UNITED STATES DEPARTMENT OF AGRICULTURE

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SHIGA TOXIN-PRODUCING *E. coli*

ADDRESSING THE CHALLENGES,

MOVING FORWARD WITH SOLUTIONS

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FSIS:

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DR. MANDY CARR
DR. DEAN DANIELSON
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I-N-D-E-X

I-N-D-E-X

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

(8:39 a.m.)

MR. GOLDMAN: Please take your seats, we'll get started with Day 2, actually a half a day of our day and a half conference on Shiga Toxin-Producing *E. coli*.

I want to welcome everyone back, both those in the room and those on the phone. For those on the phone, we were aware throughout the day yesterday that there were some audio problems for those of you listening in. We were aware of those. We have made attempts to correct them as much as possible. So hopefully the audio quality for today's presentations will be better than it was yesterday, and we appreciate your patience and your participation as well.

Just to remind everyone, when you do come to the microphone, please speak loudly and clearly into the mic and let us know who you are and what agency or organization you represent so we can get it all properly transcribed. And speaking of transcript, I think we expect the transcript usually

take about two weeks to get posted. So you can look forward to that, and again your clarity into the microphones will assist in transcription.

Let me just orient you to today's agenda, and it will be slightly different than yesterday and then we'll have Mr. Almanza come up in just a minute and kind of give us a charge for Day 2.

The agenda today is just really split into two sessions. The first session will be from three scientists who will give their perspectives about perhaps what happened last year and what might be put in place this year to prevent a recurrence of last year from the pre-harvest and post-harvest perspectives, and then the last panel of the day will have five panelists come up here that we've assembled, and we'll ask them to react to a series of questions that I think everybody should have in your agenda, and then we'll invite the participants in the meeting, in the audience, to join in, give their own perspectives or ask questions of those panelists.

I think that covers our agenda for the day. I'll ask our Agency Administrator, Mr. Almanza, if he

would like to come forward and give us a few words about yesterday and what he'd like to see from today perhaps.

MR. ALMANZA: Well, good morning. I just want to start out with kind of reiterating what I talked about yesterday morning about we're going to explore options. I think that that's important, that we keep that in mind. We saw a lot of Agency data, covered a lot of Agency information and looked or heard some policy considerations. And also, I want everybody to remember that we're here for the same purpose, to reduce foodborne illnesses. I mean that's the key to what we're going to do here, what we're going to try to accomplish here.

The one thing that I do want to focus on is yesterday you heard from us, you heard from the Agency. You saw information that we have. Today we want to hear from you. We want to know what it is that you're thinking. I know there doesn't seem to be very many shy people here. So we need to continue that.

I also want to tell you that following this

meeting, there's going to be a 30-day comment period. Feel free to comment. We need all your comments, so that we do go down the right path to tackle this issue.

With that, I just want to continue the hard work and the open dialogue that we had yesterday. Thank you.

DR. GOLDMAN: Thank you very much, Al. If I could ask my first set of panelists to come up, we'll get started with this next panel. And I will let you know that we have a substitute. Dr. Dean Danielson will be presenting in place of Dr. Reagan.

All right. We'll hear from three of these researchers in order here.

Dr. Guy Loneragan is an Associate Professor in Epidemiology at West Texas A&M for the last six years. He has a Veterinary Degree from the University of Sydney, and a Master's and Ph.D. in Epidemiology from Colorado State University. His focus at the West Texas A&M in his research is on pre-harvest controls and ecology of *E. coli* O157:H7, *Salmonella* in cattle populations and the determinants

and controls of antibiotic resistance in enteric bacteria of cattle. So please welcome Dr. Loneragan.

(Applause.)

DR. LONERAGAN: Thank you very much for that kind introduction. Dr. Raymond, Dr. Hurd, it really is an honor to be here to present today. I can't tell you how much of an honor it really is, but it also is a challenge because what we're talking today about is an unusual bacterium, and the more we look at this, the more we find that things are certainly unique about this bacterium.

And what we're dealing with here is a pathogen of people but when we start talking about pre-harvest control of this organism, we're really talking about commensal of cattle rather than a pathogen of cattle. And, we're very used to dealing with pathogens in animals as a veterinarian, and so now we're trying to modify a commensal in a natural host of the organism which makes it certainly more challenging.

So what I'd like to talk about today is what potentially could have happened pre-harvest

during 2007 that may explain the increased occurrence of recalls and illnesses. I'd also like to talk then about what are the opportunities at pre-harvest to control this pathogen and then finally make a short summary.

So when we start thinking about what could have happened in 2007, what I've done on this slide is try to break up the industry into fairly broad areas. So here's pre-harvest, the harvest, distribution, the point at which it's consumed and then the consumers, and we can go through a series of exercises whereby we propose different hypotheses at different levels of organization. So we can go through the exercise of the consumer and propose a series of hypotheses, the validity of which doesn't really matter at this stage, but we're just proposing different scenarios of what might have happened, and we can go through this exercise at different levels of organization and what I'm going to talk about today is the pre-harvest levels of organization.

And so the first one is that there's a change in prevalence that may have been attributable

to some sort of macro, microclimatic conditions. There's been a lot of talk about the use of distillers grains, changes in certain subtype, decreased use of a lactic acid bacteria, as well as different methods of finishing cattle.

So in that regard, let me begin with the distillers grain discussion, and this certainly has received a lot of press. Not long ago, in December, there were a lot of press releases about a study from Kansas State whereby they found that in cattle that were fed distillers grains, they observed an increased prevalence of *E. coli* O157 versus cattle that weren't fed distillers grains, and there were some other data that supported these observations. Grant Dewell from Colorado State University also published relatively recently where they saw brewer's grain associated with increased prevalence.

And the summary of the results are presented in this graphic here where on an X axis I have prevalence of *E. coli* O157 and the diets. A controlled diet has 0 percent distillers grains and then these two diets have 25 percent distillers

grains, and these were statistically significant. And this was a -- finding. It was also an experimental study. It received a lot of press and a lot of interest. What these data are based on is actually this graph here. So this is broken out by week now. So it's the same data in the graph previously which was summarized but here's the data over time. And if you look more closely at this, you'll see that the 25 percent distillers grain, the ones with the square here, is actually all driven by this one data point.

So when we start looking at the data in detail, there might be something a little bit more confusing. So if we block out those weeks and just look at what it began with, they're all very similar and what the cattle ended with again is very similar. And you can see that the control, the 0 percent distillers grains sits right in between the two 25 percent, and I think if we had just seen this data, we would probably come to a very different conclusion.

But, regardless of that, distillers grains

and production of distillers grains is on the increase. So the purple dots represent plants in production. The yellow dots represent plants under construction. I come from the Texas Panhandle here, and these two dots that overlap, one is in production now and one is soon to be in production. So these are rapidly changing.

And what this has done to the price of corn, we've all heard about what's happening to the price of commodities. You'll see that basically last September, the price of corn went from $2 to $4 or more than $4 in January, and if we updated this now, it's approaching the $6 mark as of now. So certainly the demand for corn has increased.

And not surprisingly as we increase the production of ethanol, we also will increase production of distillers grains. So if there's an association, we're going to be producing a lot more distillers grains and the green bars represent estimates. This estimate might be a little bit high, but who knows. Certainly there's going to be a lot more distillers grains and that has to go somewhere.

And basically what we're seeing is where is the distillers grain going, and this table represents the percent of cattle operations that are currently using distillers grains, those that are not using but are considering, and those that are not using and not considering. And, if you'll look at this, you'll see that roughly one in three feedlots are already using distillers grains and another third is considering using it in the near future. So really this has a wide penetration. So this vast amount of distillers grains are going to be used in livestock feeds.

This may seem problematic if there really is an association but I think we have to be a little bit cautious about making that association. If you cast your mind back to a decade ago, there was a lot of press about how we can change the diet of cattle to reduce *E. coli* O157, and that was do we switch them from a starch-based diet or to a hay-based diet. And so we're led to believe at that stage, that high starch diets were the culprit. Since then, we've evaluated this and this is certainly not as clear cut as it was made out to be but if we think that high

starch diets were the culprit, well, then when we add distillers grains to it, we're actually replacing a lot of starch with digestible fiber, and so now we're actually making the opposite argument that maybe starch is a benefit relative to a fiber diet.

So I'm not quite sure we're ready yet to blame distillers grains for any change in *E. coli* O157. I believe it's somewhat premature. My personal thought is I believe that distillers grains has little or negligible effect on *E. coli* O157 and at the bottom of this slide, I have some data that were published out of Nebraska by Dave Smith and colleagues, in which they compared a diet with 10, 20, 30, 40 and 50 percent distillers grains compared to a control that didn't have any. They found that 10, 20 and 30 percent were less likely to shed it than the controls, and 40 and 50 percent were more likely to shed than the controls.

And again, I think what we're observing here is endemic instability in *E. coli* O157 shedding whereby we assign treatment effects to what is essentially an unstable shedding pattern.

And more recently from the same group of researchers that had the press release last November and December, that received a lot of press, that linked distillers grains to *E. coli* O157, they've since completed another study and have just as of Tuesday of this week released the fact that the latest study found no association between the use of distillers grains and *E. coli* O157.

So my thought is that while this was an interesting finding and worth following up, I don't think we're going to find that there are substantial effects of distillers grains on *E. coli* O157 shedding.

In terms of the climatic hypotheses that we talked about, certainly there is a strong seasonal driver of *E. coli* O157 shedding in cattle. So the warmer months we see a lot more shedding than we do in the cooler months.

So could there be a macroclimatic change that could have accounted for 2007. I certainly think there's some interest in looking at that, but there's also some evidence that condition of the pen

surface may influence shedding. And this again was published out of Nebraska by Dave Smith and his colleagues and this is more micro regional climatic changes. But they found that when the pen surface is overly dry and dusty or overly wet, then shedding tends to go up compared to an optimal pen surface. So this is more the normal for West Texas. This is a feed lot with a dusty environment, more extreme than normal, but certainly this is more what we're used to seeing, whereas this certainly is a catastrophic rain event when we have extremely muddy pens. And, so the hypothesis is that one of these may have occurred more often in 2007 relative to what we would expect to be an ideal pen surface.

So we can look at precipitation deviations to see if much happened, and we can see that for 2007, certainly most of the cattle on feed are in this region of the country and there's a lot of wet areas or extremely wet areas in the areas where cattle are fed. And we can do this by month. March was a very warm and wet month in the Texas Panhandle, but fairly normal elsewhere, but if we look at

different months, we see that this is actually drier. So I'm not quite sure how we're going to pull apart some of these macroclimatic events.

But, the hypotheses is that some macroclimatic change was associated with a) a change in prevalence in the cattle presented for harvest, and b) quite a logical conclusion, increased recalls during 2007.

It certainly is an interesting concept that warrants further investigation, and there is some very limited data that may support this. However, I believe it's very challenging to develop and implement testable hypotheses to evaluate whether this actually happened.

So certainly if we can, what can we change? So is this a controllable event that we can deal with, and the answer is likely not. And it also is challenging not just to test this hypothesis, but also the other putative etiologies that were proposed that may have happened in 2007, and may even be somewhat premature because right now we don't even know that prevalence in cattle in 2007 changed

relative to previous years.

We don't have a systematic mechanism by which we can sample cattle as they're presented for harvest to evaluate what is the prevalence or load of *E. coli* O157.

If we look at our research, where we've done quite few studies, we look at the average prevalence during the warmer months from 2001 to 2006, we see a typical range in harvest ready cattle of 10 to 25 percent. And this is just purely a prevalence in the fecal samples. We did a study in 2007, and the prevalence, at the time of harvest, was 7.3 percent but never exceeded 12 percent.

So this is just one single study. It doesn't prove anything, but we certainly didn't see any deviation from what we typically see. And in this feedlot, it was similar to 2006.

So certainly we don't have the evidence that actually prevalence increased at the moment. We just don't have a systematic monitoring system that is designed purposely to generate precise and accurate estimates of prevalence.

But it does highlight the need or the opportunity, if you will, that we have where we can purpose design a sampling scheme, prospective sampling scheme, so that we can estimate prevalence with a relatively precise and accurate method. And, certainly this purpose would not necessarily be micro to identify individual feedlots, but we could think about a macro purpose of the sampling scheme to identify changes in prevalence or times of the year when prevalence is particularly problematic.

So in that regard, I'd like to switch gears now and move away from the speculative aspect of what may or may not have happened in 2007, but talk about what are the options moving forward. So what are the pre-harvest controls that we can really think about?

And before I get into that, I'd like to just focus a little bit on epidemiology principles, and I'm an epidemiologist. I like to think about things in fairly basic terms. And what we're really measuring when we talk about *E. coli* O157 is prevalence. Oftentimes we talk about incidence, incidence in cattle, incidence on carcass or

incidence in ground beef, but really what we're talking about is prevalence.

And, prevalence is a proportion of a population or a proportion of samples with a given attribute at a particular time. And this is still applicable even if we talk about load. So if we're talking about colony-forming units per unit of measure, per gram, per surface area, whatever it is, prevalence is still applicable because we're really looking at a percentage of the population that sit above a certain characteristic.

And this is important because prevalence is a function of two important attributes. Prevalence is a function of incidence as well as duration of infection. And, I'm only bringing this up because that provides people two opportunities to change prevalence. They can either target the incidence of infection or they can target the duration of infection.

They don't have to do both, and if they can target one, then the outcome is going to be the same. So if we can reduce incidence or duration, we will

reduce prevalence by definition. So in the grand scheme of things, it's not important which one we target because the outcome will be the same in that we reduced the burden of *E. coli* O157 and hopefully we reduce it to an acceptable level.

And by acceptable level, it doesn't have to be zero, and by that I mean on this cartoon that I put together, we have cattle operations, each with its own characteristic. These could be feedlots, dairies, grass fed, organic, whatever it is. They all supply cattle to packing plants that have varying burdens of *E. coli* O157, and then these cattle are harvested and they go through a series of in-plant interventions and we have the at-risk product or the primary at-risk product, ground beef or trim for off-site grinding.

And, certainly we can overwhelm the system. It's not a fail-safe system. So theoretically the burden on incoming cattle, whatever the characteristic is, is so great we can overwhelm all these interventions and ultimately have *E. coli* O157 going out in ground beef or at-risk product.

So the purpose then is not necessarily to reduce it to its lowest level, but to keep the burden to an acceptable level.

So again, in my mind, the purpose of a pre-harvest intervention is not to eliminate the pathogen, because I don't think that's possible, but the purpose is to insure that the burden of *E. coli* O157 in cattle presented for harvest is within acceptable limits such that the in-plant HACCP interventions can effectively mitigate the burden on incoming cattle.

If we accept this as the purpose of what a pre-harvest intervention should be, then I think that helps us when we start evaluating pre-harvest interventions. And in this regard, it doesn't have to be 100 percent effective because it is an additional hurdle in a multi-hurdle system, and none of the hurdles have to be 100 percent effective. They just have to be somewhat effective to effect a change at the end.

So the desired efficacy of the intervention depends on two things. One is the burden on incoming

cattle and two is the pathogen-mitigation capacity of the plant. And by that, I've done another illustration to help understand that. The blue bars represent the burden on incoming cattle without the intervention. The red bars represent the burden with the intervention. The horizontal dotted line represents the plant capacity to deal with the burden.

And, you'll see that the first scenario -- I've got four scenarios here. The first scenario, the intervention has a 67 percent efficacy and reduces the burden from here to below that threshold. The second scenario is a 50 percent reduction. So we reduce it from above the threshold to below the threshold so that the plant can deal with it, and then a 30 percent efficacy and then a 50 percent efficacy.

What you can see from these scenarios is that the first three scenarios actually move the prevalence below it despite the fact they have varying levels of efficacy. Whereas, this one which is 50 percent does not. So I would argue that the

first three scenarios fit the purpose of what an intervention should be whereas the last one doesn't even though it has a greater efficacy in this situation than one of the scenarios that do fit the efficacy.

Unfortunately, we don't know what that current threshold is. It's very poorly defined. So what should we target when we're studying to evaluate some of these interventions. And I think we can draw from empirical data, where we could target wintertime versus summertime type shedding patterns. And certainly if we look at the human occurrences, this is the number of reported cases, we have the years going across here, and the gray bars represent the warmest months, you can see that the reported cases tend to increase every summer. It's not perfectly aligned with the warmest months, but tends to be associated with the warmest months, and we see that 70 percent of cases are reported in 6 months of the year.

So certainly we have empirical data that suggests that the burden on incoming cattle is more

likely to be within the pathogen capacity, mitigation capacity of the plants during the cool months. So is that something we can target?

And, I think we can, and we can also model that. So there's some data that would help us here. In 1999 and 2000, the USDA APHIS branch did a study of 73 feedlots where they visited twice around the year. They found that on average, the prevalence in summer or warmer months was 68 percent, and in the coolest months was 5 1/2 percent. So that gives us an idea that there might be a 64 percent reduction during the winter months.

Dave Smith, again from Nebraska, went in the feedlot pens and sampled all of the animals in 44 pens in 5 different feedlots and found 30 percent prevalence. And so this is what the pens looked like, prevalence on the Y axis, pen on the X axis, and he went back in winter and sampled 30 pens and found now that the prevalence was only 6.1 percent.

So now we have some distributions that we can plug into some mathematical model and evaluate the effect of these interventions. And that's

exactly what Dave Smith has done based on his data and his evaluation of interventions. He's found that his intervention, sorry, not his intervention, but the intervention he's been working on, averages a 65 percent efficacy. He believes that's pretty close to being right but it's only a point estimate. There's certainly uncertainty in that point estimate. So he thinks it's at least 50 percent but probably not more than 80 percent effective.

So we can build a distribution around that, and then model that based on the distribution of the data we have, and this is the output that he generated from this simulation model whereas this bar represents the summer with no intervention, and this is the 30 percent mean that runs across it. This is the prevalence on the Y axis from 0 to 100 percent. Here is the winter with no intervention. So a lot lower prevalence. But then this was what the summer looks like with an intervention, and you can see that we've moved the mean down to close to what it looks like in winter but the distribution is even tighter than what it looks like in winter.

And we can look at these data in a different way. So the green bars represent summer type shedding patterns. So this is prevalence 0 to 100 percent at the top. This is 0 percent of the pens were at 0 percent. Sorry. This is percent of pens here, and you'll see that most of the pens fall in summer to the left of the mean, and then you have quite a lot to the right of the mean. So we have pens that are shedding 80 to 90 percent. Roughly 10 percent of pens are shed 80 to 90 percent *E. coli* O157.

This is the wintertime shedding pattern. So what we want to do with an intervention is make it look more like this distribution, and we find that when we apply the intervention during summer, we simulate it. This is what we get and you can see, if you compare that to this, or that to this, the intervention looks a lot more like what it does in winter than it does in summer.

So it looks like we can with certain interventions produce an effect where we can gravitate towards a winter type shedding pattern

relative to a summer type shedding pattern.

So now I'd like to present some field efficacy of various interventions. Obviously there are a lot more interventions. Some haven't taken to field efficacy. That doesn't diminish their value except that they haven't gone to being evaluated in commercial feedlot settings yet.

Some interventions worked. I'll show you that. Certainly some interventions don't work. Unfortunately I don't have time to share those with you but we probably should focus on those as well to better understand why they didn't work.

So this table, and I'm sure some of you in the back of the room are having trouble seeing this, I'm sorry about that, is that this is looking at a vaccine, the Bioniche product, and each section here that's separated by a white horizontal line represents a study. So they started in 2002 with one study. There were two studies in 2003, two in 2004, two in 2005, one in 2006. And what I am looking for, as an epidemiologist, is an odds ratio less than one, which means that the vaccine was somewhat protective.

