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THE UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

NATIONAL ADVISORY COMMITTEE
ON
MICROBIOLOGICAL CRITERIA FOR FOODS

PUBLIC MEETING

The Federal Room

Washington Plaza Hotel

10 Thomas Circle, N.W.

Washington, D.C. 20005

Monday, May 7, 2000

9:05 a.m. - 4 p.m.

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Presenters

Phil Derfler
Tom Van Gilder

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JANICE OLIVER, Substitute Moderator
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DR. DAVID THENO
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From Industry and other Interested Organizations:

DR. JEAN KAMANZI, Government of Canada, Canadian Food Inspection Agency
Caroline Smith DeWaal, Center for Science in the Public Interest

P R O C E E D I N G S

(9:05 a.m.)

MS. WACHSMUTH: Okay. Welcome. Welcome to all the new committee members and to others who have come for today's meeting. I'm Kaye Wachsmuth, the Deputy Administrator for the Office of Public Health and Science and the Food Safety and Inspection Service. And I serve as the appointed chair of the committee.

And what I'd like to do as an opening for this meeting is just to explain a little bit about orientation we had for the committee this morning. Since it is a new committee, reconstituted, we had an informal briefing. And as far as orientation purposes, what we did was have the committee introduce themselves, which will begin shortly and also the Steering Committee and the Executive Committee members of those agencies that support this committee to introduce themselves. They will tell you a little bit about what their agencies expect of the committee, describe the purpose of this committee which is to advise the members, the agencies to focus on the science, not the policy, although we all have policy opinions. Also the relationship of this committee which is science to another policy committee for USDA, and that is the Meat and Poultry Inspection Advisory Committee. And that committee very often refers matters of science to this committee for

consideration. And I suppose if we had a matter of policy, we would then refer it to that committee.

The appointment process was covered in the new charter, which became effective in September of 2000 and expired September 2002, and calls for a maximum number of 30 members. We do have 28.

We have nine representatives from academia, eight from industry, eight from federal government service, and three -- I'm going to have it so you have three from state this year. The selections were made, number one, on the area of expertise. Then you have an added emphasis now on the microbiology and risk assessment.

These are new sciences that we believe will take us into this new paradigm of food safety as an integral part of public health. It puts the focus on the consumer and on human health considerations for safe food. And we're very happy to have two or four experts from a very small pool of experts since these are new sciences. And I'm happy to have them.

Selections were also made of affiliation in that respect in diversity, geographical diversity, and all diversity. We wanted to see different perceptions and representations. And this is as much of this country's view and a new agenda as we do now. And we do have a limitation on services of six years.

The charter calls for approximately three meetings a year. But we will have subcommittees which meet between sessions. And all of their decisions and business that occurs in the subcommittee will come again in front of the session, so that this entire committee is involved in the decision and comes -- in paper or any product of this committee.

Now, we have housekeeping information. We'd like to thank our new acting executive secretary, Brenda Halbrook, for bringing this meeting together, and also Karen Thomas, our Advisory Committee specialist, here on the far end of the table, Brenda and Karen.

For today's agenda, I think it's pretty much as you have it. On the initial agenda, we had one change, and that's Tom Van Gilder, who's joining us from CDC, and also Janice Oliver will talk to us about how we initially handle the -- for salmonella Enteritidis. Now,I'd like to turn it over to our co-chair, Janice Oliver for a few minutes.

MS. OLIVER: Thank you and good morning. It's a pleasure to be with you once again. And I, too, would like to welcome you. It's nice to see so many of our former members have agreed to accept their appointment to the committee. And as for the new members, I appreciate the opportunity to get to know and to work with you personally.

It's no secret that FDA relies on your scientific

expertise, seeing the things from the Public Health Protection Program. For those of you who participated in the last meeting on the safety of fresh juice, I want to thank you very much for your thoughtful considerations and your recommendations.

I realize the ground we had to plow was arduous. And it took a great deal of effort. But as a result, we have a new regulation in place. And I think it's much more public-health protective. And I personally have spoken of the new rules with the mother of a child who had become seriously ill. And she, too, greatly appreciates the efforts that you have put in the recommendations.

I could sit here and do a litany of issues that you've taken before the committee, including -- , fresh produce, seafood, HACCP, -- , listeria, and many more to come, but much more work lies ahead.

We had originally planned on taking some issues and methodology of the environmental testing for salmonella Enteritidis -- to the committee today. But upon rethinking and looking over the issues, I realized that we had to do a little more digging into the science before we brought it to the committee. So we're doing that at the present moment. And it just means we want to dig a little deeper before we brought it to the committee's attention.

But having said this, as co-chair, you have my

word that I'll work very hard to provide you with the tools and resources you need to do your job as committee members. And if FDA fails to live up to that, I wish you would tell me, and I'll take it as a personal favor to tell me, because I think part of my job as co-chair is to really help the committee move forward and do its job.

I know you all have a lot of other jobs in taking this on, along with your other duties, and you're all very busy. I, once again, would like to thank you for your commitment, but will add one thing before I turn it back to Kaye; and that is, you have a copy of the transcript from the December '99 meeting on three diskettes in your folders. And the minutes were taken by a court reporter and certified by that reporter as an accurate accounting of the proceedings of the meeting. And they will serve as the minutes. Kaye?

MS. WACHSMUTH: Okay. I'd like to go around the table now and have each member introduce themselves and state your affiliation. We'll start with David.

MR. ACHESON: David Acheson from Tufts University, New England Medical Center.

MR. BERNARD: Dane Bernard, Keystone Foods.

MR. BEUCHAT: Larry Beuchat, Center for Food Safety, University of Georgia.

MR. BUCHANAN: Robert Buchanan, Food and Drug

Administration.

MS. DONNELLY: Cathy Donnelly, University of Vermont.

MS. DOORES: Stephanie Doores, Penn State University.

MS. DOWNES: Frances Downes, Administrator, Michigan Department of Community Health.

MR. ENGELJOHN: Dan Engeljohn with USDA's Food Safety and Inspection Service.

MR. FARRAR: Jeff Farrar, California Department of Health Services.

MR. HABTEMARIAM: Tsegaye Habtemariam from the Department of Internal Medicine at Tuskegee University.

MR. KOBAYASHI: John Kobayashi with Washington State Health Department.

MR. KUNDURU: Michael Kunduru from Dole Fresh Vegetables.

MR. KVENBERG: I'm John Kvenberg, Food and Drug Administration.

MS. LAMMERDING: Anna Lammerding, Population and Public Health Branch, Health Canada.

MR. LUCHANSKY: John Luchansky, USDA Agricultural Research Service, Wyndmoor, Pennsylvania.

MR. WEBB: Bob Webb, Department of Defense.

MR. LIANG: Arthur Liang, Centers for Disease

Control and Prevention.

MS. JACKSON: LeeAnne Jackson, Food and Drug Administration.

MS. MADDOX: Carol Maddox, University of Illinois.

MS. O'BRIEN: Alison O'Brien, Uniformed Services University of the Health Sciences.

MS. RUPLE: Angela Ruple, U.S. Department of Commerce, National Inspection Service.

MR. SEWARD: Skip Seward, McDonald's Corporation.

MR. SPERBER: Bill Sperber, Cargill.

MR. SWAMINATHAN: Bala Swaminathan, Centers for Disease Control and Prevention.

MS. SWANSON: Katie Swanson, the Pillsbury Company.

MR. THENO: David Theno, Jack in the Box.

MR. TOMPKIN: Bruce Tompkin, ConAgra Foods.

MS. HALBROOK: Brenda Halbrook, Food Safety Inspection Service and -- .

MS. THOMAS: Karen Thomas, Food Safety Inspection Service, Advisory Committee Specialist.

MS. WACHSMUTH: Okay. Thank you. One other thing that we need to talk about this morning was to -- the agenda for today. And I did mention to the committee that there is a conference report for USDA, the House Appropriations Bill for FY 2001, that directs the Secretaries of Agriculture and

HHS to take matters of performance standards and microbiological criteria to this committee.

And as part of that, we will be talking about salmonella performance standards today. And we'd like to start with that topic and start by giving you some background. And one of our first speakers will be the administrator for FSIS, Tom Billy.

And we talked a little bit this morning, too, at least I mentioned that food safety internationally has taken a slight turn, if not a shift, in becoming integrated into the public health community through the World Health Organization and other activities. And risk assessment has played a key role in how we're doing that internationally.

But Tom also serves as the chairman of the Codex Alimentarius Committee which is the big food safety agency for the world, I guess, where you try to set international food safety standards that protect the public. And once I introduce Tom in a certain way -- I was thinking about it right before he called, and I think it's something that I'd like to share with you.

My perception is that Tom is truly a visionary. And everyone talks about Tom pushing them and he does. But he also is a manager and a leader who has implemented those changes and implemented that vision. And I think he's done so very successfully. And it's a real privilege to

introduce Tom Billy.

MR. BILLY: Thank you very much, Kaye. Good morning everyone. I really look forward to this opportunity to talk to you about salmonella performance standards. Before I start off, though, I thought I'd share with you an experience I had last week.

I was down in Brazil at a meeting that the chairman of the Pan American Health Organization was holding of the Ministers of Health and Resource Agriculture for all the countries of the Americas.

And during the course of the meeting last week after a couple of years of preparation, the Ministers of Health and Agriculture decided to establish a new Food Safety Commission for the Americas and developed a draft charter to be finalized at the next meeting of the commission. And it's very important stuff, I think, in terms of this international arena to see agriculture and health throughout the Americas working together to address the problems of food safety. So I'm really pleased with the results. I'm sure you'll hear a lot more about that in the future.

Perhaps, the best place for me to start is to thank you ahead of time for the efforts of this committee in helping veteran agencies continually improve their food safety programs. This committee, in fact, has a long

history of having both FSIS and FDA to modernize programs.

Since 1988, this committee has prepared a series of reports on the development and implementation of HACCP. And they have been extremely helpful to both of our agencies. Thus, I think it's very fitting that we are here today to ask for your expert advice once again. This time, performance standards are the topic for discussion.

Performance standards have been extremely important to FSIS's food safety strategy. And I believe they'll remain so for years to come. Performance standards for pathogens have been in existence for some time, the processed ready to eat meat and poultry products, as well as other food products. However, the development of such standards for raw products occurred much more recently.

In 1996, the agency issued its landmark final rule on pathogen reduction in HACCP. We set pathogen reduction foreign standards for salmonella for various raw product passage. These performance standards are extremely important to achieving the public health goal established in the Preamble to that final rule.

I encourage all of you who haven't taken the opportunity to read the Preamble to that rule to do so as a part of your community process. As such, the framework, the science, the kinds of standards, public health and all that we are working to achieve as a result of that type of

regulatory strategy.

These performance standards in salmonella performance standards play another important role in providing industry with objective, measurable standards that can be used to calibrate their HACCP plans. They also function as a yardstick for FSIS to measure the effectiveness of industry HACCP controls in plants where they apply.

With all such standards, I believe HACCP's systems could be much less effective in improving food safety. We believe the two must go hand in hand. I've often referred to this combination as the Gold Standard for food safety.

Now, in fact, many other countries around the world are following our footsteps in using the combination of HACCP and pathogen reduction standards. We are pleased with what our performance standards for salmonella in concert with the other provisions of the pathogen reduction and HACCP rule have been able to achieve so far.

Industry has worked hard, very hard, busting in the new technology and new procedures to accomplish real improvements. Our latest progress report on the results of our salmonella testing for raw meat and poultry products show that the program for salmonella for raw meat and poultry has decreased significantly since the implementation of HACCP in 1998.

This report was the first aggregate data on all sizes of plants, including data from various small plants which came under HACCP in January of 2000. The complete report on this testing is in your packets and in your material.

