated $7 million.

CDC works with our state and local health partners to provide a vital link. Foodborne disease is a complicated arena with many, many issues and players. And we link the illness and people back to the foods that they eat and the food safety systems of the government regulatory agencies, and the food producers together.

The next slide, please. We do that providing this vital linking through a number of activities. And some of which we interact directly with the food industry, and others of which we're sort of operating in the background as far as you're considered.

We're monitoring human illness, tracing the occurrence of foodborne diseases, detecting and investigating outbreaks, but also defining what is the public health burden, how many cases, how many hospitalizations, how many deaths.

Attributing illness to specific foods or specific settings, empowering us are partners in state and local health department who do their job better at targeting prevention measures to meet food safety goals, and informing food safety action and policy with our information.

Just to take a look at that burden question, how much illness do we think is out there, in the estimates that we just published

earlier this year, here I've pulled out, say, for salmonella, what we think the actual burden of illness related to the foods that are eaten in the United States, is just over a million illnesses and 380 deaths estimated.

And that is our estimate now, and we have set a national goal after much discussion amongst the different agencies involved, of reducing that by another 25 percent by 2020.

For Shiga toxin-producing E. coli 0157 or STEC, as we call it for short, 0157, 63,000 illnesses and 26 deaths estimated per year. Many more cases of kidney failure than that. Most of whom do well now and survive, and a prevention goal by 2020 of reducing that by a further 50 percent.

The non-0157 STEC, our estimate is they are more numerous at causing infections in humans than the 0157. But not all of them cause HUS with the same frequency, and there is not a national prevention goal that's been

set for that. But I wanted to put that one on the table.

There are, of course, other pathogens that are an issue for us. For example, there's the parasite cryptosporidium which is common in young calves. And veterinary students encounter it when they're learning how to deliver a pregnant cow and may get the infection themselves. And occasionally that cryptosporidium leaks into the food supply or the water supply.

Next slide, please. If we look at where outbreaks come from and the foods that cause outbreaks, there's one general way of judging which foods are particularly important. And here are just some data from 2008, for example.

And as we look through this, I have to keep reminding myself that many outbreaks go undetected, uninvestigated, unreported. So in some sense, this is sort of the tip of the iceberg, but this is what was reported to us

by state health departments for that year of '08.

There were 481 outbreaks where a specific food vehicle was determined. That food vehicle might be fruit salad, it might be a very complex food with many different foods in it.

218 of them could be assigned to a single food commodity group like leafy greens or beef. And out of that 218, there were 31 outbreaks with 952 cases attributed directly to beef food. An additional 17 to dairy food. And the beef alone is about 14 percent of the outbreaks for which we had a single commodity name.

We put beef and dairy together, and it was 22 percent of the outbreaks and 17 percent of the associated illnesses.

And just to see, well, all right, what were those 31 outbreaks that were attributed to a beef source? What pathogens caused them? 12 of them were shiga toxin-

producing E. coli. I believe all of those were 0157 in that year. Six were clostridium perfringens. Three were salmonella of several different types. Two norovirus. Eight multiple or unknown etiology.

And out of those 31 outbreaks, there were 101 hospitalizations reported to us. And all of those were outbreaks of either STEC or salmonella.

So, looking at this range of causes, the two that are the most concern to us that caused the most severe illness were the STEC and the salmonella.

Now, when we talk about prevention from farm-to-table, that brings us a host of partners. There are many points for contamination, of course. There are many different foods. It's got to be the most complicated part of our culture.

I think this has - makes Silicon Valley and infrastructure of technology look very simple in comparison. This is

complicated. How we get our food and how we put it together and how we consume it is pretty complicated stuff. And there are many points for contamination and control and prevention.

And at each step we have a partner. And I see a roomful of partners here in one particular phase. And out of the collective dialog come, of course, the industry efforts, the regulation, inspection and enforcement that we hope collectively make the system safe.

Next, please. Here I've just broken this out of that previous diagram into something a little more schematic, production processing, final preparation and cooking. And at each point whether, obviously, a whole industry or whole set of partners who have a number of aspects of the prevention under their control.

And I think for reasons that have been outlined and discussed very thoroughly

already, a great deal of emphasis has gone into the middle, the processing phase for meat and poultry now with a lot of progress in that and a lot of effort that has really improved the situation from where it was 20 years ago.

And some effort has gone into the retail, restaurant and home food preparation area with education, how to prevent cross-contamination, worker education, hand washing and so forth.

And as we've heard before, there have been some efforts at the production level. Although relative to the others, I think less systematic and less broadly applied.

Next. Those efforts have had very important results. And we've seen various versions of this curve already today. And this to me, is one of the great public health triumphs. And I want to salute the work of the beef industry particularly in getting us this far and with the regulatory agencies that

work with them.

As we track infections in people in a series of sites around the country that have been funded since 1996 through a collaborative effort of FSIS, FDA and CDC to track these infections, and as we model out even when we add and expand the system, we are able to consistently track this, that was the point of the system, a 44 percent decline in E. coli 0157 infections that actually does come down and meet and then drop below the target for 2010.

At the same time, I got to point out that that salmonella line does not look so good. And if we combine all the salmonella that humans are getting, we've had precisely no change since 1996. And maybe we should be glad it didn't go up. What is the counter-affect? What would have happened if all these things hadn't happened? It's a little hard to know, but clearly there's a lot more that we need to think about for salmonella.

And for 0157, it came down, it went back up again, and it sort of hit a minor peak there in 2006, which was the year of the spinach outbreak, and then it's come back down again.

It's clearly not a stable fix, boy, we'll-call-it-a-big-success-and-go-home situation. It's something that can still fluctuate and where we still have to be worried and where we'd like to make more progress.

The focused control efforts before slaughter, which are what we're talking about today, I think can prevent foodborne illness in sort of three general ways. And that sort of three arenas for it at least in the way I think about it, would be helpful.

The first, obviously, reducing the contamination of animals on the farm means they are less contaminated at slaughter. And I want to walk through a few examples that I've been following with great interest of

where this has actually been where that equation of application and of efficacy has been solved.

In the 1990s, Denmark greatly reduced salmonella in chicken flocks, in pig herds, egg and broiler. And did that with a combined program of very rigorous on-farm sanitation efforts and a program of testing and slaughter that was done in collaboration with the industry and with full remuneration of the producers who had to replace their flocks or herds.

And this meant on-farm testing or sampling of animals or eggs or whatever from most of the farms in a routine way, and this continues. It is an expensive and a rigorous program, and everyone participates.

The Dutch have something that I don't have as much data about, but they did a lot of work on how salmonella in pigs was spread and acquired and could be prevented, and came up with a diet of fermented foods.

The Dutch are very big on fermented foods like cheese and beer. And I don't think this was cheese or beer, but it was a fermented liquid mash that a number of Dutch pigs enjoy. And it's basically a probiotic mixture, I think, that is important in their salmonella program.

In the late 1990s, the United Kingdom had a terrific problem with salmonella enteritidis in their broiler flocks and in their egg-laying flocks. And they introduced a voluntary program that was strictly pre-harvest, of course, for eggs.

Egg layers and broiler breeder flocks had a focused effort on sanitation, of hygiene and vaccination.

This was an interesting program because it was entirely voluntary, and it was done - essentially led and driven by the industry itself who were very concerned about the fact that with the European union eggs cross borders very freely. And there were a

lot of Spanish eggs that were being exported from Spain coming into England, and they were - it was an open market.

And they happened to have a real problem with salmonella in those eggs and a number of outbreaks happened.

And the British poultry and egg industries came up with a concept of - a marketing concept called the British Lion. And each of the eggs that was produced under this program, was stamped with a little red lion.

And the marketing concept was the consumer could look for the British Lion as a symbol of safety, not to mention it was a local product.

And so without interfering with international trade law or anything, they had a very successful program. And even though the British Lion cost a little bit more than the Spanish - I don't know what the animal would be. The Spanish egg. It appeared very

popular.

Next. And here's a graph of salmonella in the United Kingdom starting back in 1988. That bottom deeply-colored black is the salmonella enteritidis. And I put an arrow there where the intensive control program began, and included vaccination against both enteritidis and typhimurium strains.

And you can just see a really dramatic, and over the years, progressively more and more successful, I think, as it took more and more of the market. And salmonella as a human public health problem is just a ghost of its former self in the United Kingdom.

They are very worried about Campylobacter and other issues and E. coli 0157, but salmonella has had a very dramatic success in the UK.

All right. Here's a really odd one. You're going to say, Iceland? Well, what's with Iceland?

Iceland where raising chickens is an indoor sport -

(Laughter.)