And so I've highlighted that row, and it's the gold row here, and basically what you can see is that every one of these odds ratios is less than one. So universally in every measure that they took, in every study, in every year, there was a protective effect. Sometimes it wasn't statistically significant. Other times it was statistically significant. So it certainly is protective and many times it is significantly protected and these are the data that fit into the simulation model. So the average efficacy of this vaccine was 65 percent.

There is another vaccine that's under consideration for licensing as well along with the Bioniche product, and this is produced now by Epitopix. These studies come from Dan Thomson from Kansas State, and it's been evaluated in two years. The first year was in 2006. I've got the prevalence on the Y axis, the various measures on the X, feces, rectal anal junction, a sign of colonization, as well as what's on the hide. And, again we saw all the odds ratios were less than one, but unfortunately in this study none was statistically significant, and

this was because we had designed the study based on a 35 percent reduction. We saw more than that, but we also based it on a 30 percent prevalence in a control population, and you can see that the prevalence is extremely low. So this study really lacked a lot of statistical power.

We repeated the study with some modifications in 2007, and these are the samples based at the time of harvest. And, you can see looking at fecal prevalence as well now fecal concentration, that we significantly reduced both fecal prevalence, the vaccine efficacy of 86 percent reduction in shedding but not only that, those that were still positive tended to be less positive, if you will, in that those positive ones shed a lot fewer bacteria than the positive ones that weren't vaccinated. So we saw a 98 percent reduction in the number of bacteria shed by positive animals. It reduced the number as well as reduced the load within those animals.

There's also been a lot of talk about lactobacillus acidophilus, the strain NP51. This is

available to be used in cattle at the moment except that it doesn't have any label claim for control of *E. coli* O157, but there certainly has been quite a bit of research to evaluate whether it can.

And this is a MEDA analysis I performed a number of years ago. This red line represents no effect. If it's to the left of the line, then there's an effect. If it's to the right of the line, then there's an adverse effect. And, you can see that of these 13 studies, 12 of them were to the left of the line and quite of them significantly. And when we do the MEDA analysis, we come with this point estimate which basically tells us that the product has a 40 percent efficacy. So we can expect a 40 percent reduction in shedding in feces of cattle that were fed this product, and I performed a similar MEDA analysis of hide, and we would expect a 50 percent reduction in contamination of hides in cattle fed this product.

There certainly are a variety of other interventions in development, evaluation or under the licensing approval process depending on the

regulatory agent to which they work. They certainly include sodium chlorate. We've heard a lot about sodium chlorate. This is a suicide substrate for facultatively anaerobic bacteria of which *Salmonella* and *E. coli* are members.

And, it does appear to be very effective in challenged studies. I didn't present results because it hasn't got a slaughter authorization. So we can't take it into field studies yet, but certainly we hope to do that soon.

Bacteriophage technology and other probiotics, competitive exclusion, I don't want to diminish their value by not showing the results. I was just focusing on what had been evaluated in the field today.

So in summary then, certainly there's been a lot of speculation about what, if anything, happened during 2007. We can spend a lot of our mental energy evaluating that but I think we have a greater opportunity if we focus on moving forward.

We might not ever work out what happened in 2007, but we do know that pre-harvest control of *E.*

coli O157 in cattle is possible. The interventions, to my mind, the data is overwhelming. We can effect change.

No intervention, however, will be 100 percent effective but again I don't think it needs to be. It certainly adds a hurdle in a multi-hurdle system but it doesn't have to be 100 percent effective if we use the empirical data as well as the models that have been developed, it would indicate that the pre-harvest interventions are both effective but ultimately should turn a summertime type shedding pattern into a wintertime type shedding pattern. And, if we believe that that is associated with human illness, ultimately some of these interventions should reduce consumer exposure to *E. coli* O157.

Certainly, we're at a point where we have vaccines under consideration by the Center for Veterinary Biologics. We have feed additives under consideration by FDA. So as soon as we can get those approved or licensed, then we will have labeled products available to us from which we can choose. Right now we have the lactobacillus product but this

does not have a label claim supporting its use for this challenge.

So I think we do have the opportunity. Certainly challenge ahead of us, in development, licensing approval. That certainly is a slow process, but a deliberative process but I believe these challenges are certainly not insurmountable.

Again, I would like to thank FSIS for inviting me here. It really is an honor for me. I'd be remiss if I didn't thank people who provided me data and slides, Dave Smith, Dan Thomson and Nate Bauer and Mindy Brashears is a collaborator with me. She's a microbiologist at Texas Tech.

I presented you some studies that have been funded. I should mention the funding, American Meat Institute Foundation, the Beef Check Off Program, USDA's NRI Program as well as Nutrition Physiology, Bioniche and Epitopix.

Again, thank you very much.

(Applause.)

DR. GOLDMAN: Thank you very much, Dr. Loneragan for that survey of the pre-harvest

landscape. We appreciate that, and I'm sure it will raise some questions and comments when we get to that.

Next we'd like to invite Dr. Mandy Carr to present. She's the Executive Director of Beef Safety Research at the National Cattlemen's Beef Association. She leads their Safety Strategy Team which is a cross-section of the organization focused on beef safety, and implements their safety research program, and an approximate $2 million budget to address both pre-harvest and post-harvest beef safety. This program coordinates the Beef Industry Food Safety Council, which is a cross-section of industry representatives focused on improving the beef safety system. She serves as a liaison to the Joint Beef Safety Committee of the Producers and the NCBA's policy team related to safety research information. Prior to her arrival at NCBA, she was an associate tenured professor at Angelo State University, and during eight years there, developed a meat and food science undergraduate and graduate teaching and research program, led the designing and

construction of the federally inspected Angelo State University Meat Laboratory and led its operations.

So please welcome Dr. Carr.

(Applause.)

DR. CARR: Good morning, and again thank you for the opportunity to be involved in these conversations today. What I would like to share with you from our perspective at NCBA and the work we do with the Beef Check Off and Research is our perspectives as well as some of the research information. I'll build on some of the pieces that Dr. Loneragan presented, and then also our opportunities for moving forward.

If you look back over the course of the Beef Check Off's involvement in beef safety research, what you see is an approach that began many years ago. The research part of the program only took focus after the foodborne illness outbreak in the Pacific Northwest in 1993.

At that time, the producer leadership allocated money to investigate pathogen research. So that focus was then developed and at that time, it

was determined that with the thousands and thousands of cattle that are produced in this country, that funnel through the system, the greatest impact at the time could be made on developing interventions in the post-harvest environment. So at this packer processor level. So much of the research in the beginning of the research program was directed toward post-harvest interventions.

We know then those products are then transferred into other portions of the sector retail food service and then reach millions of customers. So our efforts began in that sector.

If you look at this timeline, and I'll work through it as I go through this presentation, but as you can see that effort began in the early nineties on post-harvest interventions and then that continues today. We are still looking for new and effective interventions for the post-harvest environment, but we are also looking at opportunities that we can optimize the ones that we currently have in place.

I will speak to the pre-harvest actions in our outreach program in just a moment.

But if you look at the post-harvest environment, the processing facility's ability to impact pathogen load, the research has developed and validated several different pieces, one of which is the hide wash of the animal as it's coming onto the processing floor. That can be with water at varied temperatures but it can also be with water and with chemicals, such as chlorinated water or other chemicals that are proven safe that have an impact on reducing microbial load.

Further research has looked at what applications can be applied to the carcass once that hide is removed. Several different pieces of research were conducted and then turned into interventions that are commonly utilized across the country in processing facilities today.

One of those categories is the utilization of sprays. Oftentimes these could be an organic acid, such as lactic or acetic acid, applied at a very low concentration, 1 1/2 to 2 1/2 percent, applied in a cabinet like you see here on the left so it sprays that carcass as it moves through the

processing floor. Other chemicals have been utilized as well with similar effectiveness.

The next portion, when we looked at controls beyond that, it's good to utilize temperature to have an impact on pathogen load. And what we've noticed is you can do that not only with hot water in a cabinet system like you see on the left, but utilizing steam, steam applied to spot locations on the carcass where visible contamination is seen or have the potential to be transferred. Spraying steam on those locations and then vacuuming that off.

The other application is steam pasteurization or a thermal process which is depicted in the picture in the upper right-hand corner. You see that this is a multi-chambered piece and in the first chamber you would have steam applied to the whole surface of the carcass for a short period of time, then moved into a second chamber where there is a cold water spray to reduce that temperature back down. We've seen each of these very effective.

So what you notice is, is this with other

interventions is done in what we call multiple hurdle approach. Many of you've seen this depiction before but we know from research is, is that a single intervention has effectiveness, but when they are combined in two or three or four together, then they're even more effective. And as we put hurdles in front of the pathogens, it becomes more difficult for them to make their way throughout the system.

So with these many options available, what this does is provide each facility the opportunity to pick the interventions that best serve not only their space requirements but the product in which they are producing. So it's intended to have multiple options so that it can be placed in the order which is the most effective in each location.

So as we continue to work through that and many other post-harvest interventions, in the late 1990s, the focus broadened to not only include post-harvest intervention research but also to look at the pre-harvest environment.

And as Dr. Loneragan presented earlier, some of the work took into account many different

pieces. Initially, it was important to look at the ecology of the organism in the pre-harvest environment. Once we evaluated that and understood a little bit better about the organism, work our way into how could we affect it.

So the research then focused on some of the key learnings, one of which is that we know that the hide is the most likely source in which contamination would then be transferred to the carcass.

So one piece that was learned is continuous training of employees that perform this task so that they understand their role is extremely important to prevent that transfer and then will work into other pieces such as the post-harvest interventions that I described, become that much more effective.

If you take a step back up the chain or back up the process, there are interventions that can be utilized on the animal before it enters the facility, one of which is using a live animal wash which as you see, animals are in a pen and then spray nozzles then release water in a shower formation above the animals and also comes up underneath the

animals to wash them before they ever reach that in-plant's interventions of the hide washes and others that I just showed you.

If you take one step further back up the line, we also look at the environment. As I said, understanding the environment and the ecology of the pathogens that are of interest, helps us better understand how you can develop an intervention.

So one piece that was looked at is if you look at the environment in which cattle are loaded from a feedlot onto the trucks and then transported to the processing facility, is there an opportunity there to have some impact, and what we see from several different studies, and I just picked one slide to illustrate the point, is that if you took air samples in those areas which are categorized as clean or have a hard surface, one that can be washed or water sprayed onto the soil, so that it doesn't produce the dust like you saw in the pictures in the previous presentation, you can have a significant impact on the amount of O157 or *Salmonella* that would then be in the air and can settle onto those hides.

So that is one step that can be performed from a management standpoint.

One thing we know is if you take a step back and go one step further up into the process, you see that if you look at the prevalence not only in feces but also on hides, to the point that was made earlier, is animals shed this organism at a variable rate, and it's not easy to predict.

If you look across these pens from this study, across the top, 1 through 10, and then sampling period goes down here on the left, you see that, in particular, I just selected a few different sites within the table, but if you look at Pen 5, from one sampling period you had 7 percent of the animals were positive. The very next time you had 83 percent positive. You can see similar other cases, start out with 80 percent positive here, and the next time 10 percent positive.

So that shedding pattern varies and it can be seen not only in the fecal samples but also in the hide samples. We sample the hides of those animals and again you see the same thing going from 92

percent positive in one sampling to the very next time of 11 and then down to 0. So it is not something that is continuous in the shedding patterns.

So what has been done through Check Off funded research is to look at what are the options in the pre-harvest environment that could have an impact on the shedding or on the prevalence of the load of target pathogens. And what the research has done is looked at demonstrating effectiveness or validating the researchable ideas that have been brought forth.

Many of these technologies, as was noted earlier, are in the approval process or waiting to start those field efficacy trials. However, I do want to share with you a couple of the pieces and expand on what you heard earlier.

The first is looking at the direct fed microbials. Again, if you look at this study, and this is one of many that have been conducted but if you have a control, the bar up on the top or the line on the top, and then two treatments with different strains of lactic acid producing bacteria, you see

that there is a reduction in the prevalence of the animals that were shedding O157:H7 compared to the controls, about a 49 percent decrease.

If you look over four years, evaluating this type of a compound, you can see from these studies that continuously we see an impact where you have reduced the percent positive animal shedding O157 in a feedlot type of a setting.

Another category or topic that has been researched has been the use of phages. These are viruses that target specific bacteria, and they've been widely used in Europe and in other countries as alternatives to antibiotics. And so we see here, that we're looking at the utilization of those to invade a target bacteria but not impact the other organisms that are helpful in responsible for other functions such as digestion.

And what we see, and I just selected again just one piece, though there are many, to show the impact that we're seeing is there is about a 10-fold reduction in animals that were inoculated with the target organism and then those that received a

treatment versus those that did not. So again, an impact that can be seen for a multiple hurdle approach, the possibility in pre-harvest.

Additionally, to a point that was brought up earlier, is the work that has been done through the Check Off on sodium chlorate. Where phages targeted a specific bacteria, chlorate is a compound as was noted earlier that is considered a suicide compound in that it targets a specific enzyme in certain organisms, and it happens to be that two of those target organisms that it's effective in are two of the pathogens in which we like to address in the beef industry.

So though it has not been cleared for the field efficacy trials, in the controlled research environment, we have seen some impact.

The white bars represent cattle that were inoculated during a control study did not receive a treatment. When you look at the yellow bars, these are ones that received varying treatments with sodium chlorate, and you can see that you have about a two to three log reduction from those inoculated cattle.

So again a significant impact if utilized in a multiple hurdle approach.

Another area of investigation has been the utilization of Neomycin. This is a product that is labeled for use in cattle, but it is not labeled for its advantages in food safety in reducing O157:H7. It is available in a form that can be easily applied, whether feed or water, and it has a very short withdrawal time that is easy to manage in the cattle production study.

What you see, as was noted earlier, is a reduction, and we just selected two different studies here, and there were others, but if you look at the O157 prevalence reduction, you can see in feces, it's about a 98 percent reduction, hides about a 95 percent in the one study, and then in the second study, very similar results again, in the utilization of that in a level that can impact this target pathogen.

You saw this graph earlier, so I won't go into discussion of it, but when the technology for vaccines began, we started looking at that technology

with Check Off funded research, the understanding that the summer versus winter months were different and if we could reduce summer to winter, that that would be a significant impact in the pre-harvest area.

Again, one of the studies that was conducted and there have been subsequent since, is on the technology from the Epitopix vaccine on the SRP targeting a specific -- protein on the surface of a target organism, and you can see again this advantage over time to a lower percent positive of animals shedding or have a fecal prevalence of O157 as compared to the control.

If you look that in subsequent research, again this information shows about an 86 percent reduction or efficacy and then again that concentration, those that are positive, are positive at such a lower rate as compared to those that did not receive the treatment.

Other vaccines have been evaluated in our program, and as was pointed out earlier, a different vaccine, the one from Bioniche was evaluated and, as

you can see here, from this one graph, of animals that received the vaccine versus those that received a placebo, it's about 98 percent less likely that the terminal rectal mucosal would be colonized by the pathogen, and then those that did not receive that intervention. So again, signs of success and application in a pre-harvest environment.

This reiterates the point in that cattle that were in one evaluation, where all the cattle in the trial receiving a vaccine were placed in one pen, another pen where no cattle received the vaccination, and then a pen where half of the cattle received the vaccination, and you can see 62 percent less shedding for those that received the vaccine versus those that didn't. And in that pen where it was mixed, still was a decrease for those that received versus those that did not, but there is a possibility that there's some herd immunity or some advantages acquired by some cattle in a pen receiving the vaccine and others did not when they're housed together.

That being said, as our work through the pre-harvest environment progresses, what we see is

that there are successful, validated research points for interventions in both environments, and just as has been the process for the post-harvest environment, a multiple hurdle approach is what we see as being of greatest success.

Again, we don't see anyone intervention that can be commonly applied being the silver bullet or to solve the problems, and we never expected to be able to. It would be much more effective to have multiple steps involved in a process to accomplish the goal.

In saying that, the thing to keep in mind is that the industry does not expect any of these interventions to take the place of good manufacturing practices which would include the sanitation and cleanliness not only of the environment in the production facility, the processing plant, but also of that of the employees. We know that other steps in the process, such as proper chilling within the plant, provides an environment that bacteria do not like to grow especially these target organisms. So each one of those would never be replaced by any of

the new interventions that are developed. All this goes together to provide the safest environment.

So now what I would like to show you is where we're going. So we've looked at some prospectives. What is the industry doing and where are we taking our research program through the Check Off?

What you see is the research priorities that there were developed for 2007 fiscal year. The thing to note about this is these are the projects that are currently finishing up within the next two to three months. What we did is we evaluated different studies that addressed the several different issues. Pre-harvest-wise, learning more about the pathogen in its pre-harvest environment, what is the impact of management practice changes and other intervention technologies that can be evaluated and if they show that they are effective, then how can we move forward with those.

In the post-harvest environment, one of the key pieces of research is looking at this sustained activity in optimizing the interventions that we have

in place as well as looking for new ones that may perform ever better than what we have.

A couple of pieces of key knowledge that go to some of the questions that have been raised, one is on non-O157. We have looked at that. We continue to look at that but what we see is when over 10,000 samples have been collected for carcasses, trim and ground beef, in that sampling there were only 15 isolates that machined the top 6 isolates from CDC of concern, and only a fraction of those had the virulence factors that would cause disease. So we see 15 out of over 10,000 being the rate as we looked across the country in different facilities. So I think that's a key point to keep in mind.

To address some of the other questions, one, distillers grains. Through our research, what we've seen is was noted earlier, is there have only been a few studies completed. That being said, there are variations in the corn portion of the -- that's in combination with the distillers grains. So I think that warrants little bit more investigation before a conclusion can be drawn.

As was noted earlier, the information from last fall versus the information that was released last week is not the same. So that to us notes that there's a need for further investigation before a real conclusion can be made.

In the area of multidrug resistant *Salmonella*, considerable efforts have gone in this direction, many studies. What we're seeing is if you look across those studies, the strains that are being shed by cattle in the feedlot setting are not the same strains that have been involved in the cases of illness for humans. So we continue to look at that. We want to evaluate those items. Even more so, we can monitor if there's any change.

One question that I would like to address is when we got through these projects, we're not only looking at targeting O157:H7, but we're looking at the effectiveness of these interventions across other pathogenic species because we want to know that the interventions that are in place currently and those that will be developed, have the ability particularly in the post-harvest environment to impact and be

effective on other species. And so we've looked at multidrug resistant *Salmonella,* non-O157 as well as O157 and other *Salmonella* species and what we see is each one of these interventions that have been validated or in place, are effective on these others as well. So it's not that we're targeting just O157 with interventions in a plant.

The other priority that we have with the research program is to foster the environment that is built by the Beef Industry Food Safety Council, and you'll hear a little bit more about that organization in a moment, but what that group is, is a cross-section of individuals throughout the industry from producers, processors, retail food service, that come together and on an annual basis attend a meeting called the Beef Industry Safety Summit, and not only at that time do they hear the most current information and research results, but they also address up and coming challenges that they see in the industry.

The other piece that occurs at this time is there is a series of best practice documents BIFSCo

has put together and each year reevaluates those, make sure they are up to date and include the latest information, and that group, with their knowledge, then re-issue those, and they're posted to the website you see here, bifsco.org. Those are posted there for anyone to access. They are distributed free. So there is no charge for those documents for anyone to utilize those as the basis for developing their production practices to produce the safest beef possible.

Aside from the outreach we do with BIFSCo, we also have a website, beefresearch.org, which has project summaries from all the research that we conduct, fact sheets, the executive summary, not only from the Safety Summit, but from our annual research reports. So anyone can log onto this at anytime. You can also request a printed copy if you would prefer, to see what information is being collected and what those research results are so that the next evaluations can be based on science that is produced not only through the Beef Check Off but through other organizations as well.