Well, let me give you just a few of the details. Figures I am quoting are aggregate data for 1998 to 2000. Those averaged a salmonella prevalence of 10.2 percent under HACCP during this period compared to 20 percent baseline before we implemented the new regulation.

-- averaged 7 percent over HACCP compared to 8.7 percent baseline. Cows and bulls averaged 2.1 percent compared to 2.7 percent before. Steers and heifers averaged .3 percent near compared to 1 percent. Ground beef averaged 3.7 percent compared to 7.5 percent baseline. Ground chicken averaged 14.4 percent compared to 44.6 percent. And ground turkey averaged 29.7 percent compared to 49.9 percent baseline.

However, these numbers and other tables and information are in that report. But I think the point I want to make here is that we've seen significant progress under HACCP in combination with these performance standards across the entire meat and poultry industry.

Now, in addition to these data, of the current prevalence of salmonella involving raw meat and poultry

products, we are seeing reductions in the incidence of food borne illness. Now, we believe our performance standards, working in concert with HACCP, are one of the factors contributing to this decline.

Dr. Mendover (phonetic) from the Centers for Disease Control and Prevention will be discussing their latest data available through FoodNet shortly. Now, while I believe that all of this is good news, we must continue to move forward. And we know that there's room for further food safety improvement.

We indicated in the Preamble of the final rule in 1996, the Preamble I mentioned earlier, that the performance standards, initial set for salmonella, were not intended to be static. We based the standards on the best science available to us at that time, knowing that they would have to evolve as new data, research, and technology became available.

That is why we welcome the two concurrent activities underway to review our salmonella performance standards and what they have accomplished. The language accompanying the Fiscal 2001 Agriculture Appropriations Act, as Kaye mentioned, directed FSIS to ask both this committee and the National Research Council for an evaluation of the role of scientifically determined criteria, including microbiological criteria in the production and regulation of

meat and poultry products.

We expect the National Academy of Sciences study to be underway soon. This committee is requested to review the role of microbiological performance standards generally as a means of improving and ensuring meat and poultry product safety. Further, you are requested to review and evaluate our salmonella performance standards for specifically and what they have accomplished to date.

You are encouraged to factor in other considerations as the committee may feel is appropriate. In your packets is a list of questions FSIS has for this committee. And these will be reviewed in more detail later today. I just wanted to mention a few examples. We wanted your technical input on the use of indicator organisms in lieu of a specific pathogen, like salmonella. We want to know whether it is both scientifically appropriate and wise from a public health standpoint to incorporate regional and seasonal variations into performance standards.

We want your technical input on how quantitative, baseline performance data should best be used to develop or modify performance standards. An example would be the massive amount of data we've now collected in our sample testing of the new HACCP.

We want to know what the key considerations are we should factor in when using risk assessments to develop

performance standards. Although our current standards for salmonella are not based on those former risk assessments, it is our hope in the future to use risk assessments as a means of establishing risk-based performance standards for pathogens of public health concern.

We welcome both your review and the one from the National Academy of Sciences for a number of reasons. First, regulatory agencies must be sure their policies and procedures are based on the best science available. Second, such reviews help maintain consumer confidence in the efforts of regulatory agencies to protect them. And third, our performance standards for salmonella for raw products have come under some criticism.

And it is important that such criticism be addressed, especially considering the important role, we believe, such standards will continue to play in the future. I'll look forward to hearing the discussions today. And, again, thank you ahead of time for the hard work I'm sure you're going to put in on this -- subject. Thank you.

MS. WACHSMUTH: Does anyone have a question? Right now, I'd like to introduce Dr. Tom Van Gilder.

Tom is a physician, a medical epidemiologist at the Centers for Disease Control, where he's been for nine years. And for the last three years, he's been deputy director of FoodNet. And he's going to describe those

activities to us a little bit today. And this is sort of our -- approach in terms of the real goals of the food safety regulatory agencies in terms of reducing foodborne diseases. Tom?

MR. VAN GILDER: Thanks, Kaye. I want to begin by thanking LeeAnne Jackson for making this electronic transmission possible. I'd like this morning to just give you a brief overview of FoodNet, and then talk about some of the findings we've had, focusing on the findings that we've published in the MMWR last month.

FoodNet is the foodborne diseases active surveillance network. It really came about as a response to the sense of changing epidemiology in foodborne illness. And by that, we mean that there's been changes in the agent, the environment, and the host as a form that comes to food safety. We've seen food pathogens -- transmission, pandemics really are foodborne pathogens, infections. We've seen changes in the environments of the globalization of the food supply, changes in food processing and an emergence of larger producers. And we've seen changes and continue to see changes in the host of the people who are affected with these agents, with these pathogens, with an increasing age of the population or the increasing population we've talked about, for instance, as well as new eating habits and international travel and migration.

Based on the existing surveillance system of foodborne outbreaks, laboratory based surveillance, and epidemic investigations; foodborne -- is seen as a way of uniting and taking a more active role in finding each and every case of foodborne illness possible.

It came about as a part of the Emerging Infections Program at CDC. It's the principal foodborne disease component of that program. It was established initially at four sites plus Georgia, so five sites since 1995 occurring in nine EIP sites with 33 million persons under surveillance. This represents a collaborative effort among state health departments -- the USDA, FDA, and CDC.

FoodNet's primary objectives are to determine precisely and how to better the burden of foodborne diseases, as well as to determine the proportion of foodborne diseases attributed to specific foods. We also look to develop a network to respond to emerging foodborne diseases and also to improve outbreak response.

Just to attest for you again, the size of the population has gone from 14.3 million in 1996 to now 33.1 million in 2001. And then I'll briefly show you where in the United States we currently have sites. This is the original five sites. And some of the sites have grown over time and we've certainly added three sites. We'll get into today's nine sites shown across the country.

But I emphasize here, too, that although we do have a decent representation from coast to coast, demographically our sites are similar to the nation. These are not chosen to be randomly representative of the United States, in general.

What FoodNet really helps to do is to fill in what we call the Surveillance Pyramid. The cases that we get at CDC really represent just a small portion of the cases that occur in the country. And underlying each reported case there are additional cases that were not reported to us either because they were not tested properly in the laboratory or perhaps they did not have a specimen tested at all, or perhaps never sought care and so was not able to get into the reporting system primarily.

FoodNet helps to fill in this pyramid through a variety of activities. First of all, with active surveillance as I mentioned as way of finding out how many cases are occurring, how many laboratory-confirmed cases occur of these various pathogens in the United States, at least in the FoodNet capturing area. We also hope to seek to understand what happens at the laboratory level to understand what kind of testing occurs, how often tests for these pathogens go on, and below that how often physicians actually order stool cultures on their patients with diarrheal illnesses.

And then at the base of the pyramid is our effort to understand in the population that FoodNet surveys, what are their food group experiences, what are their exposures to various risky behaviors or risky food-handling practices. There is tremendous need at CDC to see the experiences of our care-seeking population.

Just to give you some examples of what we found in active surveillance -- again, this is seven bacterial and two parasitic organisms that we surveyed for and three syndromes which are related to foodborne illnesses. -- syndrome, -- syndrome, and congenital toxoplasmosis. We also survey, as does the rest of CDC's Foodborne Illness branch, foodborne disease outbreaks.

As part of this project, what we do is survey the clinical laboratories every month within our sites. And we fill out case report forms for each of the infections that we find. And those case report forms are, then, transferred in to us at CDC. Then we, in turn, audit that data so we have a strong level of confidence in the data that we receive.

Our laboratory surveys we've done in the pyramid have helped us understand what happens in the laboratories. So how many cases do we not hear about because they are not being tested? And what we found in each of our years is that salmonella, shigella, and for the most part

Camylobacter, are routinely tested for in each stool sample that makes it into the laboratories.

E. coli 0157 is a different story. We learned that about half the laboratories will routinely test for 0157 in stool cultures they get. -- test that gets the numbers up to about 80 percent or so. And then there was an increase somewhere over the three years or in the three surveys that we've done, but has not risen dramatically.

Our physicians' survey helps understand what physicians are doing with patients who come in with potential foodborne illnesses. And we found that about 44 percent ordered stool cultures on patients that they see with diarrhea.

We have a second survey that actually starts to look at behavior of physicians in regard to what you do with the patients who come in with foodborne illnesses. The population survey, as I mentioned, is a way of looking at the population as a whole. We've done this three times so far, and the third cycle recently completed, the first cycle about to begin.

And what we found in the second cycle, for example, is that about 10 percent of the population reported a diarrheal episode in the preceding month and that translates to about 72 diarrheal illnesses per person, per year in the foodborne illnesses area. And we found that

about 20 to 21 percent of the people who reported diarrhea illness go on to see a physician. And about 16 percent of those people provide a stool specimen at that time.

In addition to the elements that I mentioned in the pyramid in helping to figure out the number of illnesses, FoodNet also seeks to understand what are the specific foods that, or specific exposures that caused illness. And we've done a series of case control studies.

We've studied the case control study of salmonella of specific food groups. We've recently completed a survey or a case control study of Campylobacter infections. It's a case control study of listeria infections -- , and we've recently finished a second E. coli 0157 case control study, as well as a Cryptosporidium study.

In the next year, we hope to launch a study of infant illness case control study. So to get back to some of the data. Here is preliminary data that we discovered in the year 2000. Listed in alphabetical order are the pathogens that are under surveillance. And you can see that Campylobacter is the number one cause of bacteria, foodborne illness within FoodNet, followed by salmonella.

While some of these general numbers are a number of trends or a number of subpopulations, which can be impacted in various ways. Here we have it looked at seasonally. And we see for the big four: Campylobacter,

salmonella, shigella, E.coli 0157. We have a strong seasonal trend. Not all pathogens, follow around the same trajectory there. We see that the type of illnesses that we study here are more predominant in the summer months. This goes on to show some geographic variation that we have in our data. So those numbers that I mentioned are really composed of various trends and various break-downs regionally.

So we see, for example, that California, Connecticut, Minnesota, New York, and Oregon all have Campylobacter as their leading cause of bacterial foodborne illness and that salmonella is the number one cause in Georgia, Florida, and Tennessee. This goes on to show some of our lower incidence pathogens: listeria, -- infections and their variation across the country within FoodNet. And it puts the numbers on that.

Again, Campylobacter is less of a problem in Tennessee, it seems, than in California. salmonella is less prominent in Oregon than it is in Georgia and so on. And there's really tremendous regional variation. And this offers us the opportunity and look at why these variations occur.

Again, another source of variation and one that will spawn an infant case control study this year is the finding that infants are at high risk for Campylobacter and

salmonella, but that risk decreases over time.

In the case of food illness, I was also able to do, in addition to assessing the -- and assessing what specific foods or exposure are causing these illnesses is how much is the economic burden or how much is the personal burden of these pathogens, infections with these pathogens on the population. And this we do by assessing hospitalization and deaths caused by these agents. And we see here that listeria is far and away the leading cause of hospitalization for frequent illnesses in this country.

Another element that FoodNet is able to add to the population-based surveillance for foodborne illness is looking at more specific infections. salmonella it is said, is not really an "it," but a "they." It is composed of really a number of serotypes that play important roles in foodborne illness. But at FoodNet, we see that Typhimurium are the top three salmonella serotypes listed in the year 2000. And this is related to our FoodNet study over the last few years.

We can similarly do this for two other foodborne illnesses, shigella and vibrio. Shigella, of course is not always foodborne but we see in FoodNet that most of the infections are -- infections. And we see a couple thousand of those a year. And with Vibrio not as many, but we're able to break that down into -- , non-toxigenic -- as we see

the breakdown of those infections there.

Summarizing just the incidence data, just the numbers of cases we see that again Campylobacter, salmonella, shigella, E.coli 0157; numbers one through four, overall, that shows substantial variation among the various sites for the pathogens, although Campylobacter had the highest incidence in five of the eight sites. So there's some consistency there. And salmonella had the highest incidence than the other three sites.