DR. TAUXE: They all used to be frozen chicken and they began marketing fresh, that has never been frozen, poultry only in the late 1990s. At which point, campylobacter shot through the roof because freezing actually is somewhat lethal to Campylobacter. If you freeze the chicken, you knock it down by several logs, usually.

And so, suddenly fresh poultry on the market, a very popular premium product as far as the Icelanders were concerned, but Campylobacter suddenly was a huge problem.

And they had to do something about it. And they launched a really innovative intervention. There aren't that many chicken flocks in Iceland, but they tested every one about two weeks before slaughter.

And the program was they test all the flocks before slaughter. And if there's

no Campylobacter, that's great. You can sell the market fresh chicken from your farm, which is at a premium. You get a -- there's a price difference.

But if it's Campylobacter positive, then, sorry, it's got to go out, it's frozen and you don't make quite as much money. The producer doesn't make quite as much money.

Well, the incentive was all on the farmers, the producers, to figure out who was positive, who was negative. It was very clear whose chickens were Campy free, and they besieged each other asking, well, what are you doing? What are you doing?

And collectively they began to figure out there really were some things that could be done.

Consumer education also was part of the package to be sure to tell people to cook their chicken thoroughly and wash their hands, et cetera.

Well, there was a 70 percent drop

in the first year after this, and it's continued to drop since then. The program has been more and more refined.

It's been quite popular. They haven't quite been able to keep up with the demand for fresh chicken. Fresh chicken is still available and very popular, but they're down from where they were. 116 per hundred thousand down to 32 of which only a very small amount is domestically acquired.

So, they view this as an enormously effective thing. And, actually, Denmark is now bringing in this as a control strategy.

So, this is an example of where the economic incentives got all lined up and actually they've got the consumer paying for something that's a premium product in their eye that also happens to not have Campylobacter.

A little closer to home, just a little data out of - this is vaccination of broilers in commercial production in the

United States. A very interesting paper that was published last year by a group at University of Georgia, which is actually trying out observing, watching, two companies that have breeding and vaccinating the breeders against three different types of salmonella and comparing that with a really very comparable company that just wasn't doing vaccination and looking at what happened.

And this is interesting to me, because this is the breeder flocks. And what they're doing is following them all the way through the next generation of chickens. And then following them all the way through to the slaughter line and getting a dramatic difference in the positives for salmonella between the vaccination and the no-vaccination group. Breeder and ovaries 14 percent versus 53 percent. The chicks, 18 percent, 35 percent. The environments on the broiler farms, 14 percent versus 30 percent positive for salmonella. And the broiler carcasses,

that's sort of the end of the line now with the consumer will be exposed to 23 percent versus 33 percent.

Which is showing me that at least some of these strategies that have been very promising, that have been very effective in Europe, might be equally promising in the United States at least for chickens.

I'm not trying to say, well, if it works with chickens, then obviously it will work with cattle.

I am interested in that the model is working and that here are companies in the United States that are doing it now routinely.

Next, please. So, a second arena, I think, is reducing contamination of animals during transport or lairage also means less contamination at slaughtering.

There's been a good deal of discussion about this already and I don't think I'm bringing any new information to the table. But I'd like to mention at least a

couple of studies that are interesting and that suggest to me that we don't want to see progress at the farm undone by cross-contamination of animals before slaughter, but after they leave the farm.

Next. This is a study from some time ago in 2002. The United Kingdom. Avery published a paper where he looked at dairy animals coming into an abattoir, a slaughter place. And he swabbed 73 animals that came from 73 different consignments, 73 different farms, 73 different trucks.

I mean, that's their hides. He you looked at a lot of different animals from a lot of different sources. And 24 were positive for 0157. There was 33 percent of the cattle had 0157 on their hides. That's no surprise.

What was interesting to him was that most of the 0157 was exactly the same type. And even though these animals had come from all these different places, what they had

on their hide was something that they all shared. And the only thing that they shared, he concluded, was the one place they had in common, the abattoir lairage pen itself, where he could easily find that same strain.

So, he was concluding that 75 percent of the contamination on the backs of the cows had arrived there after they reached the lairage point.

Next. And Scott Hurd is in the room. And I'm delighted to quote his work which I found very interesting. Similar sets of observations in pigs in the United States some time ago. 600 pigs that came from herds that were sent for sanitary slaughter.

Take half the pigs and slaughter them on the farm and sample them, necropsy them. The five percent were positive for salmonella. It was just one type on that farm.

The other half were sent to the abattoir and then necropsy - well, slaughtered

and sampled in a parallel way and 40 percent of them were positive for salmonella with 17 different serotypes.

It's sort of the opposite - this is the opposite of the Avery thing. It wasn't that they all picked up one thing at the abattoir. It was that after they left the farm where they had only one thing, they picked up a whole zoo of salmonella by the time they were slaughtered.

And the conclusion was it was happening in the abattoir. And further studies of the pigs coming in to the abattoir, lairage pen showed that two hours exposure in the lairage pen was sufficient for the salmonella not just to enter the pig, but to reach the other end of the pig and even to get into the ileocecal nodes.

So, they're very fast-moving salmonella there. And it almost didn't matter what state the pig was in when it left the farm, how clean it was, if this is what their

fate is going to be of things.

The last point, and I want just to mention this because I think it's part of the story, although it's not the primary part from you all's point of view, is we can reduce the risk of spread of other food production areas that are in the neighborhood if we can reduce the load of E. coli 0157 at the production site.

Here are a couple of examples. Let's see. This one is a bit animated. 2006 outbreak of E. coli 0157, 36 cases in a couple of states traced to Taco Chain Y.

Not the usual Taco Chain A or Z, but Taco Chain Y. And they were getting their shredded lettuce, which was the source of the problem, from a California farm.

So, the farm was visited. Here's an aerial shot of the field where the shredded lettuce came from. And it happens to be right next to a couple of dairy operations which were linked and, in fact, linked to the

lettuce farm. They were all part of the same field.

And just at the intersection where the dairy and the lettuce fields were, was a really complicated set of piping.

You can click it one more time. Sampling in the fields found that there were ten samples with the outbreak strain of 0157 from both of the dairies and from the three fields, lettuce fields, that were nearby, including the one that was the source for the outbreak.

And this complicated set of piping - I think we got to click it one more time - was sort of at the hub between them all. And there were an awful lot of things you could turn there, and no one really had a clear description, SOP.

But if you turned the right one the wrong way and left it there, you could easily connect the manure lagoons and the irrigation system. Although, that was not the intent of

the piping. And it's apparent something like that may easily have happened.

Now, it would be great if the 1057 wasn't in the manure lagoon or if that piping wasn't there. And cross-connecting like that is obviously a problem as well. But it's an example of sort of a spread to adjacent areas, environments.

One more example of that. Also a produce problem, if you could advance. Baby spinach in 2006. This was big. Baby spinach, they came from farms, different farms, in California. Traced back to four farms. One of which had clearly an environment with the operating strain on it.

Near that farm a stream ran down. The stream sediments were positive. There was on the other side of the farm was a grape arbor. There was a vineyard. And there were wild pigs that traversed the spinach field having no interest in spinach, but being very interested in grapes. And then going back for

a drink of water at the stream, and going back and forth shortcutting through there leaving manure.

Several weeks after the outbreak, the manure was positive, the stream was positive, and the pig feces in the lettuce field were positive. And going upstream a half mile to the beef cattle, the beef farm where the beef had access to the stream, the beef had it as well.

And if you could click it again, one scenario is that somehow cattle to stream, downstream to pigs, to field, now that's a lot of jumps. And it just shows how 0157 can spread through the environment once it starts to.

Next, please. So, from my rather simple-minded point of view of what I've learned over a number of years, is that the contamination often starts on the farm even if the animals are healthy.

That I think looking at what

happens in Europe, what happens with other species, on-farm interventions can work and be highly successful and means less contamination as the animal leaves the farm, but the contamination can be introduced obviously from other animals between farm and slaughter.

Lowering contamination, I think, is the goal that we all have to keep Americans healthy and should reduce recalls, as well as disease and death.

And so, I look forward to the continued discussion. Foodborne diseases will continue to be a major public health policy in this country.

We expect new pathogens, new foods and new combinations, but the constants are going to be animal reservoirs, contamination of fresh produce and processed foods with multiple prevention strategies critically needed for farm-to-table.

And that reducing contamination is going to start at the farm, and can start at

the farm. And that farm-level strategy should add value to the final product. Thank you very much.

(Applause.)

DR. RAMOS: We have time for a few questions.

DR. HURD: Scott Hurd, Iowa State University. Thanks for the commercial.