I just want to give you a little snapshot of where we're going next. As I said, the '07 fiscal year projects are in the process of being completed. We'll have more information in some of those areas soon. But in 2008, these projects will complete in May of '09, and similarly to what you saw before, we continue investigation in some areas but we also have expanded that a little bit beyond what we did in 2007, to include other emerging pathogens that we want to make sure that we understand and their role in the beef environment, and then also looking at the develop of resistance so that we can understand that category a little bit better.

Post-harvest, we're looking at the opportunity to survey the use of the best practices throughout the industry and build up on the knowledge so that we understand also what audiences do we still need to reach with these documents and provide the service to them. Looking at the risk assessment for other products as well as the continual investigation to optimize the in-plant interventions that we have.

For monitoring, the research that goes on

across the world, though we may not be involved in every particular aspect of the research, we want to make to sure that we're abreast of that that's being monitored by others, and then again, our BIFSCo initiative has not only maintained what we do by having a Safety Summit in that outreach, but we're building beyond that. To do cooperative work on small plant outreach, to take those best practices, turn them into a format which may be of value, such as the production of a video.

Our first video is on the N-60 sampling procedure, and that will be distributed before the end of the month. And the purpose for that is to take a document that is extensive and very detailed and put it into a format that can be easily understood and utilized by not only in-plant personnel that are taking the samples for that procedure, but also to be utilized by others involved in taking sampling procedures for these microbial tests.

Again, we continue our efforts for outreach in our publications, through out websites and printed

documents.

And that being said, what you'll notice then is this work not only in the pre and post-harvest environment and research, but also strive to have the outreach so that the information that is gathered doesn't just stay in our office. We want it to be distributed to the industry and to others who need to utilize it for decision making processes, so they have the science to do that with. So over time you can see the development of task forces, the organizations such as BIFSCo, the hosting of the Annual Safety Summit, the development of those best practice documents and the video, and each one of those progresses to include new and upcoming topics each year.

So with that, I'd like to thank you for the opportunity to be involved in these conversations today, not only from the Beef Check Off Program side, but also from NCBA and our work through the safety research. Thank you.

(Applause.)

DR. GOLDMAN: Thank you very much,

Dr. Carr.

Our last presenter on this panel as I mentioned is a pinch hitter. Dr. Dean Danielson is currently the Vice President for Food Safety and Quality Assurance of Tyson's Food for the last six years, and is responsible for all of the food safety and quality assurance program for red meat, poultry, processed meats and their international divisions as well. He was formerly a professor at Auburn University and has his Bachelors in Animal Science from Iowa State, a Master's in Animal Science and his Ph.D. both from Virginia Tech. And he has numerous industry affiliations and will share with us his perspectives on interventions that may be applied maybe both pre and post-harvest.

DR. DANIELSON: Well, I appreciate that. I am a veteran of more than six years. Prior to Tyson's, I was with IBP 20 years, but I appreciate the opportunity to come up here and fill in for Bo or pinch hit as you said.

I've got two memorable highlights of this trip. One is, of course, the meeting, and the other

one is the baseball game that I went to last night at the brand new stadium. It's just a beautiful, beautiful stadium, and we watched some great baseball last night, and even though your local team, you guys are very fortunate that live in town here, to be able to go out and see some great baseball when these other teams come in to play and some great players. You've got a chance to see some great baseball. Unfortunately, we didn't come away with a win last night, but I'm a Cubs fan, so I'm used to that.

(Laughter.)

DR. DANIELSON: But as I was sitting there last night, thinking about this and after having a couple of little adult beverages and a great hot dog by the way, the baseball analogies came to my mind last night and this morning about what I saw last night and what was going on and what we're doing here. The pinch hitter comes to play. As I was sitting up here this morning and watching out in the audience and some great talks here, but I saw a couple nodders going out there, and when I get done talking here, there's going to be more. The --

stretch is going to be very important for this group.

Looking at that field last night, every base had an umpire standing there watching what was going on, watching every move, making sure that the plays were made right and there were coaches at the bases, and that reminded me of our FSIS inspectors out in our plants and facilities watching what we're doing.

The behind-the-plate empire, calling the strikes and calling the balls and making the game go. Almanza came to my mind. And then the Commissioner of Baseball sitting right here in front, Rich Raymond, and then we've got the great closer, Stan Painter (laughter), the great closers in the game right here in front of us.

I saw great plays and great players. Two teams opposing each other but they have the same goal, yeah, you win some and you lose some but the same goal, and that's to make a great game and work together as a team to make it happen because it's the fans up in the stadium that are the ones that are there that making the reason for that. And the

stadium wasn't full last night. It wasn't a sellout.

So we're the players. Everyone in this room is a player. We've got coaches. We've got agents. We've got base players, but we're responsible for making the game go, and if we don't play a good game, we're never going to have a sell out, and then the game won't go on. So I saw a lot of great analogies and the baseball season and it's a great opportunity to go out there. So I share that with you.

I'm going to read to you a BIFSCo statement or a letter that was prepared for this meeting and then it will be submitted into the meeting inputs, and that is my pinch hitting effort for Bo Reagan today. It's a statement of the Beef Industry Food Safety Council members, presented April 10, 2008, Washington, D.C.

Food safety is nothing new to the beef industry. Beef safety is more than an expectation, more than an effort of any one single entity, and it is the sum of the entire beef production system from farm to table.

The industry and the scientific community realize that further improvements can e made through a collaborative effort. The beef industry believes that the optimal system of food safety assurance relies upon a food safety net extending from farm to consumer.

To this end, the Beef Industry Food Safety Council or BIFSCo is composed of industry executives, beef producers, university, Government and industry scientists, industry association executives and experts that represent each segment of the beef food chain. This cooperative effort clearly displays a deep commitment for further action to enhance the safety of the beef supply. These enhancements can be made through a collaborative effort based upon several factors.

One, the use of science-based pathogen intervention strategies which we have been looking at in these talks to enhance sanitary processes that include effective HACCP programs and microbiological testing protocols that verify process control.

BIFSCo's best practices have been in place

since 2003 and are available for all segments of the beef industry for use, free of charge, and can be accessed on multiple association websites.

Experts are available to assist with technical questions. The documents are dynamic and continuously updated to include the latest science and technology. The most recent best practice document produced was Best Practices for Microbiological Sampling, and this document will assist with the industry-wide use of the N-60 sampling protocol. In addition, a demonstration or video will soon be available for use in training personnel.

Second, an understanding shared by each segment of the beef food chain of the risks involved and the steps needed to insure safe beef experience. The Annual Beef Industry Safety Summit provides the opportunity for information sharing among all industry sectors as well as discussion on current and emerging safety challenges.

Three, the principles of prevention and risk from farm to table, including effective

monitoring of intervention strategies. These strategies must be based on data collected through research. The best practices developed by BIFSCo and embraced by industry follow this model by inclusion of interventions and systems validated through research. Next.

The notice for today's meeting included the statement, "FSIS will discuss growing evidence that may support a determination that while beef products such as primal cuts and boxed beef contaminated with O157:H7 are adulterated.

Based upon available research, the prevalence of O157:H7 on the surface of sub-primals is rare. In two studies funded by Beef Check Off, examining over 1,000 and in the second study, beef samples from multiple processing facilities, the incidence of O157:H7 on the surface of a sub-primal was 0 in the first study and only 2 in the second study. The levels of O157:H7 in the two positive samples in the latter study were less than .375 colony forming units per centimeter square.

The results indicate that O157:H7 is not a

common contaminant on the surface of sub-primals and that if it is present, it is at extremely low levels. Next.

The expansion of the adulteration policy for O157:H7 to all intact beef products is not warranted due to the lack of supporting scientific evidence and because interventions and processes exist for application to such products entering further processing. Steaks and roasts from intact beef have not been implicated in foodborne illness.

Existing regulations and policies and industry best practices are currently in place to address the use of trim intended for ground beef production from intact primals. Existing policies and industry best practices that effectively address the hazard for O157:H7 are also in place for non-intact beef primals.

These facts, combined with research, that indicates the very low prevalence and very low quantitative levels found on the surface of intact primals show that this policy expansion is not warranted. Next.

The expansion of the adulteration policy to all non-O157:H7 STEC is also unwarranted based on data that exists as a result of the most current research. This position is based largely upon the scientific literature and on the public health data studies that have been conducted to determine prevalence and characterization of non-O157 STECs on pre and post-intervention carcasses and in ground beef. 10,159 samples composed of carcass trim and ground beef were analyzed and only 50 isolates matched 1 of the top 6 CDC STEC serotypes. A fraction of these have the ability to cause disease. This data does not support making all STECs adulterants in raw ground beef.

At the public meeting held in October of '07, CDC reported though outbreaks linked to non-O157 STECs from beef. The scientific literature clearly indicates that not all serotypes of STEC are pathogenic to humans and much is still unknown concerning virulence factors and their relationships to human disease.

FSIS has no published validated and

accepted laboratory protocol for determining pathogenic STEC in beef and many analytical changes remain related to adopting laboratory methodology for industry use.

Given these facts, declaration of all non-O157 STECs as adulterants is not technologically feasible, nor would it be a wise use of food safety resources.

The best course of action is for industry and Government to continue targeting O157:H7 with validated interventions and appropriate testing since this is the serogroup that is most virulent and most often associated with severe human disease and outbreaks.

Broad spectrum interventions currently in place will have a correlated effect on the other serogroups beyond O157. This was demonstrated at study conducted by USDA scientists that showed a 7-fold reduction in carcass contamination by STEC through the use of existing interventions. Next.

Plant reassessments were recently conducted which resulted in many changes to plant processes and

policies. The effects of these changes therefore can not be evaluated since results from these adjustments have not yet to be measured. The use of data to track microbiological trends is a valuable tool used by the beef industry but this tool must utilize data that is collected over time and is not effective when used as a snapshot view of a situation.

We must allow the enhanced systems to operate for a substantial period of time before Judgment is made on the effectiveness or need for changes.

Review of the PulseNet and CDC data does not show a public health crises for beef-related *E. coli* O157 illnesses in the past year. In fact, review of the trends in FoodNet data from CDC, shows a dramatic and impressive downward trend since the baseline years of 1996 through 1998. This downward trend is no accident. Of note, the alarm sounded by FSIS in late 2007, due to increased incident rates and associated increase recalls, really probably should have come as no surprise. Both FSIS and industry have been making critical improvements in

beef sampling techniques, changes in laboratory methods that increased detection, sensitivity and accuracy, and implementing more comprehensive programs and procedures for surveillance and prevention.

Again, it is no surprise that there was an increase in samples positive for O157:H7 and associated recall outcomes based on these findings. In fact, this is exactly what should have happened in light of the system improvements that were deployed in the last few years. The increase in FSIS positive samples is not due to unknown disturbances or industry back sliding but rather is a function of system enhancements. Additional regulations are unjustified.

Beef safety has been and will continue to be a dominant feature of the beef industry. However, food safety cannot be addressed without considering the road that beef makes to the consumer's table. The food chain begins on the farm and extends through processors, distributors and ends with the retail and food service establishments having direct contact

with consumers.

While important food safety trends are impacting the entire beef production system, the final dimension insuring beef safety takes the form of optimizing the use of interventions and control points not only within individual segments but within the entire system from top to bottom.

For these reasons, the entire beef industry is committed to enhancing the current science-based industry-wide approach. Every segment of the beef industry is united behind effective programs designed to solve microbiological problems, including O157:H7 in the beef supply and aimed at long-term solutions for the problems presented by other hazards. Already existing are those that may evolve and present themselves in the future.

So in summary, expansion of the adulteration policy to include non-O157 STECs is not warranted.

Two, expansion of O157:H7 adulteration policy to include intact beef products is not supported by science.

Three, effects of recent applications of new technology and knowledge must be evaluated after an appropriate period of data collection.

Four, the beef industry is committed to enhancing current systems using a science-based approach.

The beef industry is committed to working with FSIS to discuss safety frameworks in the context of sound science.

This letter from BIFSCo representing the farm to retail production and distribution of beef welcomes the participation of USDA officials representing Government's responsibility to provide a regulatory framework for food safety, to work collaboratively on improvements that are science based and technologically feasible.

Again, we strongly believe that there's no evidence at this time to support new regulatory determinations with respect to adulteration of beef products.

This letter is signed by numerous BIFSCo members and will be submitted into the notes. Thank

you very much.

(Applause.)

DR. GOLDMAN: All right. Thank you, Dr. Danielson.

We're right on schedule. We have time now for your comments or questions for this panel, and we'll start with Dr. Raymond.

DR. RAYMOND: Commissioner. I enjoyed your analogy, but there's a few things you could have gone just a little bit further. For instance, you forgot the injured reserve list over here with Loren Lange. Just because he confused you with Randy yesterday, you still can't not ignore his presence in the room.

And Dr. Loneragan and Dr. Carr referenced a couple of times something that we know, that the warm months have a higher prevalence of *E. coli* O157 both in human illnesses and in sampling. But we can start off with warm months, perhaps, Dean, you should recognize that as baseball season is a high prevalence season and in baseball when we have spring practices getting ready for the season, this meeting may be kind of like a spring practice because as we

get together and practice or learn together, share things, hopefully we'll commit few errors and hit more home runs during the baseball season.

That said, I have a couple of things, Dean, I do need to respond to your letter.

We did not change our sampling reagents this last year. So it was a surprise to use that the positives came in higher than they had for the last three years. We did initiate a new substance, an enhanced broth in January of '08, but last year we were still using the same old broth. Industry, yes, had instituted that change quicker than we did but most of the recalls were due to our testing. They weren't due to industry and those may have been missed in previous years. We will certainly give you that. And we may very well see an increased product sampling positives this year on FSIS samples because of both the format has been changed of what we sample and who we sample but also how we sample. So we should be careful when we compare apples to oranges, that we are consistent. I will agree with you on that wholeheartedly.

What I would ask industry to consider, about 20 percent of the samples that we did last year were not held. They were distributed into commerce and then we did have to recall those 11 positive samples and it would be nice if we were able to figure out ways for the small and very small processors to hold that. I realize there's physical issue or space issues, but if we could work together on that also, that would cut our recalls down in half, and we would have less tainted product out in commerce. So that's another way we can hopefully come to some solutions and visit with industry about that area.

So with that said, I appreciate all of the comments that we heard today from the three folks. I'll get away from the microphone so those who have serious questions can answer them.

I look forward to the next panel also who have a more diverse representation to give us some other ideas.

DR. GOLDMAN: Okay. Thank you. Ms. Nestor.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Dr. Raymond actually anticipated one of the questions. I was not aware that FSIS did anything differently in the testing between 2006 and 2007 to go from 20 positives in 2006 to 29 in 2007. And I just wanted to ask, is it Dr. Danielson or Mr. Danielson, do you agree with that, that FSIS did not, and if not, can you tell us what they did so that it might explain the 20 to 29 in the one year?

DR. DANIELSON: I am not totally able to talk to that.

MS. NESTOR: Okay.

DR. DANIELSON: And so I would defer you to what Dr. Raymond said.

MS. NESTOR: Okay. Thank you. That's one question. I was asking FSIS some questions yesterday about N-60 and they didn't know some of the answers, and so I realize, you know, you're as we say pinch hitting. So you may not, and some of these are detailed, and if you don't know the answers, maybe somebody else can tell me later.

Do you know in a large plant about how many

combos of trim are produced per day ballpark to go with the baseball analogy?

DR. DANIELSON: A large plant --

MS. NESTOR: I mean are we talking 20 or we're talking 200?

DR. DANIELSON: 4 to 500.

MS. NESTOR: 4 to 500 combos of trim. Okay.

DR. DANIELSON: That's a big plant.

MS. NESTOR: Okay. And do you have any idea what the range and the mean would be of how many combos, if you're testing each combo, which apparently that's what the industry is doing now is testing each combo, do you have any idea how many combos per day might be diverted to cooking? I mean I'm sure that many days it's probably zero, but what's the most that you've heard of in a day?

DR. DANIELSON: Well, I only have my own, you know, my own experiences so I'd have to do some ciphering here on that. I don't have it off the top of my head. I'm sorry.

MS. NESTOR: Okay. Maybe before the end of

the meeting. I mean again ballpark is fine by me. Is it, you know, is the mean 5 or is the mean 20?

Can you tell us when the industry started testing one combo at a time using N-60 as opposed to five combos at a time?

DR. DANIELSON: The industry has not collectively done that. It's a movement or it's a discussion. Some are doing it. Some are still in the five combos grouping, and that is a very, very new process of discussion as laboratory capabilities are being advanced and improved, and the sampling technologies are being advanced and approved. That is not across the board yet, and may, you know, it's not a requirement across the board.

MS. NESTOR: Right.

DR. DANIELSON: So that's new development.

MS. NESTOR: Do you know when some started it? Was it in 2007 or has this been starting since 2003?

DR. DANIELSON: This, to my knowledge, would have been started back in '07 sometime, during the year of '07.

MS. NESTOR: Okay. Final question. Do you by any chance happen to know what the confidence level is if you're doing N-60 and the defect rate is not 5 percent but 1 percent? I realize this is incredibly technical.

DR. DANIELSON: Yeah, you're going to have to -- it's a -- at a 1 percent level, it takes to my understanding 300 plus N to get a 95 percent. And that may not be exact. Somebody that's a better statistician maybe could answer that but that's my recollection.

MS. NESTOR: Okay. And so N-60 would give us somewhat less, maybe much less than 95 percent confidence?

DR. DANIELSON: If your population was at -- statistically your population was at 1 percent, it would be less than 95 percent.

MS. NESTOR: Okay. And then if it's at .2 which is what the Agency's prevalence shows, it would be even less than that.

DR. DANIELSON: If that is what the true prevalence is.

MS. NESTOR: Okay. Thank you.

DR. GOLDMAN: All right. Thank you. Before we continue here, let me check with our callers on the phone. Do we have any questions, operator?

(No response.)

DR. GOLDMAN: Okay. We'll go back here.

MR. WALDROP: Chris Waldrop, Consumer Federation of America. I just had a comment. Dr. Danielson in his reading the letter mentioned that there had been significant progress in reducing *E. coli* since the '96, '98 baseline according to CDC numbers, and while I agree with that, the problem I think is that most of that reduction happened in the early years and since about 2001, we haven't really seen the big reductions that we need to. And so kind of knowing that that's the situation, I applaud the Agency for trying to look at this problem broadly and in a proactive stance.

I had a couple of questions. One for Dr. Carr. You mentioned the multiple hurdle approach. Obviously we know that that works in the

post-harvest, and you mentioned that it's likely to work in the pre-harvest. Has there been research done that put some of these pre-harvest interventions together to see how effective they are in pre-harvest?

DR. CARR: Through our programs with the Beef Check Off, we have not but when those approvals are gained and we can test these in a commercial setting, large scale, and we would like to approach that, but we can't do that yet.

MR. WALDROP: Great. That brings me to my next questions for all three panelists. If you can expand on the barriers to implementation, why are there limitation of these pre-harvest interventions, and maybe, you know, looking at it, I think regulatory implementation, economic, research barriers, all those barriers, and then what your opinion is on how we can overcome some of those barriers? Because I think most of us in the room would agree the pre-harvest is an important place to focus in addition to what we're already doing, but obviously there's some barriers to moving forward. I

would be interested in your perspective on that.

DR. LONERAGAN: Well, I think the first barrier that we have is licensing and approval of product. If we want product that has a label claim that says that it's been evaluated by a regulatory agency, it says if you follow these procedures with this product, you can expect this outcome. Right now we don't have any product that is labeled that way. There are at least two vaccines that are under consideration by the U.S. Department of Ag, Center for Veterinary Biologics, and there is at least one, probably more, under consideration by the Food and Drug Administration.

The challenge is that the regulatory approval is slow and deliberative. It's a new use and a new approval process. They haven't approved food safety type products like this in cattle before and so what are the standards to set by which they should evaluate these, it's just not known right now, and unfortunately that's hold up the process. So that is the first limitation to implementation right now, is that they're just not being approved or

licensed depending on which agency.