Looking at trends, another thing that FoodNet is able to do and one of the things that it brought to the existing surveillance system, is a way of looking at what is happening over time, as well as things that occur in the food safety environment. We've seen that, for example, in Campylobacter, in all five sites, when you compare baseline 1996 with our most recent 2000; that the five sites that began in '96 all experienced decline when you compare those two years if you combine those data together. If you look at each site specifically, we see that four of the five sites had a decline in Campylobacter. The magnitude and the pattern of these declines suggested change to a very -- site. salmonella infections declined in all five sites both in a combined fashion and individually. So each site experienced a decline in salmonella infections.

salmonella Enteritidis and Typhimurium declined

also in all five sites combined. Shigella infection varied tremendously from year to year and from site to site and a lower outbreak which I mentioned -- . Listeria infection declined again in all sites, individually and combined. Cryptosporidium and Cyclospora are two parasites that we monitored. They've declined since the -- began for those in 1997; O157 increased, if you looked at all sites combined compared '96 to 2000, an increase in four to five sites, individually. There was marked variation from year to year and from site to site. And this makes it difficult to get an overall trend for 0157.

This table is just a summary of what we've seen over the years. This is reproduced from our MMWR articles over the years. This summarizes the changes that we see in the evaluation. Campylobacter, listeria, salmonella, yersinia, each showed declines, comparing 1996 to 2000. Some other pathogens showed increases of 0157, shigella and vibrio.

Overall, we saw about 7 percent decline in the foodborne illnesses that we have under surveillance, comparing 1996 to 2000. Typhimurium and Enteritidis are the two leading causes of salmonella infections within FoodNet. As you can see, each declined, as did salmonella, overall. It was about 30 percent decline comparing '96 with 2000.

This next series of slides is just to give you an

impression of how complex these changes have been. This is to look at the changes over time in all the original five sites. You can see that Campylobacter did, indeed, have a sense of decline over time. But it had very different shapes in each of the five original sites.

So when we see E. coli 0157, although if you compare '96 with 2000, there's an increase. If you'll look at each of the sites individually over time, it's very difficult to discern a silent trend through these various sites over the last five years. Some of them for salmonella, although there is a stronger component of a downward trend here, it is not tremendous, not dramatic. Shigella again, not always foodborne, although declining in the initial years, has shown a tremendous upswing in at least two of the sites: California and Minnesota with these sorts of outbreaks.

Listeria, on the other hand, showed pronounced declines in several sites and an upswing in another, leading to an overall decline in listeria, but again, difficult to really have a silent trend out of these various figures.

In general, however, the overall magnitude of incidents in the rise of all of the pathogens has remained the same over time within FoodNet. In all the years of our surveillance, Campylobacter is number one, salmonella is number two, shigella and E. coli 0157 were numbers three and

four.

The incidence of laboratory diverse salmonella and Campylobacter infections seemed to decline over time, although the overall trends were difficult to measure with the positions and reasons that I mentioned. We have geographic variation over time and these are hard to understand but they provide opportunities for further research.

The infamous trend for E. coli 0157, in particular, is very difficult to discern. We saw a substantial increase overall of shigella infections that were driven primarily by two large outbreaks, one in Centerville, Minnesota, which is actually a series of outbreaks in daycare centers; and one in California which was a couple of outbreaks from foodborne -- .

In the year 2000, with regards to the listeria infections measured by FoodNet; we noticed that we've seen in the precursor surveillance system that FoodNet identified that in 1989 and 1983 showed somewhat higher in 1989 than in 1993, higher incidents of listeria infections. That it fell three -- per one hundred thousands -- that FoodNet -- precursor has measured.

One of the things that FoodNet has been able to do, again, is to pull together all the various data sources and generate estimates of the -- . And here's one of the

fruits of FoodNet's efforts. In other words, the major infectious diseases are -- . Paul -- gave us estimates of foodborne illness in this country. And we estimated that there are 76 million incidents across the country that can be related to foodborne mechanisms and pathogens and 323,000 hospitalizations and 5,000 deaths. And, again, it's the first comprehensive set of estimates that CDC's done in over a decade. And it's been used for cost estimates, risk assessments, as well as modeling for other disease estimates.

Another program that has benefitted from FoodNet's experience and FoodNet's data is the Healthy People 2010 Objectives that HHS puts out every decade. And for four of the illnesses under surveillance, we have targets based on 1997 and 1998 baselines, and they go to 2010, eventually cutting those in half.

And we see that in the year 2000, although I don't show the baseline, but we see progress towards those goals. They are still quite a ways from achieving the 2010 goals. So there's a lot more work to be done in preventing these and also in understanding what is happening from population exposure to our hearing about them.

Now, as you can probably tell from some of the qualifications I've put on some of the data I've presented, there are a number of limitations to this data. It's not

perfect. There are some social, local variations which, again, offer opportunities for study but makes it difficult to provide summary statistics and to provide some of the numbers that help us really see the impact of various changes over time.

As I mentioned earlier, also this is not a national representative sample. So although we do make estimates occasionally to the nation as a whole, those estimates are difficult to make and require a lot of circumspection. But the numbers that we do get from FoodNet, we feel, do represent accurately what's happening in that large population area.

We also have data, as I mentioned on laboratory confirmed illnesses. We don't hear about the people who don't seek care, people whose physicians don't order cultures or laboratories that don't do things properly. And we do try to estimate where that data has occurred and how much does occur.

Two of the things that we plan to concentrate over the next few years present challenges to us and -- the involvement of the food supply which means a potential range of pathogens and a potential range of published -- accounts of these illnesses.

The information technologies which can be solutions, as well as problems, as we see in some of the

outbreaks of food processes that were intended to alleviate some of the -- early outbreak and other problems occurred. We also see a lot of change in -- continuing changes, continuing new technologies, new and better ways to detect pathogens to linking together to identify outbreaks.

And this provides us with opportunities for finding more cases and challenges for people like us who try to follow trends over time to try to incorporate those rules, surveillance systems, and new tools for surveillance into our trends and into an understanding in trying to find foodborne illness.

We also have, as mentioned in the paper that I alluded to earlier, there are a large proportion of foodborne illnesses that we detect of outbreaks in other circumstances that are caused by agents that we mentioned; to discover what to do and to test for efficiently.

Our projects in the current year, I think I've mentioned these already -- but is to conduct the population survey again, to complete and analyze our Cryptosporidium case control study and to continue the Listeria case control study into a separate but perhaps a third year. And we also have launched an Environmental Health Specialist Network, the intensity which we hope within FoodNet will help us to look more closely at environmental and -- inspections at restaurants and other locations with -- investigations with

outbreaks and with other cases. We're also in the planning stages for an infant illness case control study.

And in FoodNet in 2002, we have to continue projects that I mentioned. We have to integrate FoodNet more fully into some of the laboratory-based or more complete laboratory-based surveillance systems, such as the National -- Assistance Monitoring System -- , as well as PulseNet. We also hope to launch that infant illness case control study that we're planning currently and we hope to embark on a more substantial retail food safety project.

We want also to do a better job of focusing on some of the high-risk groups and focus on prevention and education, rather than counting the number of illnesses.

All of this information that I've given you, plus some additional background information, and updates are available on our web site, which is listed here: www.CDC.gov/FoodNet. And this will, again, give you an example of our background and copies of our reports and then any updates and new information that we have.

And all the data that I've asserted here we found on the March 23, 2000, edition of the MMWR which is our survey online at the CDC's web site. That's all the information I have today on FoodNet and 2000 data. I'd be happy to discuss and answer any questions about that data or other pathogens that perhaps FoodNet doesn't cover, things

beyond FoodNet. CDC covers more than just what is on FoodNet.

MS. WACHSMUTH: Thank you, Tom. Thank you for the numbers. We will have a copy of your -- and the Mead article. Questions for Tom? Okay. We'll start at this end and move down.

MS. NEILL: Very nice seeing you, Tom. Peggy from Brown University. First question is to the very striking difference clearly sustained over time for -- and salmonella with respect to the virtual differences. First pass at the data, we would seem to try to look at basic ethnic demographics which is age, race, et cetera. I'm assuming that you do have other variables relating to health status, immunocompromised in particular. Do you have any hints at that yet?

And my second and totally unrelated question for you, are there efforts to try to drive that 50 percent that the laboratory's testing of 0157 higher?

MR. VAN GILDER: The first question regarding the regional differences is particularly striking with campylobacter. We are actually actively engaged in looking at that -- have looked at the data that we have to look for demographic variables that would be different from the rest of the others. We looked at food exposures which we have, not on an individual level, but as we analyze each case of

foodborne illness.

The questions about that exposure that may be the circumstance we do for that population. So for the California site, for example, which has the high Campylobacter incidence, we have general information about what the eating habits are. And we have compared that to some of the other, especially low-incidence areas and haven't really found differences.

We've looked at things, like, for instance, we do a laboratory survey of regional differences in testing and for some evidence of 0157, some of that regional difference is due to differences in laboratory testing that exactly why, for example, again, Campylobacter is high in California and low, say, in Maryland. We haven't been able to determine, but we're looking actively at that.

MS. WACHSMUTH: I think basically, like age of the case, age and sex of all the cases --

MR. VAN GILDER: It is very possible.

MS. WACHSMUTH: That, in and of itself, is very interesting.

MR. VAN GILDER: Right. In fact, there are an assembly of the demographic differences but there are other things going on, as well. Regarding 0157 testing, at FoodNet we don't have an active program to encourage testing for 0157.

And I think one of the really nice things and one of our principal objectives, as I mentioned, within FoodNet, is to create a network. And FoodNet, as far as I've seen, is really drawing together all the various components, especially at the local level, of foodborne illness surveillance so that we have food test contact with laboratories to understand what they are going through in terms of testing they are doing and how to monitor that understanding when changes are happening. And we don't have a real strong encouragement to -- for them to test. We do give them data and try to help them understand the importance to us of what they do. So I think there is some encouragement in that.

MS. WACHSMUTH: Before we get to our next advisory committee member, on both sides of me I have this fresh versus frozen culture in California. I think that FoodNet looked into that a little bit. Can you tell us a little about that?

MR. VAN GILDER: We did. And actually, the data -- . And that is a very intriguing hypothesis that has not yet panned out. The difference is not, there doesn't seem to be a difference in fresh poultry in California versus frozen in Maryland. We haven't been able to determine that, that there's a difference, that would cause the difference that we saw.

MS. WACHSMUTH: Thank you. Alison?

MS. O'BRIEN: Yes. I'd like a follow-up on -- question regarding the host. And I know that you gave the data. But what is striking to me is 1996 was the year of the -- continuing with that and treatment of patients with HIV. And it's likely to have an impact on the host. And so we did have an impact on the host. Since the population in California where they have a fairly substantial number of potential immunosuppressed people, I was thinking it's reasonable to hypothesize that the host became healthier, as well, during the period from 1996 to now. And maybe, that had an impact on the incidents of Campylobacter. Do you have any data on incidents of diarrheal disease on HIV-positive people during that time in California?

MR. VAN GILDER: Within FoodNet, we don't have specific information on HIV-positive individuals and their experiences of diarrhea. We do have a immunocompromised question. We have it listed specifically but the numbers are fairly small of any given site of persons with immunocompromised conditions who may have been exposed to diarrhea. So we don't have that within FoodNet.

Through the general literature we've done, the incidence of diarrhea, in general, among HIV-infected persons, particularly caused by Cryptosporidium, dramatic

ways are mentioned -- so surely there's a component that we don't have a lot of data on. We have different ways of looking at it. We've looked at the highest population demographically and then some view towards their exposures. That's something that, as an issue, we have to look at carefully in the future.

MS. O'BRIEN: I live in Maryland -- and the number of labs that actually test for 0157:H7 is not the majority, in Maryland, including the U.S. Navy, does not routinely -- their Class A hospital does not routinely test for 0157. So I do think that's a critical component of a very low incidence of 0157.