We all have a model in our mind about connection between on-farm E. coli, carcass E. coli and human illness. And this is the attribution question. So, that's a very pointed question.

You showed a slide that said there was about 63,000 human cases of 0157. If we could eradicate 0157 on the farm tomorrow on the cattle farm, what would that number turn to? From 63,000 to what?

DR. TAUXE: It's a good question. And I'm going to waffle because I haven't got a final answer for that.

My back-of-the-envelope would be

between a third and a half. And I think that the on-farm reservoir is the single most important source in the country, but we don't have the final number we're ready to go out with on the whole attribution question for a variety of pathogens and foods.

We're working on that. We hope to have it submitted for publication very shortly.

DR. HURD: Thank you.

DR. COURSEY: Other questions?

DR. TAUXE: My goodness. Everybody must have had a really delicious lunch. Very satisfied. Well, thank you for your time.

(Applause.)

DR. RAMOS: Okay. So, with that, we will move to the second table discussion. And that will focus on effective and practical mitigations available to reduce the pathogen load in general, obviously with the specific focus on salmonella and STECs in cattle prior to slaughter.

I'd like to remind people that the subquestions below are suggested guidance. You can talk about any other aspect that you can think of, of this particular question.

And, again, if there's anything that comes up in your discussion that's not reflected in these subquestions or questions, please let me know and we can address those later on in the day.

So, you have 40 minutes for discussion, and then we will take 20 minutes to report out. So, we can go ahead and start. Thank you.

(Whereupon, the proceedings went off the record at 1:20 p.m. for table discussion, and went back on the record at 1:58 p.m.)

DR. COURSEY: Okay. Thank you. Go to Table 6, all right.

MR. ATKIN: All right. Richard Atkin, Whole Foods. I drew the short straw for Table 6.

In talking around the ideas of where we could measure for the effectiveness and how they decide if the intervention has been effective or not, we had a lot of conversation.

We tried to decide if it was better to try to have linkage between measuring effectiveness of the intervention at the trim results, or trying to strictly handle it from the standpoint of effectiveness.

So, where we ended up at was that we felt like it would be best to measure pathogens at the point closest to slaughter. But that, you know, we needed to make sure that we were using the common protocol, because there's so many different tests and sampling methodologies people are using whether it's fecal samples or hides or whatever.

So, all of those things need to be in agreement so that we're all looking at it the same way.

We also talked in terms of what we did possibly sequentially so that we could see where in the interventions that we're finding effectiveness by looking further back into the supply chain.

So, that's something that we considered that if we were to do any type of sequential testing, it would be very important for us to have the ability to direct any interventions with the live animal.

So, for instance, if we needed the ability to segregate animals and treat those animals, we would need to be able to have control over that, and a lot of the current marketing schemes that are out there don't allow for that.

On testing, what we talked in terms of was that E. coli is really important to look at it from a positive or negative standpoint and design all the other subsequent interventions into it based upon the assumption that you're going to have the

highest level all the time and just operating from that standpoint.

But with salmonella because it's just a different animal, you need to look at it both qualitatively, as well as quantitatively, because both of those numbers come into play with your intervention strategies.

DR. COURSEY: Okay. Thank you. Any questions for Table 6?

MALE PARTICIPANT: I guess I just wanted to challenge that in that half of the human illness isn't related directly to beef consumption. Testing there doesn't do anything to prevent all of the environmental contamination that goes on in the groundwater, the lettuce fields, so I am just challenging that.

DR. COURSEY: Okay. Thanks. Other questions, comments for Table 6?

(No response.)

DR. COURSEY: Okay. Thank you.

Table 3.

MR. McCULLOUGH: When Pat Mies comes in I want everybody to glare at him, he's supposed to talk?

(Laughter.)

MR. McCULLOUGH: All right. We started out on track pretty good. We got the first question asked, and then we went way off.

(Laughter.)

MR. McCULLOUGH: When should effectiveness be measured? We started out saying that it should be immediately prior to slaughter. And then very quickly came to the conclusion you can't do that.

There has to be time to do the test. There has to be time to do the assessment. There has to be time to block the cattle if you wanted to do something with them. So, we came to seven to 14 days before slaughter.

Then we really went off track and

started discussing whether you really pictured to do this or not. If this was an academic type of question or a real-life type of question, could it be done?

Jumped right back into the academic side of it. So, we decided if there's a law of the land that really did test, what would the issues be? And went through a number of them, right off the bat. You know, how do you track, how do you lock, what do you do with the test results once you get them? You can't separate out animals very well.

Some of the stuff we didn't write down because it wasn't very proactive. So, we left that out.

But it came down to the basic question that if you did test, if you were able to test, if the science was there, what would you do with the cattle when it was done? How would you treat them? How would you reduce the load incoming to you through the system? Could you use a probiotic to feed

them? Would you take them out longer on a feed? Would you spray them with a phage and be able to retest them?

What would that retesting be so you can be confident that you've got that reduction to the point you can bring them back in your system?

Once you show that they may be higher than others, what would be acceptable? What risk would you be willing to take as a company to bring those in? And how would USDA view that, if you did bring them in and there was a positive, how would you be held - what light would you be held at with USDA or down to legal issues if there's illness they go and back that.

So, lots and lots of questions about what do you do if you do tests. And also lots of questions about how you would actually do that testing.

If it came down to currently right now that list of three questions were we able

to do this stuff? The answer is no. But then the real case is what do you do with cattle once you test them? How do you manage that whole part of the process, and what's good and what's bad?

Is a log 5 on a 36 square centimeter sample and whether -- that's a log 5 where all of a sudden we're saying is that bad or is that good? Does a certain time of the year make a difference? So, there's lots and lots of questions.

The final question was is qualitative sufficient or should we consider semi-qualitative?

We came to agreement pretty quickly that we didn't know what semi-qualitative was. So, we just crossed that out. Don't know how to deal with it, don't know how to explain it. But we do need we need reactive, solid data. Both quantitative and qualitative and what you're looking at, how you're going to measure it and how you're going to react when you do

equal sets of data.

The quantitative by itself, we know based on these presentations, we're going to see a hundred percent positive rates out there and having to deal with that.

And then cost, there's a whole list of costs. We really can't even answer that question about how we're going to test, what system are we going to use, how we're going to sample, what the repercussions are, how that's going to be addressed through legal and regulatory and individual company risk assessments. And that's about it.

DR. COURSEY: All right. Thank you.

Okay. Questions, comments for Table 3? Any follow-ups?

(No response.)

DR. COURSEY: Okay. Let's go to Table Number 5.

DR. RENTER: I don't want it. I got the short straw. That's what happens when you leave the room.

So, on the first question, the main question in bold, we were pretty focused on that one, and then we sort of got off track, too.

We looked at that as - it says effective and practical mitigations that are available. We came back to what Dr. Loneragan spoke about this morning. He listed those fairly well. There's vaccines. There's phage. There's direct-fed microbials. Potential effectiveness on all of those interventions and available depending on where you're talking about in the production system.

When we got to some of the others in terms of good management practices like Guy talked about, things like feed, water management, pest management, those are, we felt, good management practices, good husbandry practices. But as was suggested earlier to show that those have mitigation, intervention opportunities hadn't really panned out, again, much as Guy suggested

earlier.

When it came to the effectiveness question, how should that be defined and measured prior to slaughter, we looked at that or discussed that in several ways. But relative to a pre-harvest intervention if I could summarize it simply that we thought if we want to see if the product or process works on the farm, then we should first measure it on a farm.

And then if we show that it works at the farm level, then begin to look downstream to say does that also translate post-lairage in the plant, those kind of things. But the first focus is at the farm level. Then we really got off track, but we did have a pretty good discussion of the quantitative and qualitative issues. We felt from a practical monitoring standpoint if an intervention is in place, you may be able to use qualitative that you may be able to use qualitative measures to sort of monitor the

system.

But ultimately we want to see if intervention is effective that we're talking about total pathogen load reduction. And so, both the qualitative and quantitative may come into play. We discussed the semi-quantitative issue and we didn't know what that was. Guy mentioned this morning one of our studies that we did this last summer. We used a semi-quantitative test for the high shedders. So, at the end of the day, that test tells us are they positive or negative. It doesn't tell us exactly how much they're shedding. But in order to be positive on that test, they have to be shedding at a fairly high level. And if we combine that with the prevalence data, it gives us a pretty good indication of what the pathogen load is. Again, that works well in a large-scale study. Quantitative would be best if it's practical, but sometimes we felt that it might not be very practical.

On cost effectiveness, last

question, we didn't get very far. We had more questions and answers. I think there's a lot of things that are yet to be determined there.