When you get to the second one, as in the economic cost, I really don't want to speculate about what's going to happen once these get into the market. I think we let the market work out where they fit, who can use them, who can share the cost, can we add value by using these in certain situations, but until we get the approval of these, we can't evaluate them. We can't let the market force us to work out how they're going to be used and who's going to use them, and bear the cost of --

MR. WALDROP: And as part of the implementation, part of the regulatory approval, the fact that there's not enough research out there or do you feel that there's significant or enough research to be able to move forward on the regulatory side?

DR. LONERAGAN: I can't really speak to the FDA's side as much, but I can speak to the vaccine side. To me the data, I believe there is an effect. That effect is consistent over time. They provide evidence, overwhelming evidence that immunomodulation is an effective way that we can reduce prevalence.

That's a different question than is that reduction sufficient to warrant implementation. I think that's what the Agency is struggling right now with is I don't think they have a question about effectiveness. I think they have a question about is that effectiveness big enough that warrants them implementing it? I would argue yes, but that process is a slow process.

MR. WALDROP: Thank you.

DR. GOLDMAN: Thank you. Next.

MR. LOVETRO: Yes. My name is Dave Lovetro. I'm with Eka Chemicals, Incorporated. Eka is a manufacturer of sodium chlorate, so a stakeholder in the pre-harvest intervention, part of the toolbox.

I just want to make a comment about pre-harvest and this is a perfect place in line I think based on the last speaker here. Some of the issues and some of the hurdles, for a perspective of what it takes to get a product from conception into a commercial pipe or marketplace, you know, it really goes in three important circles. There's a science

and a technical circle, and we've certainly heard a lot of good information on that today. It also moves in a commercial business circle in terms of business people like myself who look at products and try to decide whether or not it's a good investment. I'm happy to say in this case, in Eka's case, that we certainly believe that the pre-harvest types of products, the one we're looking at for our own company is imported. We've invested alongside people like USDA, ARS, who has been our greater partner over the past years. Now Eka is a licensee of the technology. So we continue to invest.

I'm happy to say that from the beef industry perspective and the pork industry perspective, we have had good investment on the science side from people like NCBA, the National Pork Board. So I think the science or the technical piece goes along very, very nicely.

But there's an important piece that the last gentleman at the microphone was speaking about, and that is the fact that pre-harvest interventions will be regulated products of food animals, and it

depends on what kind of an intervention it is. In some cases, you're talking about natural biologics, which is one regulatory agency. In some cases you're talking about food additives, feed additives, or veterinary drugs which is another agency.

I'm a little bit more conversant on the FDA side because that's my particular situation with a product that's probably is a feed additive which actually is a human food safety initiative. Eka's no stranger to the regulatory process and I can't speak on the terrestrial side but we have done some work with food animals on the aquaculture side which is the fish market.

I was interested to hear it presented at an aquaculture meeting. The average time it takes to move product through, in the worst case, a veterinary drug scenario, as an original animal drug application in this country is 12 years. So that means there's a stakeholder out there today, if they start today, we should probably be looking for something coming out of the end of the pipe at 2020.

Now obviously we're all stakeholders. I

have a family. I'm interested in food safety as much as anybody else. 2020, you know, to wait that long is just too long.

So I would put my pitch in for all the stakeholders here from the consumer side, from the science side, from the industry side, if you're looking for a place to put some energy, the system as we have it today, moving through the regulatory process, is a little bit too slow, and I would encourage, and I would be encouraged myself if we can find the strategies through a partnering effort or a collaborative effort to find a way to work with the regulatory agencies to improve the timeline process. It's an important aspect of it.

And I think that if there's a way, you know, I'm encouraged to see that there are science people here today. I'm encouraged to see that at least from the business side, perhaps there are some people but it would have done my heart good to know that perhaps there might have been someone here from the regulatory side who was listening to this and realizing just how important these products are and

how important a piece that they play in that timeline.

DR. GOLDMAN: Thank you. Any comments from -- okay.

DR. DANIELSON: I agree.

DR. GOLDMAN: Thank you. Yes.

MS. DONLEY: Hello. I'm Nancy Donley from STOP, Safe Tables Our Priority.

I want to start off by mentioning that all organization represents foodborne illness victims from many, many sources of foods, and foods that have been contaminated by *E. coli* O157. Outside the beef industry, we have had victims suffer from contaminated juice, lettuce, other produce, cantaloupes. We've had victims who have become ill from drinking water and as well as swimming in contaminated reservoirs.

If you want to do the epidemiology on this, and you take these illnesses and you take them back far enough, many, many times you're going to bump into a cow. So this issue is bigger than just the beef industry, and I think the associations here have

to recognize that, that not only are you thinking that you just need to get an animal into better pathogenic condition when it enters the slaughterhouse facilities, it's a bigger problem than that.

We've been advocating since our inception for the need for much more pre-harvest interventions, that it is necessary for these very reasons that I specified before. So we are very interested in anything and everything that you all are working on specifically.

Dr. Loneragan, I was very interested to hear your suggestion that a design sampling scheme be prevalent in cattle being presented for harvest. We fully support something like that because right now, our beef plants, I'm going to go to beef plants now, are kind of working in a vacuum. If they don't know the microbial loads coming in, how do they really know what it is that their system is going to, those multi-hurdles are going to be effective enough to handle this. And maybe, Dr. Danielson, you can say if it's even feasible as these prevalence rates go up

and down, how much time it takes for a plant to adjust for such a, you know, change? So I think though that just makes really good sense, and it was just brought to my attention this morning, that there are countries, other countries who actually -- cattle that are being presented for harvest are actually certified before they even come to the plant, that there is a governmental regulatory role that does these very things and so the plants are better equipped to deal with whatever is being presented. They know what they're being presented with.

Another thing that was just mentioned during, Dr. Carr, you mentioned that interventions targeted O157 are effective on non-O157 STECs as well. And I guess I would just ask, and I'm not real familiar with studies those have been. Dr. Danielson, you mentioned -- you referred to a study done by I think it was ARS, but I would like to know what other maybe studies have been done by industry and maybe some other academia as well.

And then I guess my question to both Dr. Carr and Dr. -- and I don't mean to put you on

the spot, Dean, if you don't know this, is of your research budgets, what percentage is going into pre-harvest research and what is going into post?

DR. CARR: I'll start with that. From a Beef Check Off side, in our research program, as I presented, that has changed over time. Originally we probably spent at least 75 to 80 percent of the budget in the post-harvest area and then gradually expanded that to include the pre-harvest arena, and that has changed over time to where it is a pretty even split on some years, and now even more research. We're probably up at about 75 percent of the budget being spent on pre-harvest with a continuation that focuses on post-harvest as well.

MS. DONLEY: Thank you. Would you know, Dean?

DR. DANIELSON: On a dollar standpoint, that's very difficult because a lot of the work we do on pre-harvest is collaborative with feed lots or, you know, the drug makers, by providing facilities and access and animals and sampling and laboratory tests. So from an absolute dollar expense

standpoint, the pre-harvest, you just put it under dollars of expense, probably pretty low but if you look at the total resources committed, that we're doing with resources, we spend a tremendous effort in the last two years working with bacteria phage companies with hide washes, working with cattle in feedlots, running them through vaccination programs. We've been -- beta sites for the feedlots on vaccinations in our Canadian facilities and in some of our facilities down here where those animals are given access into our plants for the sampling of the hides, and we do the sampling and we provide a lot of laboratory support for those.

And those are even dollars that show up in our budget, Nancy, but we have, you know, big energies going at that, working with the feedlots and working in our own stockyards in the areas where we can do that. But it's very, very difficult to measure, very difficult to measure these types of things. That's one of the real frustrating things about the whole deal.

MS. DONLEY: Okay. If I could just make

one last comment. Dr. Carr, it was very interesting to hear that you're doing -- this is very interesting to me personally, the pathogen ecology studies and emerging pathogen studies. Are you looking at -- with emerging, are you looking at anything really in particular or --

DR. CARR: Yes and no. We're looking not only at the pathogens that have been seen in other food, products not only in the United States but also abroad. So that may be other strains of organisms that we currently evaluate and other organisms such as clostridium difficile, MRSA, Methicillin Resistant Staph Aureus. So we're looking at other organisms seen in other food products so that we can understand our product better.

MS. DONLEY: Thank you very much.

DR. GOLDMAN: Okay. Let me check with our operator once again and see if we have any questions from our callers. Hello, Operator.

(No response.)

DR. GOLDMAN: Okay. We'll go back to the room here. Ms. Buck.

MS. BUCK: Hello. My name is Pat Buck, and I'm with the Center for Foodborne Illness, Research and Prevention. And I have one question, and then I also have another comment that I wish to make.

My first question is to Dr. Carr. You talked about this study that you did that had the 10,000 plus samples, and out of that you found 15 that had non-O157, you know, *E. coli*, and of those 6 were at the virulent level to cause illness. Would it be possible to share with us the testing procedures or methodology you used in that study?

DR. CARR: Just a point of clarification on that. First is the over 10,000 samples were collected across multiple studies and the 15 that were found were of that top 6 list --

MS. BUCK: Yes.

DR. CARR: -- that CDC produces --

MS. BUCK: Uh-huh.

DR. CARR: -- that are of interest. So I don't have those methods right off the top of my head but I'd be glad to --

MS. BUCK: Well, that's what I'm asking.

If you could share that because I mean I understand that that's only a very small number of cases for the amount of samples, but you have to look at how those samples were collected. You have to look at other criteria within the study, and I think Barbara Kowalcyk would really like to review that.

All right. When you say only 6 have virulent levels, Dr. Danielson referred to that later, 6 out of 15, that's 1/3 and 1/3 of anything is significantly important. So I think even though this shows a very small amount, at this particular point in time in this study, I think one of the things that always I keep coming back to is that we have to continue to test. You cannot test product safety. I understand that. You cannot test enough to find all the pathogens but by the same token, when you have one-third of the ones that you found are positive, that are really significantly possible to cause disease, I think it's time to expand those testing procedures.

And that brings me to my second comment.

DR. CARR: On that particular study, we had

15 of 10,000, that were -- those 15 met that list.

MS. BUCK: Yes, I understood.

DR. CARR: So it's not six that had the characteristics. It's 15 out of 10,000, and that list of 15 is strains that are on that list of --

DR. DANIELSON: So the one-third analogy does not fit with what you have interpreted.

MS. BUCK: It's not one-third of the samples. It's one-third -- you did say, I wrote it down, maybe I misinterpreted.

DR. DANIELSON: Those 15 isolates belong to --

MS. BUCK: And then six of those isolates --

DR. DANIELSON: No, no, no.

DR. CARR: No.

DR. DANIELSON: No, no.

DR. LONERAGAN: The 15 isolates belonged to 6 serotypes. So --

MS. BUCK: Oh, I see. I didn't have a second cup of coffee. I missed it.

DR. DANIELSON: It was probably my stumbled

words.

MS. BUCK: I'm sorry. I apologize. Okay. As far as my comment, the one thing I just think, and it goes back to the testing, I realize that we cannot test 100 percent safety into a product. And right now FSIS is coming to the beef industry and saying we need to test what I call generically boxed beef because these cuts could be used later on in ground beef and once it's ground, there's a possibility for future or more complications with, you know, spreading disease throughout the consumer environment.

I happen to agree with that. I think that one of the things we have to do is we have to look at this as a possibility. In 1996, STOP, Consumer Federation of America, a lot of the people that work on consumer safety here, were in this room trying to put together the HACCP Program which was a huge, huge step and you probably were involved in it. I wasn't.

I remember thinking at the time, because I read about it in the Reader's Digest, wow, I'm really glad that the meat is going to be safe now. And, of

course, I found out in 2001 that that really was not what was in place.

As I started to look into food safety, one of the things that just absolutely drove me crazy was to find out that within six weeks of HACCP's implementation into the large meat processing plants or slaughterhouses, that they were given these exemptions for the *E. coli* testing. And I just was blown apart with that. Six weeks isn't enough time to really find out if the system is going to work or not. It was like the industry really didn't give it a chance.

And this is one thing that I have brought up. I grew up in rural America. I still live in rural America, and there is a huge resistance out there. When I asked yesterday what the barriers are, one of the barriers is that we are resistant to look at change, all of us are.

And I just feel that it is very, very important that you say there's no technology to do this type of testing. I think there is technology out there. We just have to be willing to pursue it.

You say that there's no evidence, there's no evidence that non-O157 is prevalent in this country. Europe is telling us we need to start looking at this. They're shocked that we're not looking at this. We have got to start moving toward the future. The beef industry as Nancy Donley pointed out, you go back far enough, you're going to bump into an animal, generally a cow, but it could be a pig, but you're going to bump into an animal, and it's very important for the industries that are the ones in charge of the animal husbandry, the leadership there, to start saying we need to start looking at that this is a possibility that boxed beef could be contributing to the continued rates and presence of *E. coli* O157:H7 in our food products.

DR. GOLDMAN: Thank you, Ms. Buck. Any response there?

(No response.)

DR. GOLDMAN: Okay. We are into our break time but we have a few more commenters or questioners behind, so we'll try to get through these quickly and still get a break.

MR. WOOD: I'm Richard Wood with FACT, and I always know when a break time is coming I guess, the story of my life, but I just have a comment and then a question, or a question at least to hear some reflection on.

Dr. Carr, I just want to observe -- well, FACT hasn't really been in the room, and we're certainly thankful for the other consumer groups that have been here in the interim but since our focus has been on pre-harvest and most of it has been on processing and slaughterhouse practices, we have not always been in the room.

But one time we were in the room, we were in the room as HACCP was put together and also then following that, when there was a discussion about what research was going on. And, I recall sitting in the room with players such as NCBA and asking, you know, what research dollars were being spent in terms of pre-harvest?

And then as you indicated, it was a completely different answer, that most of the research and most of the funding was focused on the

processing plant and, and it's heartening to hear that there are funds now, a sizable amount of funds being focused in that direction and the research has been indicated in that regard.

I also appreciate your comment that there's no magic bullet, and that there needs to be a multi-hurdle approach and would be interested in later discussions to learn how multiple interventions could be put together and what kind of impact they might have as the research right now is focusing on one intervention in isolation of another. But we're concerned that any intervention that has been found to reduce pre-harvest O157 prevalence be carefully reviewed to also understand what other human health impacts that intervention might create.

And this goes to the magic bullet concern, but it also goes to things like the use of Neomycin which, of course, is already labeled, already approved for cattle, has a quick withdrawal time, la dee dah, but we also know what we're dealing with in terms of antibiotic resistant bacteria and treating human health diseases. And a couple of years ago

when we all came together to look at some early interventions that were discussed at that time, Neomycin was at the top of the pile. It doesn't require a 12-year approval process. It could be a magic bullet, and it could have detrimental effects.

And so I would hope that any intervention is reviewed in those terms, that is so that we're not causing other problems as we're seeking to address this concern. I don't know if that deserves a comment but you look like you want to speak, Dr. Carr.

DR. CARR: I just want to address that and then I would also ask that Dr. Loneragan as a scientist speak to that, but as part of the approval process in this research, we do look at those things so that we make sure we're not causing any other impact by addressing one.

And we do look at the development of resistance and which items the organisms become resistant to, and we do have data on that.

DR. GOLDMAN: Dr. Loneragan.

MR. WOOD: If that data is published, we

sure would love to have a look at that as well as you go through the process.

DR. GOLDMAN: Okay. Thank you.

DR. LONERAGAN: Yes, I appreciate that comment very much, and certainly when we're evaluating some of these interventions, some of them that are going to evaluation group at FDA, obviously they have to show target animal safety, but they're also going to have to show human animal safety. So the evaluation process, while it's certainly far from perfect, it does try to evaluate some of those potential adverse effects.

When it comes to Neomycin, I think that's a good example of discussion that we would have to have if it ever got to using it, of what risks we were willing to take to achieve what benefits, and that is a discussion that needs to happen in time if that's the case. But certainly I would argue as well as that in those -- through the approval process, they're not ignoring the human safety aspect and having to show human safety.

DR. GOLDMAN: Thank you.

MR. WOOD: And related to that, also another thing I just thought was with the distillers grains and the use of that, there was concern, not only about *E. coli* O157 but also antibiotic use and the presence there as well.

DR. GOLDMAN: Thank you.

MR. WOOD: A second very quick question is Nancy mentioned this earlier about speaking about the design sampling scheme which sounds from a lay perspective, and that's who we are, in fact, we're consumers although we do research and contracting with other groups, a design sampling scheme or some kind of systematic surveillance for O157 prior to the harvesting of those animals seems like a very logical and important step and, Dr. Loneragan, you referred to the need for that kind of surveillance.

How high a scheme do you see and in terms of the barrier question, what barriers might there be to put something in place that's sufficient to measure the impact of any interventions?

DR. GOLDMAN: Thank you.

DR. LONERAGAN: What I proposed was an

opportunity for a macroscheme. It wouldn't necessarily be a micro evaluation of pen to pen, lot to lot, feedlot to feedlot. My suggestion was simply a more purpose driven for a macroscheme to evaluate are we seeing regional changes in prevalence that warrant an intervention or aggressive approach.

Also if we had a purpose driven system, we could evaluate changes in season over time. So if we go to a situation where we have to say did something happen in 200X, we could say, well, based on five years it seems to be similar or dissimilar. That was more the approach that I was taking.

MR. WOOD: Okay. Thank you very much.

DR. GOLDMAN: Thank you. Okay. We have two more in the room. We have one on the phone. So if we can have brief questions.

MR. MAIER: Wolf Maier -- I have a question for -- would currently the basis allow FSIS to prescribe that dirty cattle must not be permitted to slaughter?

DR. GOLDMAN: I want to make sure I understood your question. Do we have the authority?

MR. MAIER: Yeah, would -- allow you to make such a requirement?

DR. GOLDMAN: I don't think we have the authority to prohibit dirty cattle, is that what you said, from coming into slaughter?

MR. MAIER: -- dirty animals must not be slaughtered.

DR. GOLDMAN: I think what we've been discussing here is that the issue that dirty cattle may bring in terms of microbial loads into the slaughter and processing plant, there are interventions in place that are designed to address that. I don't think at this point we have an authority that we can exert that would establish a criteria there. You know, I think it might be open to discussion about where performance standards might be appropriate throughout the process, and I'll leave it at that.

DR. DANIELSON: David, could I just address that real quick?

DR. GOLDMAN: Please.

DR. DANIELSON: You look at the seasonal

aspects of O157:H7, summertime, in our experience and in our observations, O157:H7 is not a dirty cattle phenomenon. It's dust. It's the grit and the gruff. It's the hair. The high manure season, the wintertime, it's not an O157:H7 issue. So the mud scores and dirty cattle, it's other zero tolerance related issues but it's not O157:H7 impacting.

MR. MAIER: Okay. Thank you.

DR. LONERAGAN: I would like to comment as well on the issue of dirty cattle. Some countries have gone, for example, Australia, at the -- Quarantine Inspection Service there, FSIS equivalent, does prohibit the slaughtering of dirty cattle which has turned into basically a disaster that has led to feedlots trying to wash cattle. One feedlot that I was recently at, they spend 10 hours a day to wash 400 cattle which has a lot of labor issues. They can't keep anyone to wash them, but also if we look at the data, the large packing plants here have found that the most effective place to wash them is actually within the plant, once the animals, the hide on side of the plant. So I would reiterate what Dean

just said, that the manure time isn't the O157 risk period, but in that regard, if we want to clean those cattle, the most effective place to do it is once they're in the walls of the plant.

DR. GOLDMAN: Okay. Thank you. And we have one call, a question from a caller on the phone.

OPERATOR: You have one call, Carol Tucker-Foreman.

MS. TUCKER-FOREMAN: My question was answered earlier. Thank you.