MR. VAN GILDER: In 0157, recently, we -- and we compared them with other sites and did find that they do test more routinely than other sites do for 0157. But it doesn't make up the major difference between Minnesota and some of the other sites.

MS. O'BRIEN: Thank you.

MS. WACHSMUTH: Bill?

MR. SPERBER: In one of your slides, you showed that the highest percentage of hospitalizations were caused by Listeria monocytogenes. And by far, you have 80 percent. Do you think that in itself in isolation is a very deceptive figure, because there's so few cases of listeriosis compared to salmonella and some of the others on

your chart? So I was thinking that there might be a more useful way of checking this data. And I wonder, in effect, if you'll do this. Do you do that?

MR. VAN GILDER: Yes. That is something that we do. There is a project that I didn't mention that is underway where we are looking at -- of salmonella, shigella and Campylobacter. -- complication of Campylobacter infection. So we try to do balance that, and the slide showing listeria infections, possibly a great percentage of hospitilizations tends to be more severe incidence of -- manifestation.

MS. WACHSMUTH: Katie?

MS. SWANSON: I think that having data on the incidence of disease is something that's very useful as we try to evaluate different intervention strategies, somewhat can be useful, but I'm wondering if in addition to looking at how many cases there are; is there an effort to track the very cause of disease that's out there?

For example, inadequate heating and time temperature control, cross contamination and even at another level; are the diseases being caused by preparation in the home versus restaurant versus processed foods?

MR. VAN GILDER: We approach that in two ways. One, we do have a population survey that we've done three times, and are about to do a fourth time. The questions are

-- use of various things that have been recommended for consumer education; separation, things that sort of support -- .

So we do have estimates of what the populations are doing on an individual level to protect themselves against foodborne illness and a way of looking at anyway in a general sense of how largely the messages of food safety have been taken up. That's very, you know, very general and it's difficult to assess how reliable some of that information is.

The second way of approaching that, and looking at what is going on particularly outside the home is this -- specialist network attached to Foodnet. That we hope will allow us to get a better idea of what's happening in the restaurants and in other commercial food establishments to help us learn what are the risky practices, and if we know what the risky practices are; how prevalent are they?

In making that determination, how often can you eat out? How often they have various foods that tend to be risky outside the home? We hope that those two bits of data will help us understand better what the actual risk factors are and then design intervention strategies --

MS. WACHSMUTH: Okay. I just want to remind each person to state your name so the transcript can pick up

various questions. That was Katie Swanson.

MR. THENO: Dave Theno, Jack in the Box. Tom, I want to commend you and CDC for the work with Foodnet. Just being on the committee some years ago, having this data was a huge help as to how things go, so it's going nicely and we would encourage you to continue your efforts.

Working in the meat -- , it's hard to ignore the amount of illnesses that are of environment origin, and I wondered if Foodnet was contemplating some surveillance of viral organisms in addition to bacterial pathogens?

MR. VAN GILDER: We do not have active surveillance for viral illness in part because the diagnostic capabilities for viral illnesses and the detection in environmental food surfaces and stuff like this, are somewhat the bacterial components. In addition, the illnesses themselves tend to be shorter in duration so it's more difficult to get accurate specimens.

However, with the advance of certain technologies, PCR, for example, for the detection in both the human stool and environmental, and food samples and with advances in genetic -- and so forth, we have been able to identify more rapidly and more sensitively viral causes of foodborne illness. For example, a recent paper out of Foodnet looked at one hundred previously unknown foodborne outbreaks. That is outbreaks that we have detected, discovered, investigated

and no positive -- have been found, so no particular cause.

Well over half of those were found to be caused by -- virus which is a virus causing foodborne illness. Part of the reason that was able to be found is through FoodNet and other mechanisms; kits for testing stools and other samples, have allowed for more rapid and more accurate diagnosis.

So although we don't have and don't anticipate formal surveillance for viral illnesses the way we have it for the bacterial illnesses, I think -- detection operates and then through some additional networking will allow us to monitor better and describe more accurately the microbial viral illness, as well.

So we do anticipate we will get better at detecting viral illnesses, able to get a better idea of what the -- but will probably not translate to formal surveillance within FoodNet for these agents.

MS. WACHSMUTH: Bruce?

MR. TOMPKIN: Bob Tompkin from Conagra. I've been following your MMWR reports every year, and follow them closely, but what you presented today is much more complete and I do hope that all the slides will be available through the Foodnet site within CDC, or no?

MR. VAN GILDER: We had made them available. They're not currently available on the website. We are

looking to return them. We have previous slide sets that we've had up on the web --

MR. TOMPKIN: For future purposes, and for transferring this information within the industry, throughout the industry anyway in terms of helping us understand the issues and where to focus our energies. It's very helpful and the more that we can learn from you and the CDC, the better we can communicate that information.

Have one simple question and that was that in the year 2000, in looking at all the sites the way the disease is tracked, only one was greater than the rest. The one for salmonella had a higher number case rate when all sites were combined, as opposed to the year 2000 based on the original five sites.

All of the rest were equal to or lower than so it looks like as you expand the population base, we're getting a lower number, equal or lower number. Is that expected?

MR. VAN GILDER: Let me answer the question. I'm not sure if I understand the question. As we added new sites, we didn't expect each site to have -- for instance but I think we were interested to see how different, for example, Tennessee was from the rest of FoodNet, with its dramatic rates of Campylobacter infections, not dramatically but somewhat higher rates of salmonella infections.

So trying to understand Foodnet 2000 as we combine

all of the sites versus ninety-nine of the previous years with fewer sites, we do have to come to grips with how to integrate those data. So if we add Tennessee to the Campylobacter rates, overall decline; is that because we have in Tennessee, just sort of surprising low level of Campylobacter, or is it because Campylobacter is declining?

How we wrestle with the fact from a sort of statistical point of view is not yet been fully -- . We need to talk about this to help us understand the data. That's one of the reasons why we look at things over time just to look at the five sites, even though the population of the five sites is less than half of the total FoodNet experience. But we have not yet been able to really integrate those geographic differences, those regional differences in incidents, in such a way that we feel confident we're following trends over time.

But that's something that we are looking into and hoping to understand and again hope that by having different sites that are doing comparable looks at detecting these illnesses, than we can understand whether a difference in Tennessee and California in Campylobacter, whether that's a difference in looking at a difference in population or a difference in something else that happens in those respective environments. It presents a great opportunity to look at that illness.

MS. WACHSMUTH: Okay. Dane?

MR. BERNARD: Thank you, Chair. Dane Bernard. A procedural question first. Have you had an opportunity to revisit the salmonella data that the previous speaker introduced?

MS. WACHSMUTH: You have in our deliberations, did you consider any of the information that you had in the packet that would include the information that was introduced previously.

MR. BERNARD: The reason I ask is during our deliberations I'm sure there were, but there are some questions that I have on the derivation that David and others, I'm sure that there are people on the committee and I just really wanted to make sure that they have an opportunity to revisit that with the appropriate people.

MS. WACHSMUTH: I'm not sure if you want to ask a question at this point in the data or --

A PARTICIPANT: -- I just wanted to get that out now --

MS. WACHSMUTH: Yes.

MR. BERNARD: -- so that we don't lose --

MS. WACHSMUTH: Yes.

MR: BERNARD: -- the opportunity to --

MS. WACHSMUTH: No. As I mentioned this morning, we didn't have to have a committee report, at least on

performance standards for salmonella and then addressing that, if you want to analyze any of the data that we have, you would probably have the opportunity through subcommittee then back to the full committee in August.

MR. BERNARD: Okay.

MS. WACHSMUTH: Okay.

MR. BERNARD: Well, let me ask my question.

MS. WACHSMUTH: Okay.

MR. BERNARD: First of all, my compliments to both the speakers and their contributions. The salmonella data that was presented showed us some very good and interesting results relative to Typhimurium and Enteritidis, in terms of the downward trends. But overall, the data from all sites 2000 doesn't show much change.

Could you enlighten us a bit as to what those may mean, if there is an answer to that? I'm sure part of what you just discussed regarding looking at all sites versus the original five sites -- but I'll assume a different mix of salmonella serotypes showing up today and if we did, are we, in fact, seeing a definite trend downward or based on today, what we have today, can we see at all?

A PARTICIPANT: All right. Within FoodNet, coming from a larger public health -- information system, there appears to be an overall downward trend in salmonella that has been going on for a few years. It's again regional. It

differs regionally. It differs year to year. Part of that sort of touches on our earlier discussion to answer your last question.

Part of the difficulty for us is understanding as we add sites that are relatively high in salmonella infections to the overall picture, what that means for long term trends? It's encouraging that again, that overall -- the number of type 2 serotypes -- . That number really just seems to be fairly steadily declining. -- an overall downward trend.

We can see there have not been dramatic changes in the top five to seven serotypes, although if you look at salmonella, shigella -- there have been some turnovers in some serotypes moving up and some serotypes moving down. There is a paper in press looking at that, looking at the salmonella serotype experience enteritidis in the United States. I don't know when it's coming out but it should be coming out soon.

But to sort of summarize, the top serotypes have not been changed dramatically over the last few years, particularly from FoodNet. Enteritidis and Typhimurium have declined, probably at a sharper angle than overall. Salmonella -- . There's not one or two serotypes that seem to be making up that difference.

MR. BERNARD: What it tells me is that while the

trend appears to be in the right direction, it's too early to be specific but the steepness of the decline of changing serotypes if that characterizes what you said.

MR. VAN GILDER: I think it's a fair summary and I think although we have alot of confidence in Foodnet's ability to determine how much foodborne illness there is out there, I think it's the best information available. Five years isn't alot of time on which to hang trends or to -- specifically. But we do have alot of confidence in our data and I think it's the best. We also continue to assure you of better answers to the questions you have.

MS. WACHSMUTH: Okay. Bob? Oh, Cathy. I'm sorry.

MS. DONNELLY: I just wanted to follow-up on something. Within salmonella serotypes, looking at DT-104 strands of Salmonella typhimurium and now I understand that -- has acquired this set, is that the same data set with respect to -- possessed in salmonella serotypes on -- and does this have an impact on hospitalizations or illness?

MR. VAN GILDER: Well, you summarize neatly what we've seen in salmonella -- over the last few years. There seems to be an increase. There seems to be an increase in the multi-drug resistant strains as well. -- are chief examples of that.

We're looking at it very carefully especially within the antibiotic resistance -- which is apparent

within FoodNet but has more states participating. But we have not really seen a change in hospitalization of severe illness, but part of that is for lack of sufficient numbers of cases to be able to make that comparison to what is an active area of investigation now. So we haven't seen changes in hospitalizations driven by anocyclovir resistant agents, but we have seen more multi-drug resistant salmonella in particular.

MS. WACHSMUTH: Stephanie.

MS. DOORES: Stephanie Doores, Penn State University. How do you apportion the number of foodborne illnesses, I should say the number of illnesses associated with food? Who makes that decision as to whether it's foodborne or not? Are the organisms ever isolated from the food or are these truly confirmed cases?

MR. VAN GILDER: Well, FoodNet itself, the active surveillance portion, only counts laboratory confirmed cases of food illness. The information about what caused it -- what the exposures were, come from other sources, so alot of information that we get is simply basic demographic information.

-- what caused the illness is outside of case control study. We try to do through sort of -- associations to find out what the exposures are in the general population and then through case control studies about operating cases,

try to understand what risk factors cases have that are similar, the same type of reaction. We always seem to operate investigations to look at -- to see whether something is foodborne or not.

Globally, for example, in Paul Mead's paper of how we determine what portion of all the illnesses that we hear about are foodborne or not are based on certain data that I mentioned but in general our sort of aggregate, sort of -- analysis, if you will, of experiments over a decade of more of examining foodborne disease outbreaks and -- maybe overall.