Any questions?

DR. COURSEY: There's a question here.

DR. VAQUER: Cost effectiveness, would be the first question of the day.

DR. RENTER: Oh, right. Right. Some of the cost effectiveness issues from a systems standpoint deals with lots of other issues that went outside this pre-harvest efficacy issue.

DR. KOOHMARAIE: What assay did you use in the semi-quantitative?

DR. RENTER: We just use a direct plating method in triplicate. And we've done a couple studies to show that when we get positive on that set of tests, that they're most likely shedding above ten to the four. And then we've done some other studies to show that that is associated with carcass

contamination pre-evisceration.

It's not a perfect test, but it's, I think, a pretty good indicator of sort of high shedders within a pen or a truckload.

DR. COURSEY: Okay. When asking questions, please wait for the microphone because it helps the transcriber hear the question and response.

So, anybody else? Yes, back there.

FEMALE PARTICIPANT: Did you talk at all about who should determine the cost effectiveness? Did you have any conversation about that? Because we did at our table, and we thought that that was more of an industry issue to define cost effectiveness. I was just wondering if you guys thought that.

DR. RENTER: Yes, I think we had a similar conversation. Who determines that? At first, we thought the question was focused on the practical implementation on farms. And so, cost effectiveness at the farm level.

But as you said, it translates to

throughout the industry, who bears the cost, who bears the benefit, lots of other issues that we're not sure how to address especially when we've got four minutes to -

(Laughter.)

DR. COURSEY: Okay. Any other questions?

DR. SCOTT: Morgan Scott at Kansas State. I think I'd just like to add our group's agreement on the devalue of the quantitative measures.

I think that if you look at the history of the diagnostic assays for 0157, you see a big shift a decade ago when they went from direct plating to the intermagnetic separation, which enhanced the detection. Well, that's a singular focus on finding the organism when it's present, which is when you classify Shiga toxin E. coli as an adulterant, that obviously is a compelling argument for that test.

But what it does is it moves you

away from understanding the pathogen load, which is really in terms of quantitative risk assessment or even understanding food safety risk from pre-harvest into the plant was actually the biggest issue. It's a pathogen load, which we're not covering very well by using these highly-sensitive assays.

And so, we argue for certainly for at least a semi-quantitative approach, because otherwise understanding logs, the mathematic of logs, log tens, we really need the reduction of those that are positive in a big way as opposed to just getting rid of those and have a faint number of bacteria. That's not going to have a big affect on the food safety aspect. So, we have to consider not just the regulatory component of adulterant/non-adulterant, but how many of these bacteria find their way into the food supply.

DR. COURSEY: Okay. Thank you. Any other comments? One more back here.

MALE PARTICIPANT: All right. Table 7 discovered that the FDA does have a teat dip model of approval of disinfectants. And in that teat dip model, all you have to do is show safety, not efficacy now. For the people who are using these disinfectants in the pre-harvest, they do it before the animals go into the slaughterhouse. Maybe it will approach the FDA or the teat dip industry and put that label claim on a teat dip or have your own label and prove safety and you have board approval.

People are complaining about how long it takes when you get things done. This is a quick one. So, I challenge everybody to think about that.

DR. COURSEY: All right. Thank you. Yes, another comment here.

DR. MOREIRA: Our group was very much in agreement with yours.

It seems that our group's understanding right now is that the regulatory

hurdle that you have to overcome in order to get some of those products approved is almost impossible to meet.

Essentially unless you have proven that you have a silver bullet, the product will not be approved.

So without that, that would be something that will help, and then leave the market to decide whether this is something that we want to use it or not based on economics and of course the aspect of human health.

DR. COURSEY: Thanks. Okay. I think we're going to wrap this one up, this report-out. Let me remind you, please, the scribes, if you could write on your flip charts your table number and this is Question Number 2 that we just finished with.

All right. Dr. Ramos, I think we're going to go off and do Question Number 3.

DR. RAMOS: Thank you, Jerry. So,

for Question 3, it focuses on how can we all work together to promote adoption of pre-harvest food safety mitigations.

Can you hear me?

(Off-record comments.)

DR. RAMOS: But I wanted to point out two people who are here who might be able to answer some questions you have about the approval process. We have Steve Vaughn from FDA who heads their Office of New Animal Drug Approval. He's right here up in the front. And we also have Byron Rippke from CVB. He is all the way in the back. So, for this question we asked what are the barriers to developing these mitigations. So, I think these are two very useful resources that we have here for you to ask questions, et cetera.

And the other thing about this particular question that no one's really addressed yet is the interaction between producers and the processors and what are processors, packers, requiring now of the

producers. Who's bearing that cost right now for the current intervention in place? Is this a sustainable model for the future where you have essentially the buyers of the product really enforcing what's going on, on the farm.

So, I just wanted to throw that out there for you to consider, but you obviously can talk about other questions as well. So, we have 40 minutes again to discuss at the groups. And then 20 minutes for report out. Thanks.

(Whereupon, the proceedings went off the record at 2:18 p.m. and resumed at 3:00 p.m.)

DR. COURSEY: All right. Okay. Group 7. Table 7.

DR. KRIEGER: So, with respect to the role of government involvement in these pre-harvest issues, we thought that research was really the most important and did find these types of mitigations and options in maintaining the transparency of how

efficacious they are. However, the end result of whether or not that efficacy is worth it should be up to the packers.

Additionally, we thought that streamlining a regulatory approval process and encouraging larger studies especially on pharmaceuticals where there's no conditional licensure for these types of products would help simulate innovation, as well as reducing the government focused on efficacy and focusing more on safety of these products because, like I said, the efficacy can be determined by the industry as a whole. And I think it was very important, regulatory inefficiencies impact innovation.

This morning we were talking about barriers. We thought that some of the government folks were confusing consumers, especially the USDA's promotion of organic, national and global products, while at the same time trying to encourage the increased use of pharmaceuticals and vaccines, et

cetera. So, I don't think that was a table consensus.

And then there was also the proposal that because of the reduced funding of government research in the budget, that instead we should take the money away from the organic promotions and instead direct those to producer awareness education of these types of mitigations.

DR. COURSEY: Okay. Thank you. Comments, questions from Group 7? Any clarifications?

(No response.)

DR. COURSEY: Okay. Thank you. How about Table 8?

MS. MASTERS: We tried to look through the barriers to adoption. And as we talk through the barriers, tried to look at how me might get past some of the barriers.

And we spoke about development and application in two separate ways. We first focused on the application and then went to

development. So in the application, we talked about at the producer level, what were some of the barriers to find some of the pre-harvest interventions. And talked about - we focused on vaccines initially and some of the concerns. And interventions that might have to be applied to individual animals.

Handling the animals, there certainly is stress when you have to handle these individual animals from an animal safety perspective, a human safety perspective. So, certainly focusing on those that could be applied to the feed and water would be better.

Cost, certainly, that could be done through incentives. The incentives could come either through promoting safer, paying more to the producer, that would come to the packer, government either through tax incentives or others.

Mandate, we talked about that as a mandate pulling through the system. That could be from other producers depending on how

the animals go through the process. It could come from the packer, it could come from the government, it could come from retail. And we also talked about producers seeing the benefit of the pre-harvest adding it to the existing EQA programs.

Then we talked about barriers and developments. We also talked about the approval process and streamlining the approval process. We talked about at least a perception on these conditional approvals that a lot of times it at least appears that once the conditional approval is given, that vaccine is available for free market, and that's certainly not the case.

We talked about the process that the drug companies are going through and field trials versus the challenge models and difficulty that is with one versus the other. We talked about - and that's collecting data in the process.

We talked about the need for more

tools in the toolbox. Particularly for different size producers. And that similar to the other group that once there's -- some of these tools being approved, we see that as likely more tools will follow. That perhaps others are sitting back waiting for some of these to be approved.

We talked about phage, for example, as approved at the slaughterhouse, but not at the feedyard. We talked about the research versus the application, that it might work in the research setting, but will it or won't it work in the commercial setting?

And all of our discussions, we come back to how we measure effectiveness. Would you measure it at the feedyard with pre-harvest setting? Or is it really the ultimate goal of measuring the reduction in human illness?

Questions?

(No response.)

MS. MASTERS: Thank you.

DR. COURSEY: Okay. No questions, clarifications? Yes, over here. All right. Thanks.

DR. RIPPKE: Hi. Byron Rippke with CVB. You talk about conditional licenses not being widely available when they're marketed. Can you explain that a little bit?