DR. GOLDMAN: Okay. Thank you. And we have one remaining question in the room.

MR. NESMITH: David Nesmith, USDA, ARS from College Station. I wanted to make a comment kind of based on Mandy and Guy's data, on we are the pre-harvest intervention strategy business in our laboratory. For years, we didn't know what would be an efficacious pre-harvest intervention strategy, and we had no idea how many words of magnitude we would have to lower the burden of O157:H7 coming into a plant.

Two years ago in Jacksonville, I think both

of you were at that meeting. The packers basically said that they felt confident if we could lower levels of O157:H7 between 10 to the 3, that their post-harvest intervention strategies would be very, very effective.

And if you take a look at the data that you guys presented this morning, we're looking at 10 to the 3, 10 to the 4 log drops, like with chlorate, and recently Tom Besser's (ph.) laboratory published a paper, basically in 2007. It said 96 percent of all cattle with O157:H7 had a 10 to the 3 less, and then the remaining 4 percent had up to 10 to the 6, with a few, what we would refer to as super shedders.

So if you use that data when you're trying to shoot for what is an effective intervention strategy, that would suggest to me that any intervention strategy that can drop O157:H7 levels by 3 orders of magnitude, would cover well over 99 percent of the cattle because we, you know, 1 percent of them would may be 10 to the 6. We're down below 10 to the 3. That's how a post-harvest intervention strategy should work.

Where that becomes important to me is how regulatory authorities evaluate our efficacy data. And so a nightmare for us is to have the Food and Drug Administration be saying you need five orders of magnitude reduction for a product to be efficacious to be improved, when that would be way, way more than what we need.

So we, I think, are starting to put together a target for what an efficacious pre-harvest intervention strategy is, and I think it's imperative that the Food Safety and Inspection Service is a regulatory agency with some pre-harvest authority, have a conversation with the Food and Drug Administration, to let them know what sort of target we really need, what's important, in order to get these products onto the market and speed up the regulatory approval process. And that's one thing I hope would come out of this meeting. Thank you.

DR. GOLDMAN: Okay. Thank you. Yes, go ahead.

DR. LONERAGAN: I appreciate those last comments and I'll make two very quick comments.

Firstly, when we look at the average shedding in fecal samples across a variety of studies, they don't usually shed on average three log. It's usually low, three logs per gram. And so we have to be careful if we set a target of three logs and they shed, we'll never get anything that can meet that.

But setting standards is important and I will say that NCBA, American Meat Institute, working with FDA, USDA and the *E. coli* Coalition, to try and work out what those standards should be and help at least the regulatory agents work through that. So that process is ongoing. Again, it's slow. It's deliberated but sometimes frustrating but I think progress is being made that it needs to be at such a level that it warrants it, as well as we can get those interventions approved. I appreciate the comment.

DR. GOLDMAN: Thank you.

OPERATOR: Excuse me, sir.

DR. GOLDMAN: Yes.

OPERATOR: This is the operator. You have one more questioning cue. Lisa Shine (ph.).

MS. SHINE: Hi, I'm Lisa Shine with the University of Minnesota. I just want to ask a quick little housekeeping thing. I didn't catch the introductions and the agenda change this morning, and I just wanted to find out Dean Danielson's affiliation.

DR. GOLDMAN: He's the Vice President for Food Safety and Quality at Tyson's Food.

MS. SHINE: Thank you so much.

MR. PAINTER: Stan Painter with the National Joint Council. Sorry for getting up late. I was afraid yesterday I stood in line so long that I would be forklifted or drawn by my legs to the microphone.

So anyway, nevertheless, some comments that were made obviously that most of the contamination is on the carcass. That's what Carr had said. Obviously she's never been in a red meat plant where you have high-speed evisceration equipment at 390 per hour and you have fecal material being spread over the carcass. And it was mentioned earlier that the carcasses, the best place to wash them was inside the

plant. Obviously you've never been in a small red meat operation. I have literally been in a red meat operation that I could extend each arm and I could have one arm touching the head and gut table and the other arm with the carcasses coming in behind me. There will be no room for those operations in these small, small cattle and hog kills.

DR. GOLDMAN: Okay. Thank you for that comment.

Okay. We haven't done too badly. We are about 15 minutes behind, but everybody needs a break. We'll take a 15-minute break and resume at a few minutes past 11:00. Thank you.

(Off the record.)

(On the record.)

DR. GOLDMAN: Before we begin our last panel, Dr. Carr has asked to respond to the last comment that was made. So, Dr. Carr.

DR. CARR: Thank you. I just wanted to take the opportunity so that -- right before we left for break, we just ran out of time but to respond to the last comment that was made about my experience.

One, first of all is I have been in large and small plants for about 15 years. So I do have experience in the operations there. I realize that they're both very different and not only by their physical size but what operations can be put in place.

The comment that was made towards the washing of the animals and the hides was one as -- the other information was addressed as we know that not all interventions are appropriate for every plant. Many small plants have data that shows that they do not need to employ that intervention step. That's why we have those options.

What we do want to do is provide the research data so that they can make that choice and we can assist them in finding those options that are effectively going to be able to move that through science-based information. So thank you.

(Applause.)

DR. GOLDMAN: Thank you. All right. Thank you for your attention. We're going to begin our last panel. This will be a little bit different. So let me tell you what we would like to do with this

panel. We have Dr. Engeljohn here. We have five panelists truly from across the spectrum, not a complete farm to table continuum, but we did hear a little bit about pre-harvest and producers and growers earlier, but certainly from production to consumption and then once there is a failure in the food safety system, even to the public health role in finding cases and accurately counting the burden of the illnesses that are caused by this particular pathogen.

So what we've done is we've asked each of our five panelists to provide us a relatively brief presentation or opening statement and on the order of a couple, two or three minutes.

And then each of you in your agenda should have a list of questions that each of the panelists will be asked to address as well as, of course, anything that they may have heard during the course of the meeting that they would like to address in addition to the comments they'd like to make by way of answering those questions.

What I want to do is we're going to have

the panelists just remain up here. I think everybody can see them and hear them fine with the microphones but I want to introduce all of them to begin with, and then we'll just start in with the opening statements.

So starting from close to me, Dr. Tim Jones is an epidemiologist with the State Department of Health in Tennessee and recently named the State Epidemiologist there. He completed his medical school training at the Stanford University and a residency in family medicine at Brown University in Rhode Island. He also did a fellowship in maternal child health there. He practiced family medicine in the underserved population in Utah before he joined CDC's Epidemic Intelligence Service at which time he was assigned to Tennessee, and has been there for just over 10 years now.

He, in his responsibilities as State Epidemiologist, oversees a broad range of programs, not just, of course, foodborne and other communicable diseases but immunizations, tuberculosis, emergency preparedness, hospital infections and environmental

epidemiology. So we're very happy to have Dr. Jones, who is also one of our close partners on FoodNet projects.

Next to him is Mr. Hugh Tyler, who is here representing a relatively small meat processor. Mr. Tyler started in the meat business in 1964 and started his own company in 1974, and he has been under inspection both with the state and then more recently at the federal level, since 1983.

And to his left is Dr. Randy Huffman who is the Vice President of Scientific Affairs at the American Meat Institute Foundation. He joined AMI in January 2000 and manages their food safety research agenda, assists the members of AMI in improving food safety and quality and serves as the liaison between AMI and other scientific organizations.

Prior to joining the AMI Foundation, he was the Director of Technical Services for three years at Koch Industries, K O C H, I should clarify, and responsible for product development and food safety with the Koch Beef Company. And prior to that was Vice President of technical service at Fairbanks

Farms which is in New York State. He has a Bachelor of Science in Animal Science from Auburn University and both a Master's and Ph.D. in Meat Science from the University of Florida.

And next to Randy is Donna Rosenbaum who is Cofounder and Executive Director of Safe Tables Our Priority, also known as STOP, which is the national non-profit grassroots organization representing consumers and victims of foodborne illness whose mission is to reduce foodborne disease and deaths from pathogens in the food supply through policy, advocacy, building public awareness of foodborne risk and providing victim assistance.

Donna has been actively involved in all of these activities for nearly 15 years, and she has personally worked with thousands of victims of foodborne illness. And Donna has a degree in neurobiology from Northwestern University near Chicago.

And then the fifth panelist is Dr. Engeljohn from our Office of Policy, our Deputy Assistant Administrator whom you met yesterday.

And so again we're going to ask, just go down the row here I think and ask each of the panelists if they would like to comment generally from their perspective on something they've heard here or their perspective about what might be done to improve the situation we had last year and to prevent a recurrence.

So I'll start with Dr. Jones.

DR. JONES: Thank you very much for having me. I think that I represent a very, very different perspective than almost anybody who has spoken thus far. I am at a State Health Department which is a non-regulatory agency. I think here's probably a good place to remind people that public health laws are really all state laws. So what diseases are reportable, how they're investigated, whether or not we follow the FDA Food Code, all of those kind of things are really at the state level rather than the federal level which is really the level we've been speaking at.

Many of you have also probably noticed that almost virtually all of the talks that we've heard

thus far in terms of the farm to fork continuum has really been at the farm level, pre-production, production level with all of the arrows pointing downstream.

And, I'm really representing much more the fork level. We investigate human disease, and while many of the agencies and organizations that are speaking, all necessarily speak at the level of, you know, percentages and sampling in large populations of cattle, we deal at the human level where a unit of one is too many, and our threshold for action is basically zero.

All of the data that Dr. Tauxe and other people have discussed in terms of human disease and surveillance really is data from the local and state level, where the diseases are reported. We're the agencies in general that interview the patients, and then report the data upstream where it reaches many of the other agencies.

It also means that when trace backs or recalls and things of that nature are instigated by reports of human disease, much of our epidemiologic

data is what starts that trigger, and I'll also say that because we're not a regulatory agency, we're not a federal agency and therefore not bound by the legal and political restrictions. We're a little bit freer I guess to speak honestly, and can have a little bit lower threshold in terms of the level of evidence that in our mind, you know, are actionable and what might drive a recall or trace back, and obviously there always has to be a lot of negotiation back and forth between the federal agencies that are then using that data to do their much more in depth investigations.

I think it's important to remember that, you know, a lot of the data that you saw yesterday is based on outbreaks, the way that many agencies sort of count the burden of disease. They're the things that get attention. It's very important to remember that of all of the diseases, like *E. coli* O157 get reported to us, 3 percent are associated with outbreaks, meaning that 97 percent, in the huge burden of disease, are 1 or 2 what we call sporadic cases which it's virtually impossible for us at the

epidemiologic level to identify for certain what product those are associated with.

We face a lot of challenges. Yesterday frozen products were mentioned, you know, if there are products that are on the shelf for a long time, why are they distributed, makes investigations very difficult. I think the change in typical vehicles from, you know, ground beef which has been our assumption for many years now to products like leafy greens and fruits and some of the other things that were mentioned, make our investigations much more challenging.

And finally I guess, in terms of being at the fork end rather than the farm end of things, you know, there's a lot of discussion about attribution studies, and each agency sort of has a different interest in terms of being able to attribute disease to particular segments of industry, and when we see disease, we're working the other way, upstream. So we're often very interested in whether the disease occurred because of an error or a malfunction in terms of who cooked it, was it at a restaurant, was

it at home, where does the, you know, where should more education be directed, and obviously we're at the tail end of a very, very long chain of potential interventions that allow the pathogen to be on the fork. So I'll stop there.

DR. GOLDMAN: Thank you. Mr. Tyler.

MR. TYLER: Let me say it's a real privilege to be here today and a real honor. I come to you from the perspective of a very small meat processor and I want to emphasize that very small. I think the people who know me come to visit me at home, they come to see my place, and they just, you know, they can't believe it. They say, you know, this is tiny but I've been in it a long time and I want to bring the perspective today of what it feels like to me as a very small processor and *E. coli* and what we're facing today.

You know, as a very small processor, I am really dependent on everybody above me, and that includes the Agency and my suppliers, you know. The suppliers is a battle when we want to buy the right things from them, and most of the time your supplier,

when you're on my level, is not going to be the packer. It's going to be a distributor. So when we order and something comes in, we may get multiple lots mixed in one and then we're trying to segregate, we're trying to keep up, we're trying to track, and I cannot control *E. coli* from coming in my plant.

What I can do is I can try to control and process as though it is there, and I have to assume it's there and control it as such. And so I've got interventions, mainly temperature, we keep it cold coming off the truck until it goes back on one of my trucks and goes out and it's cold going into my customer.

So we monitor and we record and we control it that way. There's really nothing else available to me, and so that's the discouraging part. Because it's a huge problem, and this one pathogen is the hardest for me to address, but having said that, and you can understand the challenge that this is to me, let me say it's a challenge. That's what it is but it's not instrumental, and things like this meeting, and meeting the people here in Washington, trade

associations, the other processors and the universities and I go to a lot of the land grant universities when I get a chance and try to learn everything I can, all of that together gives a small person like me a chance. Not only a chance to be successful but a big chance is we don't make anyone sick, and that's the goal.

So this meeting, to give my perspective on the meeting yesterday and today, yesterday we heard some things that sounded kind of gloom and doom, and I'm thinking, well, you know, where's the hope, you know, there were some negative things said.

And then this morning, with the panelists that were up here, because my one belief has been pre-harvest is where we need to be trying to address *E. coli* and not necessarily test like -- I see testing as a monitoring tool. I do not see testing as a means to the end of what we're looking for. And this morning, everybody that was talking, was talking about the pre-harvest interventions that are being worked on and in some instances are available now, that seems to be the future.

And so I'll say what I've gotten out of this meeting is I'm really encouraged, and I think we've got this open dialogue is, is the kind of thing we need. Dr. Raymond mentioned not to point fingers yesterday morning. I agree with that, you know, we point fingers at everybody and the small processor on my level points fingers at the big packer and say, hey, this is your problem. It's not their problem. It's our fault. It's all of us, and we can work together to find solutions and I'm encouraged that we can do this.

I thought Nancy Donley made a good point yesterday when she talked about working together and supporting the efforts and supporting however we can, whether it's through monetary, you know, with vaccinations. They were talking about that there would be a cost that would come along with that. I'm perfectly willing to pay more money if I can get a safe product. I think all of us are. And support the Agency, but I'll stop with that.

But that's just giving you some heartfelt views from a very small processor.

DR. GOLDMAN: Thank you, Mr. Tyler.

(Applause.)

DR. GOLDMAN: Dr. Huffman.

DR. HUFFMAN: Thank you, Dr. Goldman, and I appreciate the opportunity to represent the American Meat Institute on the panel today. I'm not sure I can really adequately follow the comments of Tyler. I concur on his statements at the end, that we're all in this together and, you know, we need to work on it collectively.

Going back to comments that Dr. Raymond made at the opening yesterday, we concur that we need stronger initiatives and they are needed. And we agree that old responses aren't adequate anymore, you know. We accept that and we concur.

I'll also point out that as Dr. Raymond said, since this is a public meeting going on the record, and I need to be precise in the comments that I make here, rather than speaking from the cuff, which I guess we'll do during the question and answer session, I am going to make some specific statements and read to you a few things that we believe are

important to put on the public record.

The American Meat Institute represents about 650 members that process and produce meat products and supply equipment and services to this industry. And so, you know, we represent a broad spectrum from both the large producers as well as many small family owned companies.

So food safety is an extremely important issue for us and, in fact, it's been our number one priority for the last eight years since I've been at the American Meat Institute. Food safety research and education remains our top priority.

And we're committed to continuing our cooperative work with each segment of the farm to table continuum, and we're committed to applying all the available best practices that we know work. We're committed to complying with the existing FSIS regulations. And implementing validated interventions at appropriate points in the supply chain and testing raw ground beef components for O157 have proven to be effective measures in the past for controlling this hazard.

But we recognize that we need to redouble our efforts and to identify why we've seen a leveling in our improvement over the past several years and the slight uptake of last year.

We recognize that that's an issue that deserves our full attention and we'll continue to focus on that.

I have two points that I really do want to address. First of all, it's been suggested during the program yesterday that the Agency's considering the expansion of the adulteration policy to all intact beef, and we've heard some discussion regarding this. The American Meat Institute opposes this expansion of the adulteration policy. We feel that changes are not necessary, that they won't address the problem and it's not necessary for us to enhance safety. In fact, it could potentially be counterproductive.

We feel that a properly designed and executed HACCP plan addresses the risk of *E. coli* O157 in raw ground beef and in non-intact beef processing. Existing regulations and policies

regarding raw ground beef components address the hazard that may exist for O157 in ground beef and non-intact products. HACCP plans in grinding facilities should address issues presented by O157 and as we heard from Dr. Engeljohn yesterday, these steps should address the risk with the raw materials, the product during processing at the facility and also the intended use of the product.

These steps could include the implementation of validated interventions on the surface of the carcass, for antimicrobial treatments on raw material is intended for raw ground processing, either prior to the arrival at the grinding establishment or at the grinding establishment or both. Two, implementation of validated interventions on ground beef product prior to or after packaging, and there are some existing interventions that could be use there.

Screening for O157 on all raw material components use in production of raw ground beef and for treatment of bench trim. Just as any other raw ground beef component, should be dealt with and

should be either designated for cooking only or should be treated as any other raw ground beef component.

To discuss the bench trim just a little further, bench trim from primals, since primals are essentially sterile and there's plenty of documentation, that's really a surface contamination issue that we're dealing with, and primals had never been determined to present a risk from O157 prior to this meeting. There are no documented cases of intact steaks and roasts and frankly those products will receive a full thermal lethality at their final point of consumption.

So it's really an issue of the raw materials that are derived that are used in ground beef that is at issue here. And that the trim from primals or the use of primals as direct components in raw ground beef must be handled as any other raw ground beef component. The industry agrees with FSIS that establishments must take steps to minimize the risk of O157 in all raw ground beef regardless of the inputs that may be used to produce that produce.

Industry best practice recommends this. BIFSCo best practices recommends this, and FSIS policies already have an expectation that this should occur.

As I said, there's been no documented cases of O157 illness from intact primals that we are aware of. We haven't heard any reported at this meeting. The products in question that have been linked to a small number of outbreaks have all been non-intact, and declaring O157 as an adulterant of intact beef would be counterproductive we believe and it would divert valuable resources both at FSIS and at industry away from targeting the highest risk products which we believe would be ground beef and other non-intact products.

And as stated during the first day of the public meeting by FSIS staff, FSIS has collected no significant data on the prevalence of O157 or other pathogen on raw beef primals. There is some data collection going on now but no data was presented at this meeting.

There was also a statement yesterday that

there would be no formal risk assessment of this issue of the risk presented by intact primals, and we believe a regulatory decision of this magnitude absolutely must include actual data that supports the decision and a formal risk assessment that gets peer reviewed that clearly outlines the relative risk presented by these products.

My second point, and I'll be as quick as I can, Dr. Goldman, we've also heard that the Agency's considering expansion of the adulteration policy to other non-O157 STECs, and I'll state for the record that AMI opposes the consideration of expanding the adulteration policy to include all non-O157 STECs on beef, non-intact beef or intact. We don't believe that it's necessary to enhance beef safety.

As was stated earlier on the program today, the methods used to control O157, validated interventions and best practices that are in place, and the raw material screening, appropriately address the risk of non-O157 STECs. The antimicrobial treatments that are used are broad spectrum in nature. Things, such as heat, we know based on the

published literature as well as practical knowledge, microbiology, would be effective on other serotypes.

As described in the October '07 public meeting that FSIS held, and again also at this meeting, we've heard that there's currently no standardized method in the FSIS laboratory or available to industry for the routine detection of pathogenic non-O157 STEC. Therefore, we don't believe it's technologically feasible for FSIS to implement such a policy at this time.

We've heard from both Dr. Tauxe at this meeting and Dr. Hagen as well, also Dr. Griffin at the October 2007 meeting, that there have been no outbreaks in the U.S. for non-O157 STECs related to beef, and this recognizes that non-O157 STECs have been a reportable disease for several years in the U.S.