But if your question is do we know for each specific case of -- whether or not that particular infection was foodborne, then we don't know that. But we do know from the behavior of organisms that we do know from different outbreaks, and case control studies in non-outbreak settings, generally what the nature of the exposures are that caused these illnesses.

MS. DOORES: How do you treat something like a bacilliferous diarrheogenic form when it's not one of the organisms that you would be testing for but the person might be presenting with diarrhea? Does that fall into your statistics at all?

MR. VAN GILDER: Well, it wouldn't fall into our numbers in terms of the active surveillance for foodborne

illness numbers that are in the various tables. It would show up, for example, in population surveys when we ask people whom we found out had diarrhea over the last X number of days. So outside of FoodNet, particularly at the state and local level, and at the Federal level, we do an investigation of these serious outbreaks and attempt to understand the ecology of the organism and how it would be through the food supply or not, in any one circumstance. So specifically, no, we don't have information on, for example, the these serious -- foodborne pathogens but we do have other sources of information from within FoodNet and outside of FoodNet.

MS. DOORES: And my last question is if a person presents with diarrhea and it's not considered of foodborne origin, what would be the most likely source of acquisition of that disease into another category, non-foodborne category?

MS. VAN GILDER: It would be difficult because there's so many different ways for us to slice that up. I don't know if I want to hazard a guess. There are so many different ways of declaring diarrheal illnesses. Some of them are encryptedly foodborne, others are not.

But there's certainly a lot of, for example, daycare associated diarrhea in among day care and food staff, and family members. If that's the result of one

child picking up salmonella or she got salmonella from a foodborne illness at home and brought it to day care, that would allow -- foodborne in a sense -- from person to person. So it would be really difficult to hazard a guess. There's so many different ways of getting diarrhea.

MS. WACHSMUTH: Okay.

MS. DOWNES: Frances Downes from Michigan Department of Community Health. Considering the outbreaks in containing health care costs, particularly with managed care, are you seeing any differences regionally or over time on changes in the physician's likelihood to order a stool culture?

MR. VAN GILDER: We see them only access that one time. We've tried to get anecdotes about that. We don't have any systematic way of detecting whether physicians are changing their culture practices. Physicians are notoriously difficult to survey, and it's hard to understand how the different forces -- have either discouraged or encouraged cultures.

Overall in general, they feel stool cultures don't yield a lot of information, at least alot of useful, thorough information and therefore probably some are used in some circumstances and others are used in others. The numbers of times is sort of difficult to know. There is sort of a little more complexity in addition to more rapid,

more sensitive aspects for some of these organisms that there seem to be more of. Does that represent an increase in physicians or is that rather a phase -- . Are they doing more stool cultures now, than five or 10 years ago. I don't think anybody can really say.

We are trying mostly at the laboratory level to understand how that might be changing, and we haven't seen dramatic differences at least in the number of stool cultures, the number of stools tested, or the types of things we were testing for.

So while we're not -- the physicians, we are looking at the numbers of stools that are making it into the laboratory. That doesn't seem to be changing. I don't think it can be emphasized enough how different the environment within the laboratory is changing. The pressure on laboratories is tremendous. I'm sure it's going to have an effect on surveillance.

MS. WACHSMUTH: Okay.

MR. FARRAR: My name is Jeff Farrar. Excellent presentation Tom. You mentioned some of the goals, the year 2010 goals. It is important to have those goals, short-term as well, but is there any part of the discussion given to long-term goals in terms of -- long-term, what those numbers should be or ultimately should be?

MR. VAN GILDER: I think the general answer is

yes, that that kind of discussion goes on all on the time. We focus ourselves within FoodNet and CDC seeing so much on the immediate things and what the problem at hand is and what can be done to prevent the problem from happening a second time. I wouldn't say there's a formal plan that looks globally. There's certainly an effort within our branches to reduce these illnesses as much as possible. What that translates into for a specific number, I wouldn't know.

But I think that Stanley (phonetic) -- and Horizons (phonetic) --publishes with other groups, who do risk assessment and economic analysis and so forth. I think we are able to take what we do best and whether if what other people do best which is looking at interim reductions or looking at -- determining acceptable risk.

Again, specifically, we don't embark on those kinds of thoughts or those kinds of efforts. But you've got to think of us at FoodNet in other places as we have closer relationships with non-traditional public health folks, if you will, where those kinds of issues are being addressed.

MR. HABTEMARIAM: Thank you Madam Chairwoman. My name is Tsegaye Habtemariam from Tuskegee University. I also want to congratulate the presenters. I think there was some significant things about HACCP. It was really, really impressive, very significant to see these changes. I will

definitely look at it in greater detail.

But I have a couple of questions. First, the -- for FoodNet that you referred to. I know you have some very good reasons for doing that. And you can also see that FoodNet is a very powerful resource. There are a lot of -- but you had also indicated that it is not representative. That is a very important issue. Do you have plans to address that issue so that in fact, there will also be sound information that will be applicable for the nation as a whole. That's one question.

In your -- or incidents, you were indicating that the results are going down in many of the areas. I can understand that when incidents were referred to in lab data as well as physician's records. But I was curious, when you do the population survey are you actually asking incidence information or what exists at the point of time you're doing the survey, just for prevalence? I need some clarification. Could you speak to those issues?

MR. VAN GILDER: Sure. I'll take the second question first. I actually think we're probably getting a mixture of incidence and prevalence data in our population survey and asking people whether they have diarrhea in the last month. We try to eliminate some of the -- cases by excluding people out who have ongoing reasons for having diarrhea.

We also try by comparing our findings with the findings of similar and -- efforts in the U.K. and other places, particularly Western Europe to understand how different ways of asking that to get different results. But I think it's probably not a clean incidence of diarrhea that we're getting. It's a pretty good number of results and it does compare well with other efforts -- we feel like we're -- same magnitude of problems and so I think that we're getting a pretty good idea of how much time we have on our hands.

Your first question regarding the representativeness of FoodNet, the site we've chosen by competitive process so the sites represent those sites of -- application, a committee that chose them over time. So they're not explicitly nationally represented. They're chosen at random, for example.

However, in looking at the demographics of the FoodNet population versus the rest of the nation in age structure and sex and race and so forth, insofar as we have that information, it's comparable to the U.S. population in most respects. We actually have a doctoral student who is looking more explicitly at statistical issues in making inferences from the FoodNet to the nation as a whole. So we're addressing them in that sense. We are not addressing in the sense of attempting to enlist other sites or somehow

randomize the sites that we have. And that would make them nationally representative,

But it's certainly something that we are interesting in hearing more about and are taking steps to do so. Whether in the end, for one level to be the statistically national representative, I doubt, but a good idea of what FoodNet is doing relative to the rest of the country. At least be able to, when we make national estimates, know what the hazards are and what the limitations would be on those national estimates.

MS. WACHSMUTH: Bob.

MR. BUCHANAN: Bob Buchanan, FDA. I'd like to express my appreciation for a good presentation. In the question that came out, you did mention the NARMS program, which is the other half of FoodNet activities. It's my understanding that in addition to direct analysis great deal of time selecting samples that FSIS collects in terms of salmonella, including I understand -- serotyping on the organism in addition to -- resistance patterns.

It would seem to me that this would tell us a great deal about the role of foods and which foods were associated with this by comparing the serotypes coming out of the NARMS program in conjunction with the -- . Is there any claim, I did not notice any included in the 2001 or 2002 budget that actually compared serotypes

coming from the different products versus what you're seeing in the population.

MR. VAN GILDER: Right. What that is, is an active ongoing effort. Instead of going from the Foodnet side is to link the patient information that we have with the isolate information we have with the other isolates that we get through NARMS, though PulseNet and through other means including some lab work isolates so that we can get a better idea of what the epidemiology is in humans and concurring at least ecologically with the information that we're getting from our private sector.

Also, just our ongoing efforts within Foodnet to try to understand how our trends or how our numbers are lining up with the numbers that we've gotten from -- and from retail establishments. Basically, these discussions are ongoing with projects -- trying to look at regional differences in Campylobacter is a step in that direction. And try to look at product sampling data whether it's ours or someone else's --

MS. WACHSMUTH: Thank you. Okay. Larry?

MR. BEUCHAT: My question is also on the conciseness of your presentation, Tom. My question deals with NARMS also. Did the data that is being generated by that component of the Foodnet allow you to attempt to correlate numbers and types of antibiotic resistant

salmonellas with foods or foods containing ingredients that were imported versus domestic?

The second part of that question would be is there a mechanism or are you pursuing mechanisms to interact with surveillance groups in other countries and other continents, the European Union, for example?

MR. VAN GILDER: Let me take the second question first. Yes, we are both in FoodNet generally and NARMS in particular. There is a large collaboration with food sampling in the Public Health Laboratory in the U.K. and the British Culinary Services Laboratory in Denmark.

There is also through a separate program with the same cast of characters that worked on the salmonella surveillance, an effort to make salmonella serotyping globally, at least through the sharing of serotype information and then if multi-drug resistant salmonella is found then with a network set up you can ask other countries.

It's not quite as seamless as that but there are a number of efforts to try to make both general foodborne information but also pathogen-specific information with countries in the developed and in the developing world.

Now your first question regarding efforts to determine whether -- in foods. I'd have to say I don't know specifically what efforts in that direction outside the

Outbreak Center. Certainly there are a number of outbreaks that developed that in other agencies efforts to trace back things to their origin, has taken us to other countries. So we have that element. There may be others that I'm not aware of but specifically with a -- international versus domestic component --

MS. WACHSMUTH: Swami?

MR. SWAMINATHAN: Bala Swaminathan, CDC. FoodNet counts culture confirmed cases. We have seen that -- non culture identification of E. coli including E. coli 0157:H7. I have two questions. One is are we going to see an increase in the E. coli 0157 numbers in FoodNet although there is no decline in E.coli 0157 and, (2) are there plans to modify your laboratory questionnaires to ask the question (1) do you culture for E. coli 0157; (2) do you use non-cultural methods for detecting S. tec, or (3) do you look for S. tec at all?

MR. VAN GILDER: Yes. It's hard to know with the advent of probably more sensitive non-culture methods whether we'll see more or less S. tec, I guess in some ways perhaps 0157 specifically because we identified essentially -- it would be identified as -- toxin producing.

We have modified somewhat our case for -- so that we ascertain -- toxin producing E. coli whatever reference has been identified subsequent to getting serotype

information so that we know that it is 0157 or one of the other S types. So we have modified it somewhat to capture some of those changes.

So we hope that we would be able to get a true estimate of what's happening in the world of S. tec difficulty tracking 0157 specifically. However, we're working both in this effort, since we are at FoodNet, but certainly we are making efforts to understand who would be involved in these decisions but also to move forward to have states request or perhaps require laboratories to send them positive isolates, so if they detect S. tec or non-culture method, they can send that out to the state for serotyping. So we hope that if you're not, you can use that serotype information.

The second question regarding surveying the laboratories for information about 0157 testing, rather S. tec testing. We have done that actually in two of our lab surveys, the '97 and the 2000. We did ask whether they test for 0157 or not, whether they use culture methods or non-culture methods. We have seen certain amounts of -- we have seen an increase in lab culture method testing for S. tec.

I think that's probably too strong a term. There were a few labs who did in 1997, and there were quite a few more who did in 2000. But still, just a nominal percentage

of the laboratories have -- some of the laboratories that are quite large. So in terms of the number of stools being tested in that way, it's probably certainly not the majority, but there certainly are a number of laboratories who say they are testing for it.

So again, it's a potential complication and also a potential opportunity and we're hoping that -- is such an active method that we're able to begin to understand, if not have an impact on these trends.

MS. WACHSMUTH: One more question before we break.