MS. MASTERS: Sorry, Byron. I think what we were trying to say is there's a perception, at least, that once a vaccine has gotten conditional approval, there's a perception that the vaccine is available for free marketing. And at least a perception by the individuals trying to use the vaccine, that it's not available to the free market. That there is a lot of barriers they still have to go though to use that vaccine. Conditional approval does not mean a free market access. And so, there is at least the perception that conditional approval equals approval, and that's just not the case to those having to use it.

Does that help? I mean, Brandt, do you want to talk a little bit?

DR. COURSEY: Let me remind you to please state your name for the transcriber.

MR. GIFFIN: Brandt Giffin, Pfizer Animal Health. Sorry, I just walked in. So, I may have missed some of the comment.

MS. MASTERS: It's a question on the conditional approval.

MR. GIFFIN: Yes. So, I mean, one of the things when we're talking to the customers that we work with, the question we get invariably, the conditional license must not work, we'll wait until it gets full licensing. We'll talk to you then.

So, there's a built-in stigma.

MS. MASTERS: Okay.

MR. GIFFIN: And it also goes with the additional confusion, I guess, and so forth in terms of all the, I guess, the paperwork that goes with it in terms of state vets, in terms of they're allowed to get in

and the different rules are then put on top of it and confusion they have with the distributors that are sending the product out.

And we've had some folks that try to buy it. And even there's confusion between the state vets and the people trying to get the product out. So, this has a lot of bureaucracy in the licensing.

DR. COURSEY: Other questions, comments?

MS. BOOREN: Okay. I'm Betsy Booren from American Meat Institute Foundation. I'm representing our group.

We agree with much of what's already been said. So, I think what I'm going to do is highlight some of the things that are a little bit different.

One of the things purely by accident, I swear, is that we have three individuals that actually fund safety research. And so, if you could keep that in some of the context.

Timely approvals are important. Again, as three agencies, we funded direct-fed microbials for ten years and not a lot has gotten approved. We need a faster, better, more streamlined approval process for those type of technologies, all technologies.

Coordination among agencies to streamline that aspect would be greatly beneficial and move the ball forward on research. Because I would say as a funding group, we funded money until we get a sense that they'll get approved. It's really hard when you have a small pot of money, to justify -- keep funding the same research when it's not going to get approved.

Again, we need to get a better understanding of consistency of efficiency across all production areas. In some of these food pre-harvest areas, how do those different production classes differ?

Again, increase funding for research dollars. Our table in the last three

sessions spent a lot of time of what don't we know? We don't know a lot. And how do we get those answers better? Unfortunately, it's going to require a lot of research, which requires a lot of money.

And those are not going to come from the standard ways that agriculture research has been funded for the last 30 years. We have to figure out a way of getting research funded.

There was a discussion about getting a lot of these pre-harvest technologies, giving it to animals right now, see how effective they are in creating some sort of pre-harvest baseline in animals so we have a measure to measure against to see if they're effective further down the process. Not sure how that would work.

We also had a huge discussion on data management. Sharing of data, protection of data. We have technologies right now that can put DNA fingerprints, essentially, on

microorganisms and we can track them.

There are legitimate concerns about who's liable if you cause illnesses that we should be afraid to do research and find positives.

That's one of those perceptions. Having to move this forward we shouldn't be afraid to find positive samples, but we also have to protect our data. And we have to share that data whether it's isolates or all sorts.

So, maybe there is a way of creating a data depository of some sort where we can share data without the threat of any other penalties, but just to move the research forward. So, that's a quick summary.

DR. COURSEY: Okay. Thank you. Any questions for Table 9? Any follow-up?

Yes, over here. The mic is coming.

MR. McCULLOUGH: Brenden McCullough, National Beef. I'm not going to ask you a question, but there's a topic on the data.

Over the years, I guess I can't say that the research that the packer side does is less than it used to be, but it sure hasn't grown over the years. And there's a real good reason for it, that is the fear of regulatory repercussions for having data.

USDA strongly believes that they shared their pleas with us numerous times that any data inside the plant that you generate is available to them for review. That's not a problem.

The problem is how that data is reviewed and how it could be used when you have an issue outside of an investigation or an FSA or an illness.

With that type of regulatory arm sitting there next to you, it's very hard to go out and do the research, the real investigative work, do the DNA fingerprint, do the tracking of plants.

Because once that data is available and USDA comes and asks do you have it, you

don't like lie to the USDA. You tell them you have it. And then they say, can I see it? And you go, do I have to show it to you? Yes, you do.

And there's a real tough position to be in wanting to be progressive and active and going after trying to find these niches and interventions, technology to try to improve the process with. But on the other hand, you still have the regulatory side that you have to deal with.

And when the question was what can USDA do to help promote, I got to tell you if that doesn't change, if the USDA doesn't come to an agreement that not all data is used to punish -- I don't know if punish is the right word, but used to enforce -- that might be a better word -- then there can be a good portion of industry not interested in putting data on paper.

And you talk about cost benefit. You all look at the risk and decide if it's

going to cause you a lot of pain and disaster down the road and financial implications that are tied to that.

So, I don't have an answer, but I do have a major concern. That's held us up in a lot of areas.

DR. COURSEY: Okay. Any questions here?

MS. BUCK: I'm Patricia Buck. I'm with the Center for Foodborne Illness Research and Prevention and I do agree with you. But on the other hand, I think we need to be moving forward with better data management.

And I have the National Academies of Science Report they did for FDA on the role it plays in enhancing food safety. There's a whole Chapter 11 devoted towards the idea of putting together a central data management center.

And if we do something like that, that might be one avenue where industry and government and even consumer groups can come

together and work on putting something that would help us better manage and utilize the data that we have. Thank you.

DR. COURSEY: All right. Thanks. Other responses? Yes.

DR. SIEMENS: I just want to put one thing that hasn't been talked about. Our group talked about the --

DR. COURSEY: Please state your name.

DR. SIEMENS: I'm sorry.

DR. COURSEY: Thanks.

DR. SIEMENS: Angie Siemens with Cargill.

We talked a little bit about the GIPSA rule and it's trying to make its way through Congress right now. And if it passes in its current form, forget adoption pre-harvest because we will not be able to pay for people who adopt have to pay the same for a cow and have good food safety practices versus those that don't.

So, if it goes through in the original format. So, I have a real concern as there's a difference of opinion as to whether it's going to get through the system or not.

And if you're not familiar with that legislation, they're trying to separate calves from the agro community. It does not work towards a cooperative effort towards food safety in the way it's put together.

So, if you have a chance to talk to your congressman or committees to take a look into it and see if they encounter everything we're trying to do here.

DR. COURSEY: All right. Thank you. Anyone else? Comments, questions?

(No response.)

DR. COURSEY: Okay. Let's go to Number 10, Table 10. Thanks.

DR. HAYES: Hi there. I'm Josh Hayes, FDA Center for Veterinary Medicine. And the following does not represent the opinion of the agency.

(Laughter.)

DR. HAYES: So, we're talking about producer promoted adoption. And one of the issues that came up again free market-wise that it seems that there is an undue barrier for food safety and preventions from USDA CVB just because it seems that a food safety vaccine seems to be subject to more scrutiny than a normal vaccine that treats animal disease.

And then another adoption issue for the industry foods approval of any intervention that is approved, is that it's a nonintegrated type of industry. And unlike poultry and swine production, that it would be probably fairly difficult to get compliance easily.

Some of the things that could be done for producers and processors having sale/supply agreements.

Also, get an influential buyer onto the program. Somebody like Wal-Mart,

McDonald's or so involved in the system. And probably the others then will carry on.

And also try to find somebody who's closer to the buyer. The idea being that you can somehow have the value of -- for the consumer shared by the producer or farmer. Because there are so many steps in the chain that it seems to be, really, the worst from the person who's actually using the product.

And, also, we were talking about how to balance value to the consumer while not competing with regard to food safety directly in saying my product is safer than your product. That would probably be an advertising no-no. So, but it could be done perhaps in a way of adding attributes to the brand.

We also talked about possible problems with a government mandated program versus a direct customer practice.

Also, something that could help adoption is by seeking approval to see that --

to see that when products that have a known safety record, that perhaps the efficacy requirements could be relaxed where it can get conditional approval.

However, conditional approval as mentioned by other people, can be viewed negatively by other people because it offers the question why is it conditionally approved and why isn't it fully approved.

And another comment. Just increasing the government alignment of different regulatory agencies a more consistent approach.

Any questions?

DR. COURSEY: Any questions, comments?

MR. CRAIN: Scott Crain, VeriPrime.

You had mentioned a supply chain agreement, and I believe you were saying between the producer and the packer.