We support the FSIS' approach to collect further data on non-O157 STECs. We think that's an appropriate approach, and we will work collectively with the Agency to understand the risk that these serotypes may present in our products. We have a

goal of achieving food safety and preventing illnesses.

In summary, and I think you pretty much heard my summary, so I'll defer my time, but I appreciate the opportunity.

DR. GOLDMAN: Thank you, Dr. Huffman.

(Applause.)

DR. GOLDMAN: Ms. Rosenbaum.

MS. ROSENBAUM: Thank you. Good morning, and I'd like to thank Dr. Raymond, Dr. Goldman and USDA FSIS for the opportunity to be here on behalf of STOP, on behalf of the consumer community.

I think most of the consumer comments at this conference have been at the microphone. So I welcome the opportunity to be up here and I know I need to be brief. Most of my opinions and comments will probably come out in the question section. So I will be very brief in this introduction.

Our organization was born 15 years ago in the aftermath of the watershed *E. coli,* Jack-in-the-Box outbreak, and I need to add to my introduction that my now college-age daughter's best friend was

the first child that died in that outbreak in San Diego in 1992, and that's what brought me to this issue in the first place. We have a very huge desire to prevent this type of illness from exhibiting itself in the human population.

We have over the years accumulated thousands and thousands of case types and information on *E. coli* disease as well as other foodborne illnesses, and one of the things that we've been advocating for the last 15 years, in which I do see a huge movement in your having this conference here today, and I commend Dr. Raymond for doing this, is that we are very much prevention oriented and we have always felt that Government and industry have been somewhat reactive versus preventive in attacking the pathogen load in the food supply. And I think that at least in reference to this meeting, I see a little bit of a culture change there, and I do see a positive movement in terms of trying to get at something before it really overtakes us. I see movement in terms of trying to put ideas and theories and material out in front of the whole constituent

basis to have an open dialogue so that we can move towards prevention.

And when we're talking about *E. coli* disease, or any of them, if we're talking about O157 or any of the other STEC diseases, these are nasty, ugly pathogens. If you come face-to-face with this, I encourage you to go onto our website and read the stories of the people who have. These are awful, awful, awful, awful disease processes and they really need to be prevented wherever they can.

And in the last 15 years that our organization has been working on this, there has been a lot of progress in the public health side and in laboratory techniques and detection. On the medical side, in terms of treatment, there has been very, very little progress. And right now at this point, other than knowing that certain antibiotic treatments will hasten the event possibly of further future problems and the possibility of developing hemolytic uremic syndrome. When we're talking about *E. coli* disease, there really isn't a lot that the medical community can do to treat these diseases differently

than they did 15 years ago.

So we're really depending upon you and the Department of Agriculture and you in industry to prevent this wherever you can. And as we just heard recently, my co-panelist, one of the points I was going to make also was that most of these diseases present themselves, not in outbreaks, but in sporadic cases of disease. I can't tell you the numbers and numbers and thousands of people we have in our database who had hemolytic uremic syndrome, have been told they have, probably have *E. coli* disease they had bloody diarrhea, but do not have something to link that case to, and we're moving forward with a lot of techniques to get at that in a better way, but we're not there yet.

And so there's a lot of this disease out there that we have to talk about in larger preventive issues, and when you talk about prevention, I think you can't pass the notion of cross-contamination.

Cross-contamination is a huge issue out there. We feel that when pathogens -- origin are evident in restaurants and/or consumer kitchens,

something has gone wrong, and that we shouldn't have this burden to control as much as we do in those environments. So it's up to everybody to prevent as much as possible.

However, you know, the consumer community, there's only so far the behavioral modification can go, and we don't feel that that's going to get at this issue at all. You have to get prevention at the source. We really like the moving forward with pre-harvest controls as much as possible.

But I want to take it even one step further and encourage this Agency in its next moves, past this meeting, to reach out to its other federal partners and to take pre-harvest onto the farm with them because we realize that there are a lot of conflicting interest between the agencies and on farm animal management that really need to be dealt with if we're truly going to get to pre-harvest controls.

So this is a good step in the right direction for this Agency with prevention, talking with its constituency base, but I'd like to see all of us come back and talk with a larger audience at

some point. Thank you.

DR. GOLDMAN: Thank you, Ms. Rosenbaum.

(Applause.)

DR. GOLDMAN: Dr. Engeljohn.

DR. ENGELJOHN: Mine will be brief. I've had plenty of opportunity to identify from the Agency's perspective the issues that we have but I do want to just sort of tie some things together and just have it for discussion this morning. And that is, the Agency did want to have a prospective from stakeholders on where we stand with regards to O157 STECs and non-O157 STECs in terms of the products that we regulate and then what we need to do about that because we recognize that there are vulnerabilities in this system, both within the FSIS inspection system and the policies that we have, as well as what we would consider to be the vulnerabilities within the industry itself.

From that I would say that one thing different today than in '99 or in prior meetings that we had on O157:H7, where we had large attendance for public meetings, there was unanimity within the

industry itself I think at the time on how to move forward and solutions, whereas I think we're at this crossroads now where either through the experience of implementing these programs over the last 10 to 12 years, there's more segregation within the industry as to who can do what and who needs to be more responsive. And I think from that perspective, it identifies that we need new solutions.

So from the Agency's perspective, we're not pleased with the fact that we met the healthy people 2010 goal in 2004 and have since not met it and what we would see would be either the status quo or perhaps some trending upwards as opposed to trending downwards in human illness.

And we think it's now time to step in and look at our strategies and see what we can do to address this so that we can turn this trend around so that we can get back to at least being preventative for public health as opposed to just reacting to the circumstances.

DR. GOLDMAN: Okay. Thank you. As I mentioned, the questions that the panelists will

consider now are laid out for you, and I will point out, too, there's not an opportunity for the audience necessary to query this panel. We're hopeful that all the questions that have been constructed for this will bring out most of the issues, but there will be public comment period for the entire meeting in just a little bit.

I want to start with the first question to just ask any of you, I mean we've heard you, some of you echo comments from other panelists, but is there anything you'd like to further agree or disagree with that you've heard among your fellow panelists just now?

DR. JONES: I'll make one comment. There was a little bit of discussion about the amount of disease that we see from non-O157 STECs and the approach to that and, you know, the fact that there hadn't been any recognized outbreaks in the U.S. I hope that doesn't change, but one of the limitations to that observation is that until recently, in the human population, we've had no way to identify non-O157 STEC or nothing really practical, very few labs

in the U.S. that had the ability to identify them. And with the rapid increase in technology, now with various rapid tests that can detect the toxin rather than relying on culture, as a limited number of states have gotten that technology, we're finding that an increasing proportion of STECs are not O157 and in some states, the majority of STECs are non-O157.

So I think as the detection of those organisms increases, we may see a change in the epidemiology of the disease.

DR. GOLDMAN: Thank you. Donna wants to go.

MS. ROSENBAUM: I'd like to comment on that as well, and my overarching comment is you can't find what you're not looking for, and even though it's been a reportable disease, again it has not been looked for very carefully. The technology just wasn't there.

And just as we saw with O157, being declared an adulterant in 1994, that bold statement led to a lot of technological advance. We feel very

strongly in the consumer community, it takes bold action on the behalf of public health to drive the technology, that you can't wait for the technology, that the technology will come and you have to do certain things with it. Thank you very much.

DR. GOLDMAN: Okay.

DR. HUFFMAN: I'd like to respond to Dr. Jones' point also and certainly recognize that detection methodologies are improving and recognize that it's been a reportable disease for a relatively short time. I don't remember when. Was it 2002 or early 2000s. So I, you know, fully recognize that.

And, you know, if I had a crystal ball, certainly I probably wouldn't bet against the fact that we'll find certain non-O157 STECs associated outbreaks in the future. And, in fact, I guess my comment may be a question to Dr. Jones is that when Dr. Griffin was here from CDC in October, at the public meeting, she did show a slide with multiple outbreaks identified with non-O157 STECs, multiple. I can't remember the number but it was 20 or 30.

In every case I presume that the

attribution from that investigation was relatively accurate, and in every case, it was some other source and not beef. I would like a response to that.

DR. JONES: I agree and, you know, some people in the audience may have better information on that than I do. You know, I think that that sort of open the door about understanding better what the natural reservoirs are for the non-O157 STECs. It's an important question.

MS. ROSENBAUM: Thank you. I'd like to comment on that as well. From what I've read, and I have done an extensive amount of reading on that, non-O157, our organization has been following this for at least the last 10 years, and we have quite a few people within our organization who have suffered from non-O157s, and I believe the literature in other countries, the literature on imported beef coming into this country, as well as looking at cattle themselves, cattle carry this. They carry this by itself. They carry it commensurate with O157. And some of those outbreaks by the way were from dairy products and some of them were from leafy greens

again. They were contaminated potentially from cattle manure. So I think to say that it's not a cattle issue, that we wouldn't expect to find it in beef I think is not being realistic.

DR. GOLDMAN: Dan, just reporting on the fact that were presented at the meeting.

DR. ENGELJOHN: I'm not going to comment on that particular issue but in terms of other things that were said by the panelists, I do want to say that I think it was important, the comments that Randy made from the AMI perspective on recognizing that the use of primal cuts for the intended use of ground beef or for manufacturing trim, is something that the policies do already address and that industry themselves have recognized this as a thing that must be dealt with, and I think a focus on that in the short term, in fact, will be a very critical issue to perhaps address what I would view as some of the vulnerabilities that we have in the systems for these overall approaches that we have in place. So I think that would be very helpful.

DR. GOLDMAN: Thank you. We're going to

move to the other questions now, and the next two questions actually are kind of paired together because they're different. One is about your own stakeholder group and the other is about what you might recommend to other stakeholder groups, but this is really the essence of what we want to get at in this meeting. So if we don't even get past the next two questions, I think this is very important.

So I'm going to ask each of you in turn based on what you've heard, based on what you know, what practical actions can your stakeholder group do to contribute to decreasing foodborne illness related to O157 over the near horizon because keeping in mind, as we all know, we're entering this high prevalent season in cow and probably in human illness as well, and we really want to be able to attack that. So go ahead.

DR. JONES: Yeah, I think there are a number of things. I can only mention them briefly.

First, I think that standardized investigation of outbreaks across the United States and across states is critically important, and I

think it's no accident that you heard yesterday that 8 of 11 recent outbreaks were recognized and the investigations led by FoodNet states which represent only 15 percent of the U.S. population.

That's no accident. FoodNet states are blessed with a lot more resources and capacity than other states, but can do the math in your head to figure out how many outbreaks that are occurring out there in the other 85 percent of the population that just aren't investigated or recognized.

I think that not surprising anybody, maintaining an increase in that capacity depends on funding, and the funding move for FoodNet states and non-FoodNet states dedicated to outbreak recognition and investigation has been going down, not up.

There are programs like PulseNet that are threatened with market reductions and virtually all of the multistate outbreaks which have recently been recognized are dependent on detection through PulseNet, DNA fingerprinting. If anything, we should be adding the O157 STECs to it, not decreasing the capacity in any way.

Lastly, I guess sharing data quickly between our agencies, someone mentioned yesterday that you all have lots and lots of databases but very few of them talk to each other, and it's a shame that there are data in regulatory and non-regulatory agencies and in the industry that we can't all benefit from.

DR. GOLDMAN: Okay. Thank you. Mr. Tyler.

MR. TYLER: Well, coming from a very small processor's view point, I think the immediate thing that I try to tell people when they call me, and I would say this to anybody, you need to have a good testing program, write it in your HACCP plan, believe in it and do it even though I said before I don't believe there's a means to the end, and I don't, because it's a real needle in the haystack kind of thing, but it's what we have to work with right now and we need to utilize it as much as we can.

The major thing, test it, hold your product. When you test, hold your product. If Agency pulls a test, hold your product, and on both of these questions, I'm giving the same answer.

Thank you.

DR. GOLDMAN: Thank you.

DR. HUFFMAN: I actually did my homework, Dr. Goldman, so I had a response to the first question as well. I'll do that real quick, and I just wanted to say that I agree with Donna on a couple of things.

First of all, the idea that we can modify behavior of consumers and just tell them to cook their ground beef to 160, I think Dr. Raymond is one of those -- responses, that just doesn't work. We need to continue education of consumers, but we recognize that that is convincing every consumer to use a digital thermometer when they cook ground beef, is probably as difficult as trying to implement pre-harvest intervention. So I agree with you there.

We have to recognize consumers use our product in a certain way, and we need to develop programs that address the risk related to that.

Secondly, I strongly support the comments made by Donna and other consumer groups about supporting pre-harvest intervention approvals at the

appropriate agencies.

To address this question, number 2, what can we do, our segment, certainly there are multiple things we can do and I haven't prioritized that list necessarily with all of my various stakeholders but a couple of things that float to the top and are things that we have been talking through our BIFSCo organization for the last year or more. And probably the most important thing that we recognize that I think Dr. Carr mentioned earlier is trying to get what we believe to be best practices or good manufacturing practices at the various steps in the process, widely distributed, widely, you know, increase awareness among all facilities and try to provide training assistance to companies such as we heard about yesterday from one of the small manufacturers here.

As was mentioned earlier, there are experts available on each of those best practices that can answer questions. Trade associations are also a good resource. So we are focused on trying to improve our outreach.

And secondly, the other thing that floats to the top based on what I heard at this meeting that our segment needs to address, is what Dr. Petersen presented yesterday with respect to the findings of the FSAs. The common findings of those recent FSAs are -- you know, our industry, we need to address those things. We need to understand what we can do better to comply with regulatory policies.

DR. GOLDMAN: Thank you. Donna.

MS. ROSENBAUM: Yes. Thank you. Speaking more as a consumer advocate than as a representative of consumers per se, as we just heard, consumers as a group, there's not really much consumers can do at the end of the food chain and attempts to do that really have not been met with very much success.

So I'm going to speak from the viewpoint of consumer advocate groups and say that we feel we've had a larger and increasing voice and opportunity to sit at the table and engage in discussions such as this, and we truly appreciate that. We feel we do have a lot to say.

Our organization, in particular, keeps a

pulse on what's happening out there since we are a grassroots organization, and I would just make an overarching comment just that the attitude in the consumer community today is a little bit different than it was 15 years ago, pre-Jack-in-the-Box, and consumers respond to what's going on out there in a much, much different way, and I think we're a lot faster. I would just caution on everybody to be very careful about consumer confidence and trust in your products, and to not jump the gun and go out there and battle against regulatory objectives that an agency wants to do just because it's been the thing to do in the past. Just be very careful on how you handle that because consumer confidence in your product and in your industry is very, very tenuous.

We hear it all the time on our help line. Consumers call us all the time, why are they doing this? Why are they doing that? We don't just hear from victims. We hear from concerned consumers nationwide, and there's a lot of topics that they get very irritated about. So just a word of caution. Thank you.

DR. ENGELJOHN: From the FSIS perspective, being the stakeholder here, I know that there is confusion on some of the policies we have with regards to O157 in particular, which components are identified as primals that would be used for grinding that should be included in a testing program that likely are not being tested now. And I know we can improve and enhance our policies to be more specific and clear on that.

So I think that would be one thing that would help, such as information to our field force who we depend upon to collect samples for our verification testing program.

And then the thing that I think, the short-term, practical thing that others here at the table are doing is -- it was mentioned earlier in the morning panel that I know it's an industry led effort and that is the CDs and guidance on N-60 testing, I think would be extraordinarily helpful. Anytime that there is a movement towards consistency and uniformity within the industry as a whole, it helps tremendously, and I think that that would be

something that would be very good. I'm anxious to see it, to see what it does say, and then in talking with Dr. Kelly earlier, if there's the opportunity for the Agency through our efforts, our outreach efforts in her program to distribute that, that would be something that if we can sign onto that and do that, we also think that that would be helpful in that it's developed by industry, not necessarily by FSIS, that's probably a helpful thing. And we'd like to partner on that as well. We feel that's a very positive step.

DR. GOLDMAN: Okay. Thank you. Why don't we just continue down this way with Donna. We're now on the third question. So this is your chance to tell others here or even not represented on the podium, a specific short-term action that you think would be beneficial and why you think it would be helpful and then maybe perhaps any barriers that you might see from your perspective.

MS. ROSENBAUM: A short-term solution again for consumers is difficult. I think we just need to as a group continue our voice in advocating for

preventive measures. We need to make sure that all stakeholders understand our position, and I think something that has come out of this meeting is a greater understanding of the necessity for getting together and doing this more often, not just at these meetings, but having open discourse as we are not adversaries. We are in this altogether trying to prevent this in the food supply. And I know on behalf of myself, most of the consumer communities will be very happy to explain our positions or explain our opposition to certain things or acceptance of certain things. If anybody in industry would care to call us, we would be more than happy to respond. And I think it's a shame that we only come to these meetings have the short opportunities to interchange.

So I welcome the opportunity and I think a lot of the other consumers would as well.

DR. GOLDMAN: Okay. Thank you. Do you have any other suggestions for any of the stakeholders represented here for actions they might take?

MS. ROSENBAUM: For actions they may take, I would just suggest that they keep a very open mind. We don't know everything. There's so much of this that is out there that is not outbreaks. We're just on the tip of the iceberg of understanding where this is all coming from. So we need to keep a very open mind.

DR. GOLDMAN: Okay. Thank you. Randy.

DR. HUFFMAN: A couple of things. This one's for you, Dr. Goldman and Dr. Hagen, as well. You mentioned the Agency in 2007, I guess the Applied Epi Division investigated 37 potential illness clusters associated with beef, 37 illness investigations. We would be, I think our industry would be aided if we understood the learnings from those investigations at the appropriate time, afterwards, in some summary form, so that we can evaluate whether or not in those particular situations where we know illnesses may have occurred, were best practices followed.

First of all, did that implicated facility comply with all the regulatory policies which are

required by law? That's question one. Secondly, did they have an understanding of the industry best practices under good manufacturing practices, and were they implemented properly?

And those were the kinds of questions that I think would be helpful as a retrospective look in these investigations and certainly all 36 I guess didn't result in recalls and maybe, you know, there's a subset of this where there is useful information that could be shared because right now there's not, as far as we know, there's not a formal way for the industry to learn about what's occurred. And to me, that's probably where the most valuable data may reside is when products actually may have been associated with illness.

So that would be one suggestion.

DR. GOLDMAN: If I respond to that.

DR. HUFFMAN: Yeah, go ahead.

DR. GOLDMAN: I will tell you that your point is very well taken and further will let you know that the Agency is in kind of the final stages of issuing a directive which, of course, is for our

own personnel but which will be widely read about how we conduct investigations, a part of which will not only be out thinking about how and when to take actions, but also will cover issues like after action reviews and final reports and the appropriate venues for sharing that information.

So you can look forward to that, and it might help with some of your concern.

DR. HUFFMAN: Great. The only other comment I had was again reemphasizing the importance of getting your sister regulatory agencies to have a sense of urgency about addressing the need for pre-harvest interventions. That would include both FDA CDM and APHIS CBB. I don't think we have any of those representatives at this meeting which I think is unfortunate. If there is someone here, I apologize but I haven't seen any.

DR. ENGELJOHN: This is Engeljohn. If I could just add onto that, that I also think that's an important thing that we can do. I mean that's part of our responsibility, and the Federal Government is to walk across our sister agencies lines and have

those communications. I would say sitting here, I don't really know what are the issues, and so I think a dialogue obviously would be helpful, but we certainly are willing and able to step in because we do, we, in particular, agree that any incremental reduction in risk is worth the effort as opposed to going for the full vein and get a maximum benefit. Any reduction would be a positive thing to add onto the tool chest of communications.

So if we can be better informed about what you think the issues are, that too would be greatly helpful.