MR. LUCHANSKY: John Luchansky, ARS. I'll try to be quick. A follow-up I think to Sperber's question. Am I correct in assuming that the data do not reflect for listeriosis atypical cases? If so, do you have a sense for what that value or level might be?

MR. VAN GILDER: Basically, are you specifically referring to the -- manifestation of listeriosis versus others, or do you have something else in mind.

MR. LUCHANSKY: That's correct, yes.

MR. VAN GILDER: Foodnet collects, specifically collects data on serosite (phonetic) listeria isolations. So a stool listeria would be recognized but not encountered as a case of listeriosis in Foodnet. And in some of our case control studies, we choose out some of those types of issues more specifically. So far in the year that the case

control studies have been going on, we've only had one sort of atypical case come up, some kind of bizarre wound isolation. But in general the case definition for FoodNet listeriosis is an isolate for serosite, -- and CSF are sort of examples.

MR. LUCHANSKY: With that being said, do you have a feel for whether or not atypical cases might be something to consider or not consider?

MR. VAN GILDER: I don't know how to answer exactly except that we certainly, in our branch in general, look at those and certainly look them up when they come to our attention. I don't know if anybody has looked at how often they occur.

-- outbreak in Wisconsin back in '95 or so but specifically within FoodNet counting or trying to keep track of them, we don't have the funds to do so. But in general, we do hear about those kinds of things. We discuss these cases as they come up in general is interested in knowing about them as they occur. And then there are times when, in fact, we go out and try to identify them.

MS. WACHSMUTH: Tom, a splendid job of answering all the questions. I apologize to Phil Derfler. We're going to move him to right after the break. So 15 minutes.

(Break at 10:45 a.m.)

(Meeting resumed at 11:10 a.m.

MS. WACHSMUTH: Okay. You can start. Our next speaking has the privilege of doing what I've said that we can't do, he does policy. This is Phil Derfler, who is the Deputy Administrator for the Office of Policy, Program Development and Evaluation known at FSIS as OPPDE. And Phil's office does create the policies and tries to use the science that our Office of Public Health and Science collects together and analyzes.

He's going to talk to us now about the policy aspects of the salmonella performance standard. He is a lawyer, so he's very well credentialed. Phil? Don't hold it against him.

(Laughter.)

MR. DERFLER: Actually, I was going to say that it's a privilege to be here and that it's quite intimidating as I'm not a scientist, in speaking before this group. I'll do the best that I can.

I'm going to talk about the salmonella performance standard for raw product, for carcasses and for ground beef. I passed out, in addition to the materials that you have in your book, the current standards that we have in place. I'm going to discuss three aspects of the procurement standards.

First, why FSIS chose salmonella as the target organism for pathogen reduction. Second, how FSIS arrived at the levels in the performance standards and, third, how

FSIS ensures compliance in the performance standards.

Please keep in mind that FSIS also has in place salmonella performance standards for other types of products, in particular for cooked, ready-to-eat meat products. These performance standards were arrived at in a different way and serve a different purpose than the salmonella performance standards for raw product.

We're not going to talk about those and any questions that you've got that deal with those performance standards, we want to take those off the table. My talk is going to focus on the raw product performance standards.

So why was salmonella chosen as the target organism? As Mr. Billy stated earlier, HACCP and performance standards are intertwined in the Agency's regulatory strategy for improving food safety.

In the pathogen reduction HACCP final rule that FSIS promulgated in 1996, the Agency gave four reasons for why it considered salmonella to be the appropriate organism to use as the measure of performance in pathogen reduction.

First, salmonella is a problem pathogen. As the previous speaker pointed out, it's among the most common causes of foodborne illness associated with meat and poultry products.

Second, salmonella is relatively easy to find. Current testing methodologies can recover salmonella from a

variety of meat and poultry products.

Third, salmonella is a useful indicator. Interventions that end up reducing salmonella are likely to be beneficial in reducing contamination of other -- pathogens.

Finally, it's role in determining what's happening with salmonella, as it occurs at frequencies that permit changes in its occurrence to be detected in and monitored. These four factors make clear that FSIS chose salmonella as its target because it would provide ready indication as to whether SSOP's, sanitation standard operating procedures, in HACCP were succeeding in controlling and reducing pathogens.

How was the level of salmonella in the performance standards determined? The pathogen reduction HACCP system final rule set pathogen reduction performance standards for salmonella that must be met by all slaughter plants and all plants that produce raw, ground products.

There are separate performance standards for carcasses of cattle, one for steers and heifers and one for cows and bulls, for market hog carcasses and for young chickens. There are also pathogen reduction performance standards for ground beef, ground chicken and ground turkey.

The pathogen reduction performance standards for salmonella are based on FSIS data collection which are referred to as baseline studies. There was a separate

baseline study for each product category. The Agency used the results of these baseline studies to provide a national estimate for each product category of the percentage of product that contained salmonella.

In the final rule FSIS concluded that these national estimates for salmonella prevalence was the best available data on which to establish salmonella performance standards. So the performance standards have been set based on national estimates of salmonella prevalence. For example, the standard for ground beef is 7.5 percent because the results in the baseline study support a national estimate of 7.5 percent of ground beef contains salmonella, or at least they did based on the studies that were conducted.

The performance standards, however, are not directly translatable into an enforceable measure. After developing the standards the Agency set out to design a sampling approach for determining whether an establishment is meeting the applicable standard. The Agency decided to measure individual plant performance using a series of sample sets.

FSIS defines sample sets based on two parameters: the number of test results in the set and the maximum number of positives that can occur and there still be compliance.

As for the former factor, FSIS decided that the

set size should be greater than 50, so that in doing sampling, FSIS would be measuring process control over a period of time.

As for the number of positives, FSIS set these numbers so that establishments that are operating at the performance standard, that is at the national prevalence level, would have an 80 percent probability of passing the set.

The Preamble to the final rule was when FSIS decided to choose the 80 percent level based on the balancing of three factors: the need to prevent establishments from failing to meet the standard based on chance results, the need to ensure that plants that were not meeting the standard would be readily detected and the need to give plants an incentive to perform beyond what would be minimally required.

Given the decision to use the set size over 50 and an 80 percent probability of passing the standard a number of samples and the number of positives to achieve the standard in a set, were determined using binomial probability distribution.

Now to explain how that works from a prior statistician which I am -- but to give you an example, for ground beef, the performance standard is 7.5 percent. A plant would be considered to meet the standard if out of 53

samples, five or less were positive.

The approach that FSIS used in setting the performance standards results in the levels of performance that establishments must achieve varying from product class to product class. This led some to complain about inequities in the standards. For example, that boilers can have a 20 percent positive for salmonella to pass, while steers and heifers can only be one percent positive to pass.

The standards are consistent however, because what is required is the same for all establishments. They must achieve at least the baseline level of performance for the product classes that they produce.

It is important to note that the salmonella performance standards are not based on quantitative assessment of the risk posed by any particular incidence of contamination, more on the determination of a safe incidence level. In other words, the levels are not based on how much salmonella it takes to make a person sick. There's not an adequate scientific basis for making such an assessment.

The salmonella performance standards are based instead on the public health judgment that reducing the percentage of product with salmonella will reduce the risk of foodborne illness. And that it is important for an establishment to demonstrate that it is able to control the occurrence of pathogens in its product. That is, that it is

able to consistently produce product that meets the performance standard.

Data collected in 2000, and Mr. Billy mentioned before, indicate that salmonella prevalence in each of the product categories subject to performance standards have dropped since HACCP implementation and that overall, 90 percent of all plants tested are meeting the standards.

Despite these encouraging results there has been some concern expressed by people in the industry that the standards are too stringent. The Agency's response to these concerns is this, it is feasible for all establishments to meet or exceed the baseline prevalence of contamination of salmonella particularly if the plant maintains sanitary conditions, meets the sanitation standard operating conditions and operate in accordance with an adequate validated HACCP system.

These fact are strongly supported by the results of the testing that FSIS has done which, as I stated, show that most establishments are meeting the standard. Now -- how does FSIS enforce the performance standards?

It is important to point out that establishments must meet the salmonella performance standard not on a lot by lot basis, but consistently over a period of time. In other words, the standards for raw product are not used to judge whether specific lots of product are adulterated or

not, rather the standards are intended to be a basis on which to evaluate the adequacy of an establishment's HACCP system in controlling and reducing hazards including pathogenic bacteria in the product.

FSIS determines an establishment's compliance with the salmonella performance standard by taking the appropriate number of samples, generally at a rate of one per day, testing each sample for salmonella and determining whether the number of positives is above the maximum for permitted for that product.

The Agency's goal is to achieve pathogen reduction by ensuring that all slaughter and raw ground establishments meet the performance standards established by FSIS. Enforcement is based on a two part testing program. Ongoing testing which includes all establishments at regular intervals, irrespective of performance, and targeted testing that's focused on establishments that have been unable to meet the performance standard.

If I'm going with targeted testing, and an establishment evidences that the performance standard is not being met, then FSIS will decide whether to conduct follow-up testing on the basis of several factors.

FSIS initiates another set of tests immediately at all establishments, with test results that significantly exceed the standard. If an establishment has salmonella

test results marginally above the limit, and takes corrective action, FSIS may decide that immediate follow-up testing is not necessary. If on the other hand, that establishment were not to take -- corrective action or if it took no action at all, then FSIS would institute another series of tests despite the fact that the results were only marginally above the standard.

If an establishment fails the second targeted series of tests, then it is acquired to reassess its HACCP plan for the tested product and to modify its claim as necessary to achieve the salmonella performance standard.

If the establishment fails to reassess its HACCP plan and make the modifications in its plan that the reassessment suggests or if it fails a third series of tests, FSIS will give the establishment notice that it intends to suspend inspection services.

The suspension will remain in effect until the establishment comes forward with a credible plan through modification of its HACCP plan, that will likely enable it to meet the performance standard.

In closing, I'd like to reiterate what I think are some of the more important points to remember about the salmonella performance standard. First, the standards are based on what FSIS concluded were the best available data on the prevalence of salmonella in raw products. The standards

were established based on FSIS' public health judgment that reducing the percentage of carcasses in ground product of salmonella will reduce the risk of foodborne illnesses.

Second, we know that the salmonella performance standards are achievable because they are based on nationwide baseline surveys of what establishments were achieving prior to HACCP implementation. In fact, an overwhelming majority of plants have been able to meet those -- standards since they were implemented.

Third, the salmonella standards are not for use for judging specific product, but instead are used to evaluate the performance of an establishment overtime, and finally, as Mr. Billy said, there's reason to believe that the salmonella standards are working. Salmonella numbers are down in the products for which standards have been set and there is at least the suggestion in the CDC FoodNet data, that foodborne illness is down, as well.

MS. WACHSMUTH: Thanks, Phil. Any questions from the members? Swami?

MR. SWAMINATHAN: Bala Swaminathan CDC. You mentioned in the beginning that there should be an incentive to the plants to exceed the salmonella performance standard, but you never discussed what the incentive would be.

MR. DERFLER: Well, I didn't say that there should be an incentive. I said that we established the 80 percent

as an incentive. That was one, in fact, incentive that we set in arriving at the 80 percent level. We wanted to provide some incentive to the plants.

MS. WACHSMUTH: Katie?

MS. SWANSON: Katie Swanson, Pillsbury. Was E. coli testing implemented at the same time that the salmonella performance standards were implemented by the facilities and could those data also contribute to the reduction in salmonella levels because they've got a quantitative measure to collect against?

MR. DERFLER: The generic E. coli standards in the regulations are voluntary that are done by -- they were not done by FSIS.

MS. SWANSON: Right.

MR. DERFLER: You know, I'm not going to judge what those measures -- it was intended as a measure of process control. That's how we describe it in the final rule, not as a measure of pathogen reduction.