And just for consideration, two things. I'm cattlemen. So, I'm feedyard

level. Every dime that comes through this system that pays for everything, comes from this.

And so, all I would suggest is that we would consider an agreement that goes from retailer, packer, to producer so we have widespread adoption. Thank you.

DR. COURSEY: Thank you. Anybody else?

MR. ROACH: Yes, I'm Steve Roach with Food Animal Concerns Trust.

I think one of your comments was that you shouldn't -- a producer or a marketer shouldn't say my product is better than yours, but that's -- the only way that you'll actually have the market work is if people are able to describe those profits being different and differentiating with the food safety thing.

So, we either need a market approach which requires people to be able to say my product is better than yours, or we

have to have the government mandate in some way. There has to be some way to incentivate a change in the system. And I think there also has to be a way of capturing costs of the changes.

So, if somebody is spending the money on farms to actually make the changes to protect the consumer, to say that they shouldn't go around and tell people that they're doing that, it makes it really hard for them to cover the costs.

So, I think that there either needs to be -- there has to be some mechanism incentivating change and I think the market is one tool. I think there's some externalities related to the problem you're talking about that aren't going to be captured by the market in any way, which requires, appropriately, probably some intervention.

But the other thing is if the market is to work, it has to be able to -- there has to be ways for producers to use

signals that say my steak is better than your steak because we use less faulty data.

DR. HAYES: And I think the comments came from a situation of like being the direct advertisement on the product itself.

It may be a brand issue with a particular product or a -- McDonald's will only buy chicken that does not -- is not produced with antibiotics, for example.

That's a different situation than saying no product with antibiotics on the product itself.

So, it could be kind of baked into the image or brand rather than getting a direct compositional marketing of saying we're better than one versus the other.

MR. ROACH: It would be easier to say our meat has no E. coli.

MR. HAYES: Good point.

DR. COURSEY: All right. Other comments? Yes, right here.

DR. HURD: I just have to say this -

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DR. COURSEY: Will you introduce yourself?

DR. HURD: Scott Hurd.

DR. COURSEY: Thank you.

DR. HURD: Iowa State University. And so, I don't work for the government anymore. So, I can say what I want.

(Laughter.)

DR. HURD: And so, I have to state what I think is a clear message. I came here thinking about incentives and do the analysis and do the data. What I heard Dean Danilson say and I heard Dan Schaeffer say is that if we have an intervention that works, we will use it.

What I heard is at least five examples of government getting in the way of those interventions. GIPSA, which will not allow the incentives to work. Chlorate has been hanging around for ten years waiting for FDA approval. Conditional license for the

vaccines that are currently available, the phage is being used under very restricted circumstances.

I think I heard Dan and Dean say if we didn't have such a strict label, they'd use it more.

So, there was one other example. A very important one, the use of data in the packing plants. They have a tremendous amount of research data. They use those data to make changes.

But if they're afraid to collect those data because there's going to be an unhappy visit from FSIS, that's a tremendous disincentive.

So, I vote that no one goes away in your thinking that it's the industry to take the next step. To me, the message is pretty clear that every government agency can go home and then take some steps.

We can say the ruling process is long and so forth and so on. But when I was

in D.C., we got the Downer Cow rule approved in three weeks, was it? When there's incentive, okay.

To me, there's been incentive here. We have things that work, there are people who want to use them, let's get them out there.

DR. COURSEY: Okay. Thank you. Other comments?

MR. CORBO: Tony Corbo, Food and Water Watch.

You're not going to have to worry about GIPSA after what USDA did to the rule.

FEMALE PARTICIPANT: Have you seen it? Because we haven't.

(Laughter.)

(Off-record comments.)

DR. COURSEY: Okay. Anyone else want to comment?

DR. McCLURE: Kent McClure with the Animal Health Institute.

I think one thing we forget about

all of these different interventions with different agencies involved in their evaluation.

Most of these agencies outside of FSIS aren't accustomed to looking at a product as one of several hurdles that are all leading to an end result.

They're accustomed to looking at them as standalone interventions. And not to fault them, because that's a lot of times the regulatory environment, but I think there's great merit in setting down with the folks that are in this room providing input to those regulators about what's good enough to have a meaningful impact before the product comes out to the grocery and to the marketplace.

And whatever level that is, I think having that consensus from a group like this that, yes, that's what we think would be meaningful, would be powerful information for them to have.

Because I think it's very hard for

them to decide where to set that target when they're not accustomed to looking at it as anything other than a single standalone intervention.

DR. SHULTZ: Craig Shultz, Pennsylvania Department of Agriculture.

Along those same lines, I think it's important to appreciate some of the examples we saw today, for example, the UK system with egg safety.

We have a similar system in Pennsylvania that has used the marketing carrot rather than then the enforcement stick. And the enforcement stick had a tendency to cause regulated entities to recoil, to withhold information, to not be forthcoming.

We've had a long term, 20 year success story with egg safety in Pennsylvania with our intake program. Now that we're going to a federal program, we've got some challenges. And we're having some issues because it's an important debate and having

issues with our producers being as forthcoming and wanting to participate and wanting to provide that information that we were able to get using the former system. I think that's worth consideration.

DR. COURSEY: Okay. Thank you. Anybody else? Comments?

Let me just check in with groups one through six quickly. If you have anything on your charts that no one else has brought up and could add it to the group? Look over your charts again and see if there are any key points that haven't been raised yet.

DR. SCOTT: Morgan Scott, Kansas State University.

What I wanted to say is not the opinion of everyone at this table, for obvious reasons.

One thing some of us feel is if you want to understand something, you don't turn it into a pariah.

So, the idea of classifying

pathogens, bacterial pathogens as adulterants, while probably well-intentioned in certain regards, creates problems in some ways that have been discussed already, but we're particularly thinking about on-farm and pre-harvest settings.

The danger is, if you really want to understand what's going on with these pathogens on the farm and you need to do things like quantify their loads and other things, is that you start to think things are either black and white or present or not, whether they should be there or shouldn't be there, you may stifle the knowledge required to actually, to really get at the end of the line problem.

So, for some of us, I guess, we're questioning such approaches and would like that to be considered.

DR. COURSEY: Okay. Thank you. Further comments, questions on that?

(No response.)

DR. COURSEY: Other tables? One through six? Other issues you want to raise? Yes.

MS. BUCK: This is Pat Buck from the Center for Foodborne Illness again.

I don't know if it's a comment more than anything else, and I think it's probably directed to FSIS.

I don't know all the regulations. FSIS historically has not been able to go up to the farm.

But I think they are allowed to look at the farm in the sense of what's coming to the plant and make some decisions about the pathogens that are coming in.

And I would challenge FSIS to become a little more creative in seeing how they can help us work on the on-farm pre-harvest intervention. Thank you.

DR. COURSEY: Okay. Any follow-up comments?

(No response.)

DR. COURSEY: All right. Anyone else in groups one through six? Other issues?

MR. ROACH: Actually, this is in response to Morgan Scott's comment. This is Steve Roach, Food Animal Concerns Trust.

There may be - there is probably a risk of making a pathogen virile, but I also think considering that making E. coli 0157 an adulterant in the meat is part of the reason that - that line going down means people that aren't sick or people who don't die.

So, I think there may be some challenges to the research. But I think - I really think maybe I'm wrong. Maybe that line would have gone down without 0157 being considered an adulterant, but I don't believe that is the case, that it would have gone down.

DR. COURSEY: Okay. Comments? Anything additional?

(No response.)

DR. COURSEY: All right. Dr. Ramos,

do you want to move on to the next session?

DR. RAMOS: Yes.

DR. COURSEY: Thank you.

DR. RAMOS: Okay. So, we have about 45 minutes or so to talk about anything that we haven't talked about. I think this last portion covered some of that.

But if there's something someone wants to bring up now, I can open up the floor or I can go into asking you what the next steps - we have a vision for what the next steps should be. But I think it would be very helpful and very beneficial to us at FSIS, as well as to you, to have a little bit more discussion of how we can not be here 17 years later having a pre-harvest meeting.

So, I guess the question is: what are the outcomes that would be most helpful to you, especially producers, for adoption? Is it more research? Is it demonstration projects? Is it a best practices guide, which is what we were thinking along the lines of in

our Federal Register notice? But I'll open the floor to you and see what you think.

MS. PARKER: So I'll open. Hi. Thanks for the question, Adela. Elizabeth Parker, National Cattlemen's Beef Association.

I think it's pretty simple. Listening to all the different conversations from all the questions today, what the government can do is we need some products approved. Especially the ones that we have efficacy, all the eggheads in here have done all the work.

It is hard work. These pathogens are not easy to understand. And we have data for efficacy, we need them improved and let the industry figure out how it works. And we will do that.