DR. GOLDMAN: Okay. Go ahead.

MS. ROSENBAUM: Just a quick comment and a quick request based upon that comment that Dr. Engeljohn made. When you do reach out to the sister agencies, it would be greatly appreciated if you could make that as public a forum as possible and not be done behind closed doors. Thank you.

DR. GOLDMAN: Thank you. Mr. Tyler, do you have any suggestions for actions that others may take?

MR. TYLER: Well, yeah, and I'm not sure how it's going to be received. It may -- but in talking about getting the sister agencies working together, I totally agree with that. I think we're going to hinder ourselves if we don't. You know, we need to be talking all stakeholders and everybody.

And I think about down below me, in the chain, we have the retail level and we have people processing meat on the retail level that none of this is available to, and so there's a sister agency through FDA that they need to be part of this. And I think that's an immediate need. Thank you.

DR. GOLDMAN: Thank you. Dr. Jones.

DR. JONES: I guess my primary suggestion just has to do with encouraging rapid and thorough and uniform investigations of disease and things that sort of slip through the cracks. That's going to require very rapid communication amongst sister agencies. There are a lot of reasons for delays but I think they can be relatively easily fixed, and it's incredibly frustrating both for the victim, for us and certainly for industry if we are trying to do an

investigation about something that has occurred a month ago, and that's a frustratingly common occurrence.

DR. GOLDMAN: All right. Thank you. Okay. I'm just going to open this next question up to any of you who might want to share any personal lessons learned, successes or else recurrent barriers that you want to share with the audience here that might help us move forward. That's question number 4. Anyone want to respond to that?

DR. ENGELJOHN: While they're thinking, this is Engeljohn. I would say that a personal experience here that has been insightful and one for which we constantly are learning or at least I am, is that in dealing with O157 as an adulterant, at a time prior to the HACCP regulations issuing, it created the necessity to look at what the HACCP process is able to do or is expected to do and in particular with raw products, where we have an adulterant which is a unique situation.

And so I think from that from the perspective of lessons learned and just issues over

time, it's taken a substantial amount of time for everyone to understand how to implement HACCP in a raw food system where it's much easier to do in ready-to-eat operations, but that is required that there be great understanding amongst all stakeholders involved in terms of what is the minimum expectations for either eliminating, preventing or reducing to an acceptable level, and the Agency's defining that acceptable level as being undetectable, and we have since then established that the N-60 testing process is one for which we can use as a standard to move towards.

But in any case, just implementing a nationwide regulatory system on raw products has been quite enlightening and I think is something that we always have to attend to as we think about going forward and how we would address expanding the policies.

DR. JONES: I hate to harp on the resource issue, but I guess it's been very clear to me in the last couple of days that the responsibilities that USDA, also FDA and other federal and state agencies

are expected to do is just unbelievable and unrealistic given the funding and the support that they get, and as you all know, you know, federal agencies here can't go out and lobby to get themselves more resources very easily. So I think one of the consumer groups stood up at the mic yesterday and said, you know, what can we do? I know that many of you do a lot of lobbying and contacting influential people for increased financial support for these agencies, and that's a critical function that I would just encourage you to keep doing, and it's not going to come from state legislatures. It's going to have to be at the national level.

DR. GOLDMAN: Anyone else want to address this question?

(No response.)

DR. GOLDMAN: Okay. Well, we'll move to the next question, and we have addressed this question in part through the course of the day and a half, but are there any other gaps in our knowledge for data that we could fill and especially practical gaps that could be filled that might help us

ultimately reduce O157:H7, and if you can identify what they are and how they might help, that is to fill those gaps, let us know that, too. Anyone have -- Randy.

DR. HUFFMAN: Well, just to reiterate the question that I asked from the microphone yesterday, with respect to the risk assessment that was conducted early in this decade, it seems given the significant amount of new data that we have, more reliable data than what was used in that first risk assessment, it seems that, you know, redoing that and understanding the relative risk of various product categories would be useful.

DR. GOLDMAN: Okay. Donna.

MS. ROSENBAUM: Yeah, I just wanted to reiterate again the necessity for pre-harvest, but pre-harvest not necessarily meaning just within the scope of what this Agency and the beef industry can do when cattle approach the slaughter facility, but try to take it out of that box and just look at, like Nancy said at the microphone, we deal with diseases from cattle that come in water supplies, that

contaminate lettuce and crops, that get into reservoirs that people swim in, that it affects the human population in ways other than just beef.

And the reason I mention this to this group is I know that's not necessarily directly under your control. However, in addressing an approach to a societal problem, I think we have to step out of the box and for every incremental level include production, when you take from the farm to the table, I think as you go through that continuum, you lose the ability of control at each level. You have a much greater capacity to control it at an earlier level than you do once it's going through that system. So I would encourage again that collaboration early on with sister agencies and other organizations, it can get to on the farm practices that would reduce the load coming in, in the first place, and making those interventions much more practical. Thank you.

DR. ENGELJOHN: This is Engeljohn, and from my perspective, I don't disagree at all with what Randy identified about the risk assessment, its

updating and using that to inform us where the mitigation, in fact, would be perhaps most beneficial and which products perhaps present that greatest risk. So I think the Agency accepts that that's an area where we need to focus in and move forward with, but I would say that the one thing that we do probably need now because of anticipation of where we might end up in the future is that we really don't have a good picture of the prevalence of O157 or non-O157 or O157 STECs on cattle, coming to slaughter before any interventions are applied or at least are applied in a meaningful way, such that we can really know what is there now and then once these pre-harvest interventions become either more widely used or available, that then we can really measure some success that's occurring at that point.

And so because we don't have the interventions from pre-harvest that are necessarily effective or widely available, now would be the time to at least initiate that kind of information either through the industry, the Government or some joint effort there so that we can really have a good

picture of what's coming to slaughter.

DR. JONES: I guess I would just follow up on that to reiterate the point about encouraging development of reliable and rapid diagnostic testing, both on the industry side and the clinical side, that waiting three days for a culture doesn't do anyone -- is very frustrating and the faster that you recognize a problem, the more effective your mitigation can be.

DR. GOLDMAN: Mr. Tyler?

MR. TYLER: Well, listening to everybody and what they've said, I agree with all of them. I think it's a collaborative effort and like Donna said and Randy said and Dr. Engeljohn and Dr. Jones, we need to work together on this and the more data we can get, the more we can advance and the better off we're all going to be. It's a joint effort.

DR. GOLDMAN: Okay. Donna.

MS. ROSENBAUM: Another comment just in summation, I'd like to add that our organization is extremely concerned about the lack of data and control we have. As Nancy mentioned at the microphone yesterday, regarding imported products,

coming into the United States, with potentially other pathogens that what we look for here, that are then mingled and not visible to the American populace when it reaches their table, that people don't know that they're eating product from multiple countries when they buy their products, and I believe that's a huge gap. If we have 22 percent rate of imports into that product category, I think we really need to look at the pathogens of origin in those countries that are providing that product, look very carefully at them and make sure that we are screening for those.

DR. GOLDMAN: Thank you. Any last comments on data or knowledge gaps?

(No response.)

DR. GOLDMAN: Okay. The last question for the panelists to take up are whether you can identify any additional ways that stakeholders can improve their collaboration and communications. We certainly have heard already a call for more meetings like this, larger meetings. There are some perhaps missing participants in this meeting. We've heard that as well, but do you have specific suggestions on

next steps for our agency to perhaps host by way of things that might improve communications and collaborations in particular? Let's start with Dr. Jones.

DR. JONES: Again, I come from a little bit different perspective than others, but I think a lot of the collaborations on the disease end have already been initiated. We heard yesterday about OutbreakNet, about CIFOR, Council to Improve Foodborne Outbreak Response, and several others, all of which are multiagency collaborations and it's encouraging to me but there's still a long way to go and particularly the involvement of industry and consumer groups in those efforts is something that could use a lot of improvement.

DR. GOLDMAN: Okay. Mr. Tyler.

MR. TYLER: I think communication is so critical and the best way to reach the small and very small meat processors, especially very small, is going to be through state and national trade associations. I can tell you now, they're going to feel intimidated to come to somewhere like this and

they won't but they will come to a trade association and they'll sit and they'll listen. And if the different agencies would work with the trade associations and come to them and the consumer groups, too. I mean it would be good for consumer groups to come to the meetings and have, you know, and let some of the very small processors see that, you know, we're all just people because right now I can tell you they think this is boogie land up here. (Laughter.) They're scared to come to this place.

DR. GOLDMAN: Thank you. Randy.

DR. HUFFMAN: I guess I would make one suggestion that we all keep in mind as we continue to communicate on this challenge that we all face, I think, you know, to cover it briefly, as I've been in boogie land here for the last eight years, in this role, I've seen communications improve between various stakeholders in my own experience. So I think that's great.

But one thing I'd like to emphasize for all of us to keep in mind, it takes off a comment that Nancy Donley made yesterday with respect to

cost, and many of the things that we've talked about here with respect to new Agency regulations or policies, and reactions that the industry must take to those policies, also with respect to any additional interventions that might be put in plant, and the interventions that have been put in plant in the past, all have cost. Testing as we do it today has an enormous cost. We estimate, and this is a very, very rough guess, but -- well, let me just say hundreds and hundreds of thousands of tests for O157 are conducted every year. We've estimated it's approaching a million samples a year by industry. It's an enormous cost.

We talked about pre-harvest interventions that are potentially effective, but they won't come without a cost, and so I guess what I'm encouraging, I'm not saying that that's the primary objective is to only formulate our policies based on a low cost objective, that's not what I'm saying. I'm just saying that was communicate on how to solve this problem, we need to keep in mind that each of these actions do come with a cost, and I guess that is, you

know, part of the reason for the particular comments I made earlier with respect to our objection to the simple declaration of non-O157 as an adulterant, an expansion of the policy on intact products.

We're not convinced on the data that we've seen that those actions will have an effect on the issue and we know, as business operators, that they will come with very large costs. We don't know how much but I think my point here is that as we have communication about solutions, we need to keep in mind that these solutions don't come free.

DR. GOLDMAN: Thank you. Ms. Rosenbaum.

MS. ROSENBAUM: I'm glad to see that there was such broad participation in terms of attendance in a meeting such as this. I'm a little disappointed that we haven't had -- well, we've had a lot of opportunity to open mics but we haven't had as maybe open a discourse as we can with, you know, outside ideas perhaps flowing as readily as they could have, picking outside the box and so forth, and I think, you know, consumer groups and consumer representation in this room is maybe 10 percent of the total

population, and I think it's probably been about 90 percent of my time, other than the panels, and I think that's a shame because I think we'd like to hear from more of you around the room. That's one comment.

The other comment is that in talking about long-term solutions and collaborations, briefly different panels brought up throughout the last couple of days, there have been mention of, you know, there's been mention of imported food safety in different prevalence levels and different countries of different Shiga toxin *E. colis* and different attention to the adulteration issue in different countries as well. So perhaps as we grapple this and kind of move forward, we shouldn't be so insular to just think that we need to solve this all on our own. This is an increasingly global market that we're living in, and perhaps we need to look at what some other people are doing. So as we move forward with future meetings, I think it would be encouraging to see more international participation and input into what we're doing and ideas coming from outside of

what we've thought of ourselves.

DR. GOLDMAN: Thank you. Dr. Engeljohn.

DR. ENGELJOHN: Well, the issue for me really is opportunities just to have the dialogue and if these large public meetings inhibit certain sectors from participating, we do have to find ways to get at that, and I know the Agency particularly is focused on outreach to small industry to address issues and if the issue is more technical meetings, that do have representations from consumer groups, industry and Government there, or whatever that mix needs to be, as opposed to just being a technical meeting or an interaction that's just with one particular stakeholder, I think anytime we can find ways to increase the stakeholder participation in any meeting that we have, it's a good thing. So I think we're always open to suggestions to how we can improve that.

DR. GOLDMAN: Okay. Thank you. I'd like to ask you to help me thank the panelists for their thoughtful comments.

(Applause.)

DR. GOLDMAN: And they can be excused from the podium if they'd like. We're now going to transition to our public comment period. There were sign up sheets. We only had one commenter sign up. However, of course, this is the opportunity for any of you here to make a statement for the record that, of course, will be transcribed and will be part of the Agency's considerations in addition to whatever else has been presented at this meeting.

So we have Felicia Nestor who was the one who signed up. So you can begin.

MS. NESTOR: Thank you. I actually didn't even sign up. I asked them to sign me up. So it looks like they did that.

Felicia Nestor, Food and Water Watch. First, I didn't say before any of my other comments because I was trying to rush, I really appreciate the Agency putting on this meeting. I appreciate the Agency bringing up this issue for public discussion, and I also really appreciate all of the Agency people that tried to help us get information prior to this meeting.

Second issue, you know, Randy Huffman was just at the end of his comments saying something about, you know, we can't forget that there's a cost to this and, you know, I'm more than agree with that. I think we've got two problems here. We have the problem of the pathogen, and we also have the problem of the economics of dealing with the pathogen, and I think more discussion on that, the better. I went to the MMA conference and I heard a lot of the meat processors talk about what they have to do to try to, you know, promote food safety and, you know, my heart really went out to them. It's difficult and from what I'm hearing, and I don't know, I'm not an expert on this at all yet, but from what I'm hearing, you know, the beef industry is having a rough time right now, and margins are shrinking and so perhaps some of this problem is, you know, who's going to get caught holding the hot potato. You know, is it going to be the slaughter that has to apply the intervention to the primal or are we going to hold the grinder responsible for applying the intervention after it gets into the grinding plant. I don't know if

there's a scientific reason for one or the other, but my guess is that economics come into play pretty significantly and if I were on one end or the other of that, I would probably have a strong opinion.

You know, I appreciate the Agency taking action in this, but to me it's a little bit arbitrary that we're saying 2007 demonstrated that efforts were ineffective, you know, because we had 29 positives, but we could say that in 2006, with 20 positives, we could just all relax because everything was effective. I really hope the Agency, once we get back down to 20 positives does not, you know, put this on the back burner.

I thought the reason for this meeting was, you know, what happened in 2007, can we put our heads together? What the heck happened there? From what I got from Dr., and I'm just going to mispronounce just about everybody's name, Dr. Loneragan, there was no evidence of significant increase in the cattle. So we have to look at what's happening in the plants. It looks like we may have had a previous inadequate focus on bench trim. The question, were primals more

contaminated in 2007 because of the way things were handled? Did something that there was a decreased focus on slaughter and the dressing procedures, and this is why I focused on the N-60 sampling.

The first thing, Dr. Samadpour said that, you know, not all sampling is equal and FSIS inspectors don't watch the plants do the sampling. And what his data showed was that a plant can say, yeah, this is what our evidence shows but if you really do a thorough investigation of N-60, you know, it's a much higher percentage that were contaminated.

As I understand the history, from 2003 to 2007, the large industry was testing about five combos using N-60 and they were diverting the whole five combos if that was positive. As I understand it, in 2007, some have started testing one combo, and if that is positive, they divert that.

Now that's, as I understand it, accepted sampling and the danger that the Agency was saying, that N-60 gives us a 95 percent positive rate of finding the pathogen if there's 5 percent in the combo. I never heard the Agency say there's 5

percent in the meat but, you know, from what I've heard, they said .2 percent last year. Let's say 1 percent, the Agency just gave me the statistics this morning. If there's 1 percent in a combo bin, there is a 45 percent change of finding it if it's positive. That means you are less likely to find that it's positive if there's only 1 percent in the combo. If we're talking .2 percent prevalence rate which is what the Agency says, there is about a 90 percent chance that you will not find it in the combo bin if it's there. So, you know, yesterday I was asking, you know, why N-60, why N-60? And some of the answers I got were, well, it's practical, you know, it's the best the industry is doing at this point, you know, but I think we need to understand it may be practical, it may be the best, it may be the only economically feasible thing we're doing right now, but it's still a 90 percent chance you're not going to find it if the combo is positive.

Dan told me today I am not understanding the way the program works. I asked the Agency on February 28th about this. I submitted questions.

I'm really trying to understand how this works, and if it is not acceptance sampling. But what I got back was, you know, you test the single combo. If it's positive, it goes out to consumers. Dean Danielson said 400 to 500 combos per day in a large plant. Dr. Samadpour says up to -- let's say in a bad time 20 percent of those could be positive. If to whatever extent N-60 is being used as accepted sampling, that is a heck of a lot of potentially positive product going out to consumers. So that's all I'll say on N-60, and I just have one other point to make.

I noticed that the Agency stopped doing *Salmonella* -- well, decreased *Salmonella* testing in ground beef at least in the large slaughter plants in 2003. About two-thirds of the slaughter plants were not tested for half or more of the full last four years for ground beef. Some of them were tested for steers, heifers, cows, bulls, but there was a radical decrease in the *Salmonella* testing in ground beef. The Agency seems to believe that *Salmonella* testing is an effective way of boosting food safety practices

in broiler plants, and I think the Agency -- does the Agency believe that the decrease in *Salmonella* testing of ground beef could that have had an impact? Thank you.

DR. GOLDMAN: Thank you for your comment. Yes, sir.

MR. STEVENS: My name is Shawn Stevens, a food safety attorney from Gass Weber Mullins in Milwaukee. First of all, I want to thank everybody for a fascinating discussion over the last two days, and before we leave today, I think it's absolutely imperative that we remind ourselves and we not let ourselves forget, despite the issues that we're grappling with, that we do have one of the safest food supplies in the world, and that's in no small part to the efforts of consumer advocacy groups, our researchers, our FSIS inspectors, our regulators, and most of importantly, industry itself.

And when we look at industry, we look at a system, a food safety system of hardworking Americans feeding Americans. And we've seen incredible success over the last 10 years, despite the fact, as one

commenter put it yesterday, that sometimes industry is being asked to do the impossible because of what we know with respect to bacterial loads at the farm level.

One of the reasons why we've seen success, despite this, and I think it's very important to remember is that industry, whether we're talking about the larger packer or the small processor represented by Mr. Tyler, is that industry, in addition to feeding American consumers, is also feeding themselves and their own families.

So as we move forward and we grapple with these issues and we ask these questions, I think it's very important that we keep in our minds, and we not let ourselves forget and frankly I think we do need to congratulate the industry for making our food supply one of the most plentiful, one of the most affordable and one of the safest this world has ever known. Thank you.

DR. GOLDMAN: Thank you.

MR. LOVETRO: Dave Lovetro with Eka Chemicals. Just a follow-up on a couple of comments

I heard from the last panel. Several of the panelists mentioned the idea of perhaps an open form, a transparent forum, where we could have all the stakeholders, science, business and, of course, regulatory who we think is perhaps underrepresented today. I would certainly affirm that. I think that the regulatory people need to hear the great information that was presented at forums like this and I would encourage USDA, FSIS, that that's the appropriate vehicle to get something like that rolling with the sister agencies. I think that's a very important piece.

I can tell you that what you hear from people like FDA and perhaps CDM, is that they certainly are very well versed within the law and with their guidance on how they deal with formal and strict pharmaceuticals and drugs in feed additives for example, which have actions on the feed.

This is a unique situation with many of the pre-harvest interventions. You're talking about in some cases dealing with an organism inside the animal gut which we need to remember, even pathogens inside

the animal gut don't make the animal sick. It's not an issue of structure function. So it's not the true pharmaceutical drug claim that they're used to handling.

They certainly need to hear a wide spectrum of voices. They need to hear the voice of Government who needs the toolbox to get the job done for food safety. They need to hear the voice of industry who will tell them what their needs are in terms of the efficiency of how these products will work, and they need to hear the voice of consumers so that they realize the importance of the problem that we're dealing with here.