MS. SWANSON: Yes. I only bring it up because one of the questions that is posed is related to are there indicators that could be used in lieu of salmonella testing?

I just am wondering since the E. coli indicator was implemented at the same time that salmonella testing was, the reduction might be a combination of both results.

MR. DERFLER: All I can say is the Agency's intent

at the time --

MS. SWANSON: Thank you.

MS. WACHSMUTH: If I can recall correctly, E. coli testing was implemented six months before the salmonella testing. It's done by plants. I don't know if there will be comparability. Bruce?

MR. TOMPKIN: Bruce Tompkin from ConAgra. To what degree does the Agency provide information to those plants that do not meet the performance standards, information that could help them meet the standard? Is there any guidance provided for these establishments?

MR. DERFLER: One of the things that we do for plants that have failed two sets in a row -- the first set there is no particular consequence. But after the second set is failed, we do an in-depth verification at the plant.

Now a lot of plants view that as a threatening gesture. It's really not intended to be threatening. It's intended for us to go through the plant, through the company and try and suggest where we see problems, as a way to help the plants come into compliance.

We've learned that small and very small plants view the HACCP implementation process as part of the next steps initiative. We intend to continue and to renew those efforts. We've put out guidance to brand new plants for E. coli 0147, but that guidance could have some turnover to

salmonella levels.

We intend to provide additional guidance sometime in the future -- E. coli 0147 but probably would have some carryover. So we have made some measure of efforts to try and provide information to small plants.

MS. WACHSMUTH: David?

MR. THENO: David Theno with Jack in the Box. In the ground beef operations, specifically ground beef operations where it's not a -- operation. Clearly these people are taking what I'm sure doesn't convert into ground beef and they don't have an intervention -- purposes. Has anything been done to -- grinding operations back to the slaughter plants. Because that's, you know, where originally the -- are coming from, although it could be SOP issues or sanitation issues within the grinding plant?

MR. DERFLER: I'm not aware of -- but I trace it back to the -- the Preamble to the final rule. Some of the things -- make clear that we believe that the appropriate -- for a -- plant is intake. It may be necessary to establish ground standards, standards for the incoming product so that we are able to control salmonella levels and other pathogen levels.

MS. WACHSMUTH: Okay. Dane?

MR. BERNARD: Thank you. Dane Bernard. This is getting a little confusing.

(Laughter.)

Thank you for your presentation. Are we going to have copies of Mr. Derfler's, and the other speakers' presentations? There were a number of items in there that I'd like to have a chance to look at and become more familiar with.

The question I had asked earlier about revisiting the -- information referred to in the first talk, I'd still like to come back to that. A lot of what we just heard about I think would be informed by going back and looking at the derivation of the performance standards. The comparison that we're asked to make with today's performance versus those performance standards, I don't want to do right now. I'd like to resume the opportunity later.

What I'm going to do is ask a question regarding linking things back through the supply chain in terms of working from the ground beef producers back through the supply chain. I know that the information that was referred to earlier, the very last table we were -- refers to the number of sample sets taken and passed.

If my quick math serves me at all, we've got about 70 sample sets this is all -- represents several establishments for cows, bulls, steers and heifers. Ground beef is going to come from one of those, versus 653 samples from ground beef. If the interventions really can be

applied at slaughter, are we a little out of balance here?

MR. DERFLER: -- salmonella, the Agency said at that time that it would look at slaughter, particularly in plants that -- slaughter -- and would look at the grinding level, at the grinding product, the ground product. In part because it was closer to the consumer, and in part because it was happening in the plant. Simply that judgment is one that this committee formed, but that is what they were saying in the Preamble to the final rule.

MS. WACHSMUTH: I think the fact that product was manipulated further, it was closer to the consumer. Also, the E. coli testing that Katie mentioned in terms of process control was not applied to the grinders. It applies to the slaughterers because it is a surrogate for fecal contamination. So we have a lesson to mention to the grinders as well. Dave?

MR. ACHESON: Dave Acheson. To come back to a third point on why salmonella was chosen. It's a useful indicator of other enteric pathogens. How good was the data was salmonella really telling you what's going on with 0157 and Campylobacter, two other major enteric pathogens?

MR. DERFLER: I'm not sure that I am equipped to answer that question. But I can tell you that in the Preamble to the final -- proposal and the final rule the Agency made the point. I don't know that the Agency ever

said that there was a specific correlation between salmonella and 0157. But what I think we said was that generally salmonella -- and other pathogens as well. I think that's what the agency said.

MS. OLIVER: Control efforts for one might -- control.

MS. WACHSMUTH: I was trying to keep things in order. John, your reaction?

MR. KOBAYASHI: John Kobayashi. Regarding those plants that fail to meet the standards, is there any effort to determine whether plants that fail to meet standards to reduce foodborne illnesses, either by sharing the identities of the plants with the Centers for Disease Control or submit human isolates to the PulseNet system see if there's any relationship to human illness?

MR. DERFLER: I don't think that happens as a matter of course. I think that's happened on occasion, but I don't believe that occurs as a matter of course.

MS. OLIVER: Swaminathan may be able to help, but to date we don't have a regular program for subtype within FSIS. The regular program for subtyping by -- the salmonella isolates. We do that with listeria and 0157. That information goes into PulseNet but not routinely with salmonella. Swami would you --

MR. SWAMINATHAN: Bala Swaminathan, CDC. That is

correct. We get mostly 0157 and listeria from the USDA/FSIS, and from the -- laboratory, special projects and -- support laboratory FSIS --

The pathogens that we get usually do not have much information associated with it other than an OB designation the outbreak, and then a number which matches the human isolates. Then we contact the appropriate people at the USDA/FSIS office to ask for the names and then later on some information comes through. I understand there's a problem, a regulatory problem that the USDA has that they cannot share additional information with us.

MS. OLIVER: Tsegaye?

MR. HABTEMARIAM: Thank you. Policy is being driven by science. When you were referring to the estimate, the 80 percent estimate, you indicated that there wasn't enough scientific information and I can appreciate that.

Were there a broad representative of experts other than FSIS involved in the decisionmaking for that cut off point. Because that kind of a number comes to really affect alot and comes to the bottom line without any flexibility?

The second question is I know small and very small processors, especially in the South that -- . So to follow up on the previous questions, are there some plans or mechanisms to assist these processors who are already out but are now interested in coming back in business? Do you

assist them to somehow get back into the system?

MR. DERFLER: In answer to your first question, the 80 percent level that we ultimately came up with was the result of a public meetings and comment process. So our decision was ultimately made in the Agency. It wasn't a common process. Let me just sort of point out more definitively.

For a plant ultimately to be suspended they have to be failed three sets in a row. So we're very concerned that it not be a chance occurrence. So we -- one set of 50 something that they failed -- they failed a second sampling, they failed a third sampling. You know, there's plenty of opportunity during that time -- if they're operating at the current national prevalence level, it's going to come out. If they're not, then there's a significant problem with the process. They have two opportunities during that time to correct and improve their process.

As far as the small and very small plants; as part of HACCP implementation, we've created a small and very small plant -- that remains in effect -- and we've been putting renewed emphasis on small and very small plants as part of HACCP Next Steps so there will plenty of opportunity for them to get assistance when they need it.

MS. OLIVER: Bob?

MR. BUCHANAN: Bob Buchanan, FDA. I just wanted

to make one comment and a question in regard to what we heard in relation to the charge that we were provided.

The first comment is just one on state statistics. I take it that someone being in the plants wouldn't and that three times in a row just by chance is less than .008 -- .

The second comment relates to the ground beef versus -- control standards. I just want to clarify that a separate baseline study was done to identify the technological -- for ground beef; and (2) evaluating what questions you asked about -- . In slaughter in the past, -- ground beef.

Can we assume that that product will be held under conditions between the chiller and the slaughter house, and subsequently under refrigerated conditions throughout the rest of its stay in making ground beef products -- . Do I know these are the differences that they're making between -- chilling of the original -- ? Should we make that assumption when we're looking for the technological -- defect rate of -- plants?

MR. DERFLER: The answer to your first question is that --

MR. ENGELJOHN: This is Dan Engeljohn with FSIS. I can answer the second part of that question about assumptions made. I would say you should assume that --

distribution of the product around the country is not --

MR. DERFLER: Our assumption would be that the plants would control that in your HACCP plans.

MS. OLIVER: Okay. Peggy?

MS. NEILL: Peggy Neill from Brown University. Now that you've got two years worth of data, I'm wondering if you have interest or experience in trying to look at comparing the various aspects of suppliers who are consistently meeting their target versus those who sporadically meet their target versus those who consistently don't meet the target.

MR. DERFLER: I think when we look at the data -- our resources allow us to do. We don't have a particular plan, if that's what you're suggesting. But we do tend to look at the data as -- and it is our intention to meet the standards over time so that they -- that will certainly be part of our consideration in reassessing the standards.

Only one way, at least in -- for all size plans under HACCP, that only occurred in January. So what we do in looking at the data that we have, we're now starting to consider that at part of --

MS. OLIVER: Bill?

MR. SPERBER: Thank you, Madame Chair. I'm Bill Sperber from Cargill. I'd like to follow-up on the point that Katie Swanson raised. It was a very good question.

Since generic E. coli monitoring is included in the pathogen reduction regulation. And it started about the same time as enforcement of the salmonella performance standards. How do we really know if the subsequent reductions now being recorded on listeria are because of the generic E. coli monitoring. Kaye stated that generic E. coli monitoring had been done six months earlier.

So a minor point of clarification I'd like to make, and I assume this is accurate is that when -- did generic E. coli monitoring begin immediately and very quickly in 1996, and the salmonella performance standard wasn't implemented in large plants until January of '97.

My point here is if you wanted to compare the effects of these two standards in the industry, the baseline data that was collected to develop the salmonella performance standards was collected -- before 1996. So I think it's accurate to say that generic E. coli monitoring and E. coli testing, salmonella performance standards occurred at the same time relative to the collection of the baseline data. They both occurred after. By that logical order then --

MS. OLIVER: One set of data are Agency data, the other data belongs to plants and are generated by the plants. We set national averages to help a plant compare themselves to the nation, but it's for the plant. It's for

the internal use of the plant, to make sure that the process is under control. Alison?

MS. O'BRIEN: I'd like to follow-up on the previous question with remarks and then get to my original question. If a plant has data, internal data they generate from generic E.coli testing, and that plant fails the salmonella standards, now let's say for the second time; do they go back and look to see if they mixed something up on generic E. coli testing? Is that question addressed?

MR. DERFLER: It's not addressed as part of the regs. We would hope that they would do that as part of the assessment that they do.

MS. O'BRIEN: That would, in fact -- the question -- each assessment is saying the same thing. You would hope that if they had picked up generic E. coli and found a problem, they would have done something about it immediately.

My original question is what percent of plants fail twice for performance standards or three times?

MR. DERFLER: Three times, I believe there's been four plants. Three -- and one slaughter plant failed. I don't know the percentage that have failed two sets. I can tell you that of the four plants that failed three sets, three of the four were back up and running very quickly. Only one of them failed a fourth set and was suspended for

an extended period of time.

MS. OLIVER: And the ones that were back up and running, was their problem properly taken care of and not come again.

MR. DERFLER: One of them is in bankruptcy and no longer operating. One of them is -- and the third, I'm not positive as to whether or not they finished their first set. But they came back fairly quickly because they did change their HACCP plan and have been operating since.

MS. OLIVER: Thank you. The other part of the generic E. coli testing is that it does not apply to the grinding. John?

MR. KVENBERG: John Kvenberg. Phil, my question just goes to the data we were looking at on these tables as it relates to large plants. I don't know if any conclusions can be drawn by these percentages. Extracting large plant data from total data, there appears that, well, considering ground beef 6.4 the first year, -- and 3.3, a decline over all, yet large plants were going from 4.9 percent and 6.7 to 5.4.