The other thing is the pathogens and the universe we live in isn't easy and we do need more research, and probably need to have more conversations on focused research.

I think you brought up funding

sources and all of that. And that's a conversation for another day. Probably varying sources. We need to communicate and collaborate so everybody knows the research is out there. We need to better identify the data gaps. And then each of us individually and collectively can focus our efforts to get further answers. And then, therefore, have better tools and more information.

That's easy. See? I'm done.

DR. RAMOS: You have all the answers. Great.

Anyone else have comments or questions?

DR. McCLURE: Kent McClure.

Adela, the paper that was in our packet, the U.S. Department of Agriculture Pre-Harvest Safety Act initiatives, does not have the attachment that appeared on the website that had 12 and a half pages of research projects, both competitive grants and formula grants to projects that were being

funded.

Who was assimilating that information? Is going to be FSIS? Who's going to channel this, because this seems to be lots of little pieces that could fit into a big, big puzzle.

DR. RAMOS: You mean all of the research projects and such? That came from the mission area REE, Research Extension Economics.

We've been, throughout this process, working with ARS and NIFA to get a better grasp of what work they're doing so that we can at least provide at some point input as to what's most useful or not.

I don't know if anyone brought - I don't know if Dr. Torrence is still here. I don't think she is.

But, yes, that's all being tracked by the research mission area.

DR. COURSEY: Other comments to Dr. Ramos' question?

MR. ROACH: Steve Roach, Food Animal Concerns Trust.

One of the questions I actually have is what criteria did the FSIS use in defining which pathogen or what pre-harvest areas are of concern? Because there's two other areas - or at least two other areas that I see that could have been addressed by this meeting.

But I actually feel like there was enough to talk about today and it seems to me that actually salmonella got a rather short shrift in the discussion as well.

But I think there are two, at least - I would think three other areas where we really need to think about in terms of pre-harvest controls which relate to cattle production.

The first one is campylobacter. Normally, we don't find a lot of campylobacter on meat, but there's pretty good evidence that at least it's an environment contaminant.

People do get sick rather frequently from exposure to campylobacter that comes from a cattle reservoir. So, I think that is something that at least going on in the future.

Another issue that wasn't really discussed, but has come up in a couple points in this, is antimicrobial resistance related to particularly salmonella, but also antimicrobial resistance.

And there are specific pre-harvest controls in terms of reduction in anti-microbial use that are probably more clear in their efficacy than some of the things we looked at for E. coli 0157 and just point out the importance of this of the 2008 outbreaks that were of a multi-drug-resistant salmonella Newport. They were actually resistant to cephalosporin, the treatment of choice for salmonella infections.

And the third area which I think we really need to start thinking about is, what

is the role of food in cattle, in particular in this case, in the spread of extraintestinal E. coli infections.

In the United States, there's 40,000 deaths a year, extraintestinal E. coli infection.

So, if just one percent of those is related to food, that means they eclipse, they're higher than all the other causes of food-borne illness deaths in the United States.

And there's growing evidence from numerous studies looking at mainly in Europe, but there's also U.S. studies, they're finding very good evidence, and as we get better tools in genotyping and being able to trace things, that at least a portion of the human E. coli infections are coming from food and food animals. I think that's something we really need to think about.

And, you know, we're looking at a piece of a problem. But I think the general

problem with E. coli is much broader.

In Europe, it seems that there's a certain type of resistance in E. coli extended spectrum beta-lactamases that seem to be associated with poultry.

But in the U.S., we're actually finding it more in cattle. So, CTX-M genes have been found in cattle in Washington state.

So, what I'm saying is when we talk about pre-harvest intervention, I really think there is a broader framework. And I realize that one day, and there's really not enough to address all of this, but I don't think these should fall off in ongoing and future discussions. We should look at antimicrobial resistance, extraintestinal E. coli infection and also campylobacters.

DR. RAMOS: Thanks. I think we can partially address that. We do want this to be a sustained conversation. And we are planning future meetings - well, we're not planning them right now. But after this discussion and

the next steps that we'll take, which is publishing the transcript of this meeting, any public comments we receive from you at this meeting and afterwards.

I should note that we, FSIS, is accepting public comment on this meeting until January 3rd of 2012, but we do plan on having a larger conversation or, I guess, longer conversation on pre-harvest food safety. But thank you for bringing up those points.

MS. DONLEY: Thank you. I'm Nancy Donley from STOP Foodborne Illness. Some of you may know us as Safe Tables Our Priority.

First of all, I want to thank FSIS for holding this meeting today and the representatives from FDA and CDC as well.

I think it's really, really good to have the producers engaged in conversation. I really look forward to the impact that the producer community can have on public health in the future not just before the animals are presented for harvest, but also we heard today

of just how the pathogens that are in the natural reservoirs on these animals may get into other food products via water routes and other contamination routes.

And I just want to say I think we have such a tremendous opportunity here to, like I said, to really impact public health. And I want to thank all of you in the producer community for really wanting to wrap your arms around the issue, to take ownership of the issue and continue the dialog and to really make progress forward.

And I look forward to folks coming forward in the future with new statistics saying that, listen, hey, we've now got the numbers down to this level, and this level, and this level.

DR. COURSEY: Quick comments? Yes.

MR. CUSTER: Carl Custer again.

I'd like just to emphasize again that we've been talking about connection between growers and packers, but growers also

have an impact upon the environment. We get the bugs out into the waterways to crops.

There's a recent paper here. Mindy and Guy were co-authors. And it says this is, potential for microbial contamination spans to the feedyard air and dust blowing in close proximity to cattle in feedyard operations.

There's got to be a typo in this, but it says after 24 -- 50 urine samples containing 12.96 logs less salmonella than zero a yard. It's got to be a typo.

Anyway, it spread. Generic E. coli, salmonella, 0157, were spread through air and dust.

They're also spread through flies, through rodents, birds. So, let's not forget the environmental contamination that pre-harvest or lack of pre-harvest controls across this.

DR. COURSEY: All right. Thank you. Other comments?

(No response.)

DR. COURSEY: Dr. Ramos, do you want to restate your question once more?

DR. RAMOS: Next steps. What should they be? We have an idea, but we want to hear from you.

What would encourage adoption? What would move us forward in this area?

DR. COURSEY: Anyone else?

DR. RAMOS: There's someone over here.

MR. McCULLOUGH: Brenden McCullough, National Beef.

I'm not sure I have an answer of what the next step should be, but I think I want to caution that based on what was shared today, we've known for some time now that there really is no good answer at this moment of what the intervention or process steps or best practice should be on the live side that gives a solid measurable impact.

We should not, USDA and the rest, have the mandates and the regs ask FSIS

whatever the most information is or have the requirement in the system at the packer require an intervention or processes on cows coming to us at this time.

When the data, when there is a system out there that does show there is a measurable impact, I guess that you're not going to have a mandate where everyone will jump on board anyway.

There are many, many parties that all believe they have -- that they are the ones that really feel the most pain. When there are issues, we're right there with them.

None of us want to see 0157 in our trim, we don't want to see it on the customer, we sure don't want to see anyone getting sick.

We have a moral and economic obligation to ensure that that doesn't happen.

The reason that we don't have requirements in place right now for the most part is we don't know what to do. And there was a USDA best practice out and I applaud

USDA's effort to try and release something out there.

It wasn't very helpful, but at least it was a step in the right direction. But we can't make HACCP rules, HACCP decisions, HACCP pricing based on something that is not solid.

MS. BUCK: Patricia Buck from the Center for Foodborne Illness. And in answer to your question as to what the next steps need to be, I think it's pretty clear that everybody needs some direction from the agencies, NIH, CDC and all the rest of them combined with you.

And I think some of those directions should lead us to greater research, but also targeted research on risk communication, as well as on the various environmental factors or the various pathogens.

And however you are going to put those efforts together, I think as you do

that, you will bring more and more of the right people together in the room so that they can discuss our best options.

Because we have a significant problem with foodborne illness not only in this country, but in the world. And it's time that we recognize that we have a limited amount of time to resolve some of these until they could eventually overpower us. And none of us want that to happen.

DR. COURSEY: Thank you. Let me check real quick before we go on. Anybody else who hasn't had a chance to make a statement or talk about next steps yet.

MR. CUSTER: Very quick. Just a retort about mandates. I'd like to paraphrase from James Madison, the Federalist Paper, Number 51. If all men were angels, there would be no government.

DR. COURSEY: Okay. Other comments, responses to Dr. Ramos' question?

MS. PARKER: Actually, I'm a little

shocked the government folks have this morass on a daily basis. Elizabeth Parker, NCBA.