The last point, just to follow up on Donna Rosenbaum's comments, she would have liked to have heard more in terms of new ideas and such. I think the public forum is an important aspect of that as well. The reason I say that is because I don't believe that as a person who makes his living in the world of business development which is trying to develop products that I'm going to try to sell five years from now, I don't believe that this problem

will be eliminated by science or technologists. I think there's plenty of science and technology out there but despite the fact of trying to move some of the good interventions through the pipeline that we heard this morning, you want to make sure that you continue to draw people from industry and new sponsors with the new products as well. But those people will not necessarily come forward if they're facing a regulatory environment which is going to limit the probability of success of getting to the end gate. So I ask everyone to keep that in mind as well.

And again, I congratulate USDA and FSIS for a really stimulated discussion.

DR. GOLDMAN: Thank you. Let me pause herein the room for a second and see if we have any public comments from phone participants?

OPERATOR: Once again, if you have any questions or comments, please press star 1. One moment please. If we have any questions or comments from the phone line, please press star 1.

(No response.)

DR. GOLDMAN: Okay. Thank you.

OPERATOR: The first question comes from Jeannie Meehl.

MS. MEEHL: Hi. Mine is in regard to the information because -- through the phone, I really appreciate you guys putting this on and letting us call in and hear the thought, but because of the background noise, I'm wondering is this going to be posted on the web, in case I misheard something, I can go back through and reread it?

DR. GOLDMAN: Yes. Thank you. The entire transcript of this meeting will be available probably in about two weeks and will be posted on our website. Thank you.

DR. GOLDMAN: Any other public comment from the phone participants?

(No response.)

DR. GOLDMAN: Okay. We'll go back to the room then.

MR. CUSTER: Carl Custer, and I'm unaffiliated, but I did retire from FSIS last year,

after over three decades of service.

I have a comment and a proposal. The comment is in the case of Butts v. the American Public Health Association, the Judge opined that the American consumer is not stupid and they know to thoroughly cook their meat products. Over three decades of epidemiology have certainly poked a hole in that Judge's opinion. And not only that, but they did ignore cross-contamination in kitchens.

A proposal, premise number one. The scientific literature has pointed out that there are certain feedlots and dairy farms that are carriers of O157:H7. Academics have also identified, and ARS, have identified certain interventions that may work.

And then the next premise is that through *Salmonella* performance standards, there are some slaughter establishments that are optimal, do not have a *Salmonella* performance standard failure, and they have not had any O157:H7, but there are other establishments that are sub-optimal. The proposal is we could test animals anti-mortem and identify the dairy farms and the feedlots coming into those

establishments that are carrying the O157:H7, either testing fecal cavity, hides and fecal samples. And then those animals in those establishments would be passed for cooking, to be O157:H7 carrier animals, in the same category as brucellosis, tuberculosis, that secretaries have determined in the past that consumers should not be exposed to. It would lower the value of the animals from positive farms and feedlots going to those establishments that are sub-optimal. It would reward those slaughter establishments that have been optimal because they could take any animal and produce fresh beef from those animals. It would be a cost and as Randy Huffman said, you know, none of these actions go without cost but inaction also has a great epidemiological cost.

DR. GOLDMAN: Thank you.

MS. DONLEY: Nancy Donley from STOP, Safe Tables Our Priority. I would just like to say I think that the benchmark where we could really take a look at, are we doing the job or are we just maintaining or are we getting better, is in the

foodborne illness data.

We've been flat for the last couple of years on the incidence of *E. coli* illness, and I think that's a big black eye on the Government and industry that we're maintaining the status quo and not doing better. 2007 I think you each got dealt a double black eye by just the enormous number of recalls, foodborne illness outbreaks and I have to applaud the Agency here, the USDA, for saying we're not going to just stand here and take this black eye and let this go on but by going forward and creating initiatives being progressed, in their initiatives, to say, this isn't good enough. We're not getting the job done, and therefore looking to be proactive in protecting public health and safety by moving forward and declaring non-O157 STECs adulterant, by moving forward in saying and looking at expanding the definition of adulterated product to include intact product, because frankly what's happening right now just isn't having any impact on foodborne illness and disease.

I have to say I'm really disheartened,

disappointed, by the extreme pushback I have been hearing by industry on these new initiatives that the Government is trying to put forward. I think that there just deceiving themselves by thinking that they can just continue along as usual and hold their breath until we don't have another huge Jack-in-the-Box in this 15th year anniversary, another huge Jack-in-the-Box of a pathogen that is a non-O157 that we know to be disease causing and death causing, until they are willing to acknowledge that there is more that needs to be done.

I applaud the Agency for being proactive. I think industry here and trying to correct itself, and frankly, trying to redeem itself in the public's confidence by moving forward with these things, I think industry has a lesson to learn here.

I want to thank you very, very much for a very invigorating day and a half. I think that this is a discussion that needs to keep going forward and I hope that we can see some good news in the future about trending down on these illnesses. Thank you.

DR. GOLDMAN: Thank you. Ms. Buck.

MS. BUCK: My name is Pat Buck, and I'm with the Center for Foodborne Illness, Research and Prevention and, Nancy, you did a great job, stole a lot of the things I wanted to say but I will start off by this.

Agriculture in this country for the past decade has been over a trillion dollars each year in revenues. That's big business. That's huge, and when you look at the estimates, the cost of foodborne illnesses and that type of thing, I know the USDA, U.S. Branch put out a cost for foodborne illness back in 2000, and said it was 6.9 billion. Well, you know, that's a drop in the bucket when you're looking at over a trillion.

However, the recent economic societal cost on foodborne illnesses, have been based on willingness to pay. How much is a consumer willing to pay for food so that they don't get that tummy ache or the three days or the more serious things. And those estimates came out in 2007 saying that the cost to society for foodborne illness is 1.4 trillion -- 1.4 trillion. That is huge, and I think

it's time that we all just start looking at this and saying, people really don't want to get sick from the food product and, yes, we do have one of the safer food supplies in the world. We want to maintain that. We certainly don't want to go backwards.

So everybody is going to have to start looking to the indicators, those things that Dr. Raymond asked us, you know, what are the predicted indicators out there? This was at the risk-based inspection meeting over a year ago now. What are they? So we have to start looking to the future to see what we can do to identify the areas where it is likely that the enteric pathogens will get mixed with the human intestinal tract and cause tragedies or cause loss productivity just on a regular basis.

I think the biggest thing I have gotten out of this meeting is I feel encouraged, but like Nancy, I feel discouraged. We need to have more access to the type of dialogues where industry can interact with consumer groups so that we know what's going on. One of the gentlemen on the panel said, you know, why

don't you come to the trade shows. Well, it's simple. Most of the consumer groups do not have the money or the resources to go to the trade shows and interact.

So I challenge industry, come and talk to us, explain to us why you feel boxed beef is not a problem. I look at it and it makes sense to me. Why do you think that when Europe is reporting cases of non-O157:H7 Shiga toxin-producing *E. coli* as their major problem, and we don't really even consider it here, why are we ignoring that?

Okay. So congratulations, FSIS, you did a very good job in bringing together a lot of people. I think the other thing that has to be mentioned is that FDA is not here. FDA should be here. You need to reach out and drag them over here because this is where I speak to the people that I speak to, I say we need to start bringing these agencies together, talking more, so that we will have the basis for a more collaborated approach to food safety systems.

The gentleman on the panel that talked about the lack of public health resources, he is

absolutely right. Until we have more surveillance opportunities on foodborne illness and until we have more surveillance opportunities for food attribution data, we're not going to get to the root of this problem. I really believe that these public meetings are important. I truly from the bottom of my heart thank you. I think when the head of the FSIS Agency says to everybody, it's time for us to look at boxed beef, it's time for us to look at non-O157:H7, I think that's a good indication that this public health oriented leader is giving us some direction, and I hope everybody pays attention to that. Thank you.

DR. GOLDMAN: Thank you.

MR. PAINTER: Yes, Stan Painter with the National Joint Council. To start with, I want to say that I appreciate the opportunity to be here. I said to Dr. Raymond yesterday that I don't think that my organization has had access to the Under Secretary as we have Dr. Raymond, and we certainly appreciate that. And I'm sure that we come here and we say things that probably Dr. Raymond don't agree with but

that's okay. When you get two people together, you're not going to always agree.

I'd like to start out by saying we're all consumers, and I don't care if you work with a consumer group or for a consumer group or you work for the Agency or your work for industry, we're all consumers. It's not like just saying, you know, there's a particular defective product, and I'm not going to buy that product. We can't say that we're just not going to eat. And I don't care if you're a Ph.D. or you're just, you know, a regular person, that's not highly educated, that, you know, fecal material is not edible, and we all have to understand that fecal material and the bacteria that comes with it is not edible.

And, you know, I see people at these meetings that they're with one organization and they're preaching one sermon and then they go to another organization and they're preaching another sermon. We have a saying in the south, bless your heart. (Laughter.) Then, you know, you need to take a look at everyone being a consumer. Thank you.

DR. GOLDMAN: Thank you.

MR. WALDROP: Chris Waldrop, Consumer Federation of America, and I wanted to address the earlier comment about the contention that the U.S. has the safest food supply in the world. And, as we've heard over the last two days, there are people in this room who have lost loved ones because of the safest food supply in the world.

As Tim Jones said, one person who is sick or ill from something they ate is one too many. I think 5,000 every year is certainly way too many. So I think that perspective is also important to keep in mind as FSIS continues its look at this issue. And, I commend the Agency for trying to take a more public health-based approach to its activities than has been done in the past, and for looking at these issues in a broad way and trying to come up with preventive strategies. So I think that's appropriate and I'm glad the Agency is focused in that direction. Thanks.

DR. GOLDMAN: Okay. Thank you. Let me check with the phone one last time. Anyone on the

phone want to make a public comment?

OPERATOR: Anyone who would like to make comments on the phone line, please press star 1. One moment please.

(No response.)

OPERATOR: At this time, there are no questions or comments.

DR. GOLDMAN: Okay. Thank you.

DR. HUFFMAN: Thank you, Dr. Goldman. Randy Huffman, American Meat Institute. I would like to make just one final brief comment on behalf of the meat industry. I appreciate Chris' comments earlier, that while we do believe we have the safest food supply in the world, one of the safest, and by many measures I think that we would all agree to that.

We also realize that we have progress yet to make, and I think the participation of industry at this meeting is indication of our commitment to do everything that we can to control pathogens in our product.

I'd like to, you know, make a couple of comments in response to earlier statements that were

made. Industry is strongly committed to science and research and solutions to solve this problem. We have invested hundreds of millions of dollars. There was a question asked to Dr. Danielson earlier, to try to quantify that. It's very difficult to do but it's hundreds of millions if not more than that, and we'll continue to do that. As I mentioned earlier, it remains, food safety research and education remains our number one priority at the American Meat Institute.

So with that, you know, I offer our olive branch to work with the other groups represented here in the room as well as FSIS to work on solutions. And we encourage FSIS to consider some of our comments that were made earlier with respect to simply implementing a testing policy. We're not convinced that that will make the product safer. So let's look at the data and try and understand that better.

What we know works and what we know will work are interventions and solutions that are proven and validated and the implementation of those, and

that's what we're committed to working on, to continue to enhance the safety of our beef supply. Thanks.

DR. GOLDMAN: Thank you very much. And thanks all of you who have provided your comments both now and earlier in this meeting.

One other just program note, some folks have asked whether some of the presentations which were especially delivered today would be available and it is our intention to post all of the presentations to our website, so you can have access to the PowerPoint presentations at that time in the very near future.

Sir, do you have one last comment?

DR. BAKER: Yes, thank you. I finally decided that I should stand up and speak. First of all, I wanted to introduce myself as Dr. Merv Baker. I'm currently representing the Canadian Meat Council but I'm also a former executive of the Canadian Food Inspection Agency. So my background is quite relevant to the matters at hand.

I wanted to thank FSIS for allowing

international participation. There was a comment made earlier about approaching FSIS and others to look beyond your borders. That's what we do. That's what we're doing. When I was with CFIA, we always tried to learn from other countries because the problems that we face often appear in other countries before we face them, and we were able to be prepared to address issues because of that exposure. And I'd encourage the U.S. to do the same thing.

I also wanted to say that, you know, we've been trading for years. We're neighbors. We used to talk about the longest -- border in the world pre-2001, but we remain friends and very strong trading partners. Massive amounts of product go back and forth across the border.

And I just wanted to add that societally we're not all that different either. We share the same concerns that you have with food safety. We also share similar challenges.

We have in Canada the same concern about food safety. We are doing everything that we can, that we feel we can, to enhance food safety. We

believe that as you do, Canada has one of the safest food supplies in the world. But often I feel that when you say that, and when I say that, it's a pretty hollow remark. Yeah, it's safe, but it could be safer.

I want to also reassure you that while we have a concern about enhancing the safety of products for Canadian consumers, our concern extends just as much to foreign consumers of Canadian products, and this is taken into account and covered by the certification that CFIA does and the laws that Canada has in place to insure the quality of products that are being exported from the country.

The other comment I would offer from past experience is that risk analysis is recognized around the world as probably one of the most important tools for dealing with issues like this. It's also recognized as a critical tool by international standard setting bodies and the World Trade Organization. When you ignore risk analysis, you often run the risk of doing the right thing -- not doing what one should. Risk analysis comes in

different forms. Some take years. Others may take minutes and I imagine Dr. Raymond has already done his personal risk assessment and that's part of the reason why he's advocating certain things but there are intermediate positions as well. You can do risk analyses in a relatively short period providing you can generate the data that you need.

A critical part of risk analysis -- there are three components of risk analysis. There is risk assessment, risk management and risk communication. At this meeting, there was a lot of discussion about risk assessment and risk management, not very much about risk communication, at least directly. And that's something that I think we all perhaps need to pay more attention to.

A component of that is to help consumers, to help everyone understand and to help the regulator understand the consumer point of view. One of the things that you never -- with foodborne disease is the importance of consumer education. It sounded to me like you may have given up on that in the United States, and I would recommend very strongly that you

consider that position. You won't change the world, you won't change the whole country, but you will help enhance the protection of many people. And I believe there's sufficient evidence of that having been done successfully in other countries and also in parts of the United States.

So I share those comments with you.

DR. GOLDMAN: Thank you. Thank you very much.

Okay. We are now at the end of our meeting, and it's my pleasure to introduce our closing speaker. Dr. Scott Hurd was fairly recently named the Deputy Under Secretary for Food Safety. It was February 12th to be exact, and Dr. Hurd most recently was an Associate Professor at Iowa State University's College of Veterinary Medicine and prior to that, worked for about 15 years in USDA, both at the Animal and Plant Health Inspection Service as well as the Agricultural Research Service. So he has quite a bit of experience in epidemiology and in research as well.

Dr. Hurd received his Bachelor of Science

in Biology from Virginia Tech where he also happened to play football during his time there. He also received Doctorate of Veterinary Medicine from Iowa State University and his Ph.D. in Epidemiology from Michigan State University.

Please welcome to provide our closing, Dr. Hurd.

(Applause.)

DR. HURD: Thank you, Dr. Goldman. I suppose you folks are happy that he was introducing the last speaker because I know everybody wants to go. I see people looking at their watches. So I don't really have a lot of significant or am not going to take a lot of time.

This was certainly a dynamic, interesting gathering for me, being my first public meeting as Deputy Under Secretary, but it's not my first experience with *E. coli.* Actually, before Jack-in-the-Box, in APHIS, in the National Animal Health Monitoring System, I encouraged us to test for the prevalence of *E. coli* in dairy cattle. So we published the first national prevalence estimate of

E. coli before Jack-in-the-Box. So I've been watching this debate go on for many years, and I want to reiterate what Dr. Raymond said, that this meeting is just meant to open the dialogue and particularly to work on what are the data? What are the science that we need to respond to this issue?

Related to that, I can share with you today that CDC just released their results for STEC, human illness estimates for last year, 2007, and the national prevalence estimate is 1.2 per 100,000. So that's just a little bit down from the year before, in '06, which was 1.3, '05 was 1.05.

So the good news is the rate of human illness, even though we had recalls and issues like that, the rate of human illness in the U.S. doesn't seem to have increased.

The interesting thing to think about that from a data standpoint is that if we say 1.0 per 100,000 times 300 million people, means about 3,000 cases of STEC O157 in the U.S. per year, and -- those who die and each one of those is tragic and not acceptable.

But then you take the other data that I heard this last couple of days that says about 60 some percent of all those cases apparently, we think, are due to meat and 44 percent of those are due to beef, that works down to about 800 cases that we can maybe do something about.

Now that's not to minimize the issue but it's to bring out an important epidemiologic principle. When you get to the bottom end of the curve, for eradicating disease, it gets to be very difficult.

Our sister agency, APHIS, has been trying to eradicate tuberculosis for over 50 years, because when you get to the bottom, it's very difficult.

On the good side, we think about there's 800 cases per year. We've got 100 million cattle, a billion dollar -- in the meat industry. If everybody just agrees to take one case off that list over the course of a year, then it should be a relatively small problem.

What we're struggling with is how to do that? How do we take a big bite out of it or how do

we take another bite out of this issue?

I heard a few pieces of science mentioned that are worth reiterating here. One is on the issue of the non-O157s, the prevalence seems to be very low, industry reports about 0.15 percent of their samples, 10,000 samples, seem to be positive for these. FSIS is going deeper into that question. We're not actually expanding. If you remember what was said, we're testing those samples we pull for O157, will then be tested for the non-O157. Those methodologies are actually still being developed and you can recall Dr. Engeljohn's comments about specific reactions to those. So we're just beginning to understand what is the prevalence of that.

On the issue of pre-harvest, that's a challenging one. Back when I was with APHIS in the beginning, we launched into pre-harvest and started a debate about whether APHIS should be in pre-harvest or not, whether FSIS should be doing that, and what we should be doing, and it's not an easily solved issue.

As was explained to us today, the

prevalence is variable. Sometimes a pen, 5 percent of the cows are positive and next month, same pen, 80 percent of them are positive. The challenge is, recalling what Dr. Loneragan said, this is a commensal organism, which means it's just passing through the cow. It's just a passing participant which makes it much more difficult to diagnose it in the animal and to nail it down and do something about it.

There's some good interventions that might be able to help, particularly the one vaccine. Yesterday the Deputy Under Secretary from Marketing and Regulatory Services told the Secretary that the train has left the station in the issue of vaccination. So I think they've gotten their details worked out and they will be able to approve acceptable products for vaccination of *E. coli*.

Other additives like Neomycin, a very good point raised there. When you start too mess with this ecosystem, you add some antibiotics, you change a lot of different things. So realizing that we're involved in this dynamic ecosystem that involves

people, animals, bacteria, business, so sometimes you push on one place and another area pops up.

Lastly, on the issue of plant processes, what can be contributed, I take to heart the point that AMI mentioned, the issues of investigations. When we do an investigation, are there learnings from those, and as Dr. Goldman mentioned, the Agency is moving forward to getting more specific on those so that when we do have an investigation, we find out what the learnings are from that, and we try to feed that back to people who can do something about it.

The other piece of data that I saw that was most interesting was that only 15 percent of the plants had a perfect score on those food safety assessments that we came back and did, which means 85 percent of the plants can today improve in some way on their existing processes.

So there's a lot of different ideas. Those are just a few that I chose. I reiterate that the store is open for public comments until May 7th. The transcripts as noted will be available in the next couple of weeks, as well as all the presentations.

We will take your input that we received and we will act on it. I believe that major strides have been made in this meeting, lots of good ideas, and I think we're all moving forward to doing something about this problem.

So with that, I'd like to thank Dr. Goldman for moderating this, keeping us on time in an excellent fashion, the other people who organized it and hope you all have a safe trip home. Thanks.

(Applause.)

(Whereupon, at 1:00 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

SHIGA TOXIN-PRODUCING *E. coli*

ADDRESSING THE CHALLENGES,

MOVING FORWARD WITH SOLUTIONS

Washington, D.C.

April 10, 2008

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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Dominico Quattrociocchi, Reporter

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