Earlier I think it was after Guy's talk to us and questions and comments, there seemed to be a lot of folks that were not any farther ahead than ten years ago.

And I think that the presentations and the discussions today, that that's not the case at all.

So, for once I'm going to say something positive on a regulatory issue and on a difficult topic. We're a lot farther ahead than we were ten years ago.

Just the data that Guy presented and all the efforts that have gone on, the industry efforts and, Adela, as you know, we struggled with the concept of this public meeting.

But I kind of want to say, while the industry has done a lot of work, one thing we haven't done well is articulate all the successes and the information we do have and

what we've been doing the last 30 years.

And so, in the mid-90s APHIS had a meeting, I will say I was happily not cognizant of what went on in D.C. at that time. So, missed it. So, the industry needs to get more of our information out and articulate it to our government partners and our view on this is one of teamwork. We're all members of the team in food safety and we all have a role to play.

So, there is a positive here, Adela. So, we probably need to learn from those things and what's already out there before we start going too far down the path of what we need to do next.

DR. COURSEY: Okay. Thank you.

DR. RAMOS: I will wrap up very quickly, and then I will introduce Dr. Parham.

As I already mentioned before, public comments will be taken until January 3rd, 2012. We do plan on publishing the transcript, as well as the flip charts are

going to be on the record and we will assemble those.

The comments will be posted on our website. We hope to have a very transparent process moving forward. And we hope to have future meetings like these on pre-harvest food safety not necessarily just on cattle, but -

MR. McCULLOUGH: As you go forward next time you have a meeting, could you have it in a place a little easier to get to?

DR. RAMOS: Well, to address that comment, we don't have a lot of spaces like this in Washington. And in these times of budgetary constraints, we wanted to keep it in-house and APHIS offered this facility.

I know it's a little out of the way, but sometimes it's nice to get outside of the Beltway. But of course I'm inside the Beltway, so, but thank you for that comment.

(Laughter.)

DR. RAMOS: I'll just go ahead and introduce Dr. Parham.

Dr. Gregory Parham is the Administrator of USDA's Animal and Plant Health Inspection Service, APHIS, as you know. Dr. Parham became the APHIS administrator in April 2012, and the agency carries out the broad mission of protecting and promoting American agriculture, regulating genetically engineered organism, administering the Animal Welfare Act and carrying out wildlife damage management activity. So, they have a lot on their plate.

Previously, Dr. Parham served as APHIS' associate administrator until his appointment as administrator. In this role, he worked closely with program heads to provide leadership and direction in science while focusing special attention on international and trade activities.

Prior to his role as associate administrator, Dr. Parham spent two years as the Deputy Administrator for Marketing and Regulatory Programs Business Services. In

this capacity, he was responsible for providing resource management and administrative services to support the objectives of APHIS, AMS and GIPSA.

Dr. Parham joined APHIS in March 2006 as the Agency Chief Information Officer and provided leadership related to the Agency's Information Technology Initiatives.

Dr. Parham began his federal career in 1980 as an Epidemic Intelligence Service Officer with the Public Health Service at the CDC. He joined USDA in 1982 and has worked for several USDA agencies during his career, FSIS, the Extension Service, CSREES now known as NIFA, and the Office of the Chief Information Officer.

Dr. Parham holds a Master's degree from Johns Hopkins in administrative science, and a doctorate and Bachelor degrees from the Ohio State University in veterinary medicine and microbiology.

Dr. Parham is a University of

Maryland adjunct graduate faculty member and is a diplomate with the American College of Veterinary Preventive Medicine.

He is a native Ohioan, and he resides with is family in Mitchellville, Maryland. So, with that, please welcome Dr. Parham.

(Applause.)

DR. PARHAM: Wow. Thanks for that introduction.

I am so pleased that you have all come together here today and had such productive discussions.

Growing up in Ohio, my family had a small herd of registered Polled Herefords. And earlier in my career, I was also the national program leader for veterinary medicine and livestock production with CSREES.

So, I'm intimately familiar with the entire farm-to-table continuum. And speaking of table, my lunch today was a roast beef sandwich.

(Laughter.)

DR. PARHAM: I want to thank Under Secretary Hagen for her remarks this morning. And Drs. Goldman, Torrence and Ramos for moderating today's sessions. Thank you.

The pre-harvest food safety issue has challenged us all to work collectively and collaborative to address the issues raised and the concerns expressed.

And I would also like to thank all of you who are here today representing consumers, industry and academia, as well as my government colleagues who worked with us on this important meeting.

I know the perspectives and ideas gleaned from your discussions will prove invaluable as we take the next steps.

This meeting marks a major advance in our efforts to collaborate on issues involving pre-harvest food safety. Of course bringing people from all the agencies and interest groups together in one room and

listening to concerns and discussing potential solutions together face to face represents another crucial step forward.

Dr. Loneragan spoke about a meeting 17 years ago, a meeting that examined some of the same questions that we were asked today.

And at that time, the world population had not yet reached six billion. It reached seven billion last week, and will reach eight billion before another 17 years have passed.

So, just imagine the world's interlaced web of agricultural, medical and public health systems must now try to keep seven billion people fed and healthy, with more on the way.

Thank you. We're done.

(Laughter.)

DR. PARHAM: It is critically important that people not only have sufficient and economical food, food security, but that they also can trust that the food produced

from agricultural production practices is safe to eat. Food safety.

I am encouraged, however, that so many producers recognize the benefits of working with veterinary and medical experts to try to resolve pre-harvest pathogen issues.

The concept that links these together, the human, the animal, the environmental health, is often referred to as one health, and USDA certainly embraces the concept.

We strongly support the idea that finding solutions to complex health problems involving humans and animals requires an interdisciplinary approach. One Health planning plays a very vital role in the future vision for our veterinary services program activities.

I want to be clear, however, that APHIS does not seek to enact any new regulations pertaining to on-farm pre-harvest practices. Let me repeat. APHIS does not

seek to enact any new regulations pertaining to on-farm pre-harvest practices.

Instead, we are offering our extensive veterinary, technical and scientific resources within, of course, current financial restraints, to serve the industry and the public in helping to find simple, practical, and, I believe, implementable solutions as we heard this morning and best practices to reduce pre-harvest pathogen loads in cattle.

Veterinary Services has a long and successful history of working with industry to carry out our animal disease and animal health programs. Ever since the agency's inception in the early '70s, our veterinarians, scientists and technicians have been working to prevent the spread of zoonotic disease. And ones historically were tuberculosis and brucellosis.

We began collecting data in the 1990s to determine the prevalence of pathogens such as campylobacter, salmonella and E. coli

species. We are also working to determine the prevalence and antimicrobial resistance of emerging pathogens.

VS has the services, they have the tools, they have the laboratory networks, and they also have the interdisciplinary knowledge needed to effectively partner as a team with industry and academia and other government entities to develop strategies that effectively address pre-harvest pathogen issues.

Our Center for Veterinary Biologics is working as quickly as possible to evaluate pre-harvest pathogen vaccine technologies presented to them for review.

As with all vaccines, CVB must be able to determine that a product has a reasonable expectation of efficacy.

The challenge is determining how much of a reduction in pathogens actually demonstrates acceptable efficacy, and we heard some of that today. So, that is why I am

confident.

Our agency's scientists and veterinarians have an important role to play as we balance the impact equals efficacy times adoption equation both as part of the efficacy, and as part of the adoption variable.

For example, third party audits of compliance with voluntary standards for pre-harvest practices. Voluntary standards for pre-harvest practices based upon the Beef Quality Assurance Program are already becoming accepted and commonplace in industry.

With our VS field force, our offices nationwide and our network of accredited veterinarians, this is just one potential role for the lead that we can take to assist the industry and to assure consumers.

Finally, let the legacy of this day be that we lived up to the challenges before us so that 17 years hence when we or our sons

and daughters meet again in Riverdale, Maryland, and hopefully the access will be a little better then -

(Laughter.)

DR. PARHAM: -- to discuss the pre-harvest food safety, the sense of deja vu will have dissipated and will be supplanted by a spirit of cooperative and collaborative progress as exemplified here today.

Thank you again for your participation, and are we closing out now? Okay. Jerry, are there any other comments or questions we need to address?

DR. COURSEY: Just real quick. On the tables, again, the salmon-colored paper is for comments.

We also have evaluations that you can fill out. They're very quick to do. And that is all. You can drop the evaluations outside the door in the box there.

DR. PARHAM: And, again, thank you for your participation.

(Applause.)

(Whereupon, the above-entitled matter went off the record at 4:02 p.m.)