And on the second table presented is the number of plants mean, and look at the averages for the whole industry of ground beef, 88 percent, 87 percent and 91 percent, and we're achieving at really large plants starting at 88 percent, then 85 to 81 percent.

Is there something wrong in looking at this data relative to these percentages as they relate to large plants, that indicate a point where they're not making progress, or why do these numbers look the way they do in large plants?

MS. OLIVER: Bruce?

MR. TOMPKIN: Bruce Tompkin from ConAgra. Actually I was supposed to give a summary from '98 through 2000. Knowing what's going on in this industry, the various industries, I -- anticipated the large firms having spent the money up front for all the interventions and so on. But many of the smaller plants Just how the very small plants with fewer employees ultimately perform this is not certain because the numbers of samples is so few. But I think that in a way it points out perhaps if you track the difference between large and small which is really the break of 500 employees. Ours is five hundred and one. Small is between ten and five hundred. So the question then really is a question of what have we learned from that experience and how can that information be transferred to other operators.

In the very small though, it states that ground beef, in that time period, 10,460 collected. The very small plants, for those three years. So 10,460 was collected from facilities in which there were ten or fewer employees. Where are these? Are these grocery stores? That's a big

number. It surprised me.

MR. DERFLER: We wouldn't be taking samples from grocery stores for salmonella, unless we had some sort of a --

MR. TOMPKIN: But for -- '98 through 2000, is 10,400 samples for -- percent positives. That's the fourth page of the Progress Report. We don't have to have an answer to that now, but it's a question for you. That only came out just a few weeks ago, and I was trying to figure out, well, does this make sense? And then something didn't.

MS. OLIVER: I think one thing may have been the requirement by the school lunch program that suppliers have a HACCP plan in place. So they came in early and the school lunch program suppliers are very small, small businesses. So that could explain it. Skip?

MR. SEWARD: Skip Seward from McDonald's. Just a couple of points I wanted to follow up on about the emphasis on slaughter plants as compared to ground beef facilities just from the standpoint that it's been the experience I think through our business that the people who grind the beef really are dealing with what comes in the back door and don't add significant contamination if any, to the ground product. Therefore, the more emphasis that could be placed on the upstream, I think would benefit the overall program tremendously. And I think that that's a good move to

decrease the risk.

I know that in the case where excellent plants have come up against a possible problem with performance standards they usually at that point adjust their -- go out and look at their raw material sources and do sort of a pick and choose based on the history of the raw materials sources to make sure that then they limit their opportunity for any sort of failure.

So again, I think it emphasizes the importance of the raw material control in meeting the performance standards in a large grinding operations and, if you will, I'm not sure that's a -- of the system but I think it speaks to the importance of the raw material supply in choosing a standard.

Most suppliers, most buyers do have E. coli target guidelines for generic E. coli and in general the large grinders for sure in many cases have a very difficult time ever finding E. coli contamination in the ground meat products or the levels are just so low nowadays, you'll get spikes sporadically, but very low. So it's a relatively, I think, good indicator of high quality beef and raw materials that are used to produce, at least, ground beef.

Then the last comment I have is just I'd like to ask whether or not there's been some consideration to enumerating some of the positive samples with the emphasis

today on quantitative risk assessments in trying to establish potential risk from this organism and others. It seems prudent to take this opportunity to begin to -- I know it's a huge effort both monetarily and staff-wise, and so forth, to do that. But it seems like it would be prudent to do some enumeration of these samples so they would begin to better understand the level of contamination that is showing up in some of these products. And if that information is available on some level, I think the more you can get that out to people, that that will add a lot of value to what you're accomplishing here. Thank you.

MS. WACHSMUTH: Bob?

MR. BUCHANAN: Bob Buchanan.

MR. DERFLER: I don't know the answer to that question. I mean if you look at, with respect to ground beef subsequent --

MS. WACHSMUTH: maybe you can --

(Laughter.)

MR. DERFLER: I'm not sure -- the question. I'm going to take Bob's -- questions and answer yes to all of them.

(Laughter.)

MS. WACHSMUTH: That's a good strategy. And so we've requested that material. I'll come over and try and get it. There are also some other documents that were used

in some statistical documents in the development of the regulation that we are going to get copies of for people before the subcommittee meeting but we'll get the copies to all of the members of the committee who then will have that beforehand. Okay. Any other questions? Oh, Swami?

MR. SWAMINATHAN: Swaminathan, CDC. Are these isolates from these studies -- or is any serotyping done with these?

MR. DERFLER: I think the answer is no until --

MS. WACHSMUTH: We do serotype. We send all of the isolates -- at first we made decisions at 10 percent just because of the numbers, but I think we've done much better than that. I think they send most -- I'll get a number for serotyping because -- well, we have an arrangement for the serotyping but then those isolates can also be -- and screened for resistance. We try to do it as soon as possible. So does anyone have any other information?

MS. WACHSMUTH: Ok.

MR. KAMANZI: Jean Kamanzi. Canadian Food Inspection Agency. My question pertains to the methodology, the method used when you do your FSIS set of testing for salmonella performance. There are many labs that do testing. Do these labs use the same method? The second question is this method the same as it was when you were

working on the baseline survey two years ago?

MR. DERFLER: There's three labs that are similar. The answer to both questions is yes.

MR. KAMANZI: Okay. This is an interesting issue because when the FSIS baseline survey was published -- balance of salmonella, for example poultry -- 20 percent. So in Canada when we looked at the survey which was done in 1994 and the balance at that time was 60 percent. So when we looked at that baseline -- . So what we did was develop a new baseline survey in 1998 for the poultry industry.

We had to get permission from the -- . We used that different method -- and we did a survey. So using that method we came up with 20 percent in Canada. In using the Canadian method we come up with 40 percent. So you need to use the same method if you do performance standards? Otherwise, you may get differences in the results. Thank you.

MS. WACHSMUTH: Thank you. One reason that I mentioned to Katie that we don't look at the data that we don't generate is because there can be such differences even when the same methods are applied in different laboratories. But the data for the baselines and the data for the testing is as controlled as possible.

Hopefully, by the end of this year all of FSIS labs will be iso-certified which is not necessarily that the

quality will change, but the documentation and the harmonization of data between labs should be as identical as they can be.

Okay. I think since we're getting close to lunch the best strategy would be to ask Dr. Engeljohn to read the charge to the committee and that will give you lunch time to think about it a little bit and then maybe he'll read it for us again and we'll start discussions following lunch. Dan?

MR. ENGELJOHN: Thank you. This is Dan Engeljohn. I'd like to read from the materials that you should have in the green tab in your folders which identify the FSIS questions to this committee regarding performance standards.

FSIS designed the salmonella performance standards to measure prevalence. FSIS uses data collected through testing that measures compliance with the standard to verify the adequacy of HACCP systems. FSIS proposes that advising the salmonella performance standards to make them more reflective of current salmonella prevalence in the various raw ground product classes may be appropriate.

FSIS seeks from this committee guidance on what might meet the scientific decision points for such revisions of the existing standards. FSIS also seeks information on alternate methods to make improvements to the current system. To address these questions FSIS requests this committee to consider the following:

1. What constitutes scientific sufficiency to support use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard?

2. What constitutes scientifically appropriate methods for incorporating regional variations when developing performance standards? Seasonal variations?

3. Qualitative standards appear to have more technical challenges associated with them than do quantitative standards. What special considerations need to be attended to in the development of quantitative baseline data? What special considerations need to be attended to in using quantitative baseline data for the development of quantitative performance standards?

4. What are key scientific considerations that need to be attended to when developing risk assessments for application to development of performance standards? What are key scientific considerations that need to be attended to when using risk assessments in the development of performance standards?

Within that package you have a number of background materials which we felt would be helpful to you as you would identify -- together. But you have -- evaluation of the current role and criteria to ensure the safety of meat and poultry products. This is the charge that FSIS is giving to the National Academy of Sciences to

examine the role of criteria in the current HACCP rules in ensuring the safety of meat and poultry products.

This is more specific in the charge that this committee has. When you have an opportunity to read through that document I would ask you to go to page four. We're asking specific questions of the committee and they relate to performance standards in general as to the specific raw salmonella performance standards that you will be asked for.

Number B is the progress report on the salmonella testing of raw meat and poultry products -- the year 2000. This is an FSIS report that we had some discussion on this morning.

Item number C is the Mobility (phonetic) and Mortality Report from CDC. Item number four is the Mead study on food-related illness and death in the United States. Item number E is just specifically that which was contained in the Congressional language that gave us the specific charge that we have today.

Then Item No. F is a section of the Preamble to the final rule for the HACCP pathogen reduction -- which deals with microbial performance standards. So we pulled that section out and gave that to you. If someone needs the full HACCP regulation, please let us know and we'll make sure that you have access to that information.

Then this morning you were given a copy of the

actual regulations, it should be a copy that has an introduction with black around the edges. That deals with specifically the salmonella performance standards for meat and on the second page you have the salmonella performance standards for poultry.

MR. TOMPKIN: Several of us did not receive them --

MR. ENGELJOHN: Okay. We'll make sure it's available out front. This is what it looks like.

(Pause.)

MS. WACHSMUTH: We'll make sure there's some out front, but in the meanwhile you can borrow this one.

MR. ENGELJOHN: It should have been sitting on the table in front of you when you walked in this morning.

MS. WACHSMUTH: We have a couple coming around. So think about this over lunch. We'll review the questions again right after lunch and then discuss them, knowing that we'll take these into consideration and that's in a subcommittee which would prepare a strawman report that comes back to this committee hopefully in advance of the next meeting of this committee so that the committee can then finalize that report in August. That's the hope. That's the plan. Okay. Now Brenda has a few words before lunch.

MS. HALBROOK: For those of you who are new to

this neighborhood, I just wanted to give you some ideas as to where you can get some lunch. There is a restaurant in this hotel. Also, there are a number of eateries in this neighborhood. As you go out of these glass doors here and take a left, you'll find quite a selection down either on Vermont Avenue or 14th Street. If you continue on down a couple of blocks to K Street you can go up one block or so on either side of the intersection and find things to eat. So we'll convene here in an hour.

MS. WACHSMUTH: Okay. See you then.

(Lunch break at 12:05 p.m.)

(Hearing resumed at 1:15 p.m.)

MS. WACHSMUTH: Looks like almost everybody's back.

(Pause.)

Okay. We'll get Dan to lead us through the questions again. I guess you can tell from the questions we definitely want to analyze where we are in terms of our performance standards but we're also, more importantly, wanting to look forward to if what we've done is not the best way to do it, then what is the best way to do it? So that's, hopefully, going to be part of the focus.

Do you want to run through the questions one more time, Dan, and then we'll open it up for general discussion? Oh, David. Sorry.

MR. THENO: David Theno with Jack in the Box. Just listening to the discussion this morning this is a question to the Agency. Could we not take a look at the data that we've gotten and a ton of data collected, both from the FSIS side in terms of the, if you will, refereed sample or whatever we call them, the official samples?

We could run the statistics on the official samples, which I think you may have already done, and also run the statistics on the plant samples acknowledging that we have, you know, some variability and stuff. But I think you probably going to get a pretty good look at what goes on because you've got a ton of samples out there to review.

MR. ENGELJOHN: Just for clarification -- this is Dan Engeljohn. When you say -- or do you mean the --

MR. THENO: Actually both is what I was thinking. I mean you've got all of this base data. If you could take a look at the statistics behind them to see where all this sorts out. If you've got a -- and I don't know how your data tables are set up, you might even be able to look at some of the geographic questions and seasonality issues.

MS. WACHSMUTH: Well, I think you may be a little step ahead of us, because I think that's exactly the kind of advice that we like. But let's go backwards for a minute and start with the questions again. That's precisely I think, what we're going to come out of this with, advice for

the Agency and the best way to do this. We do more and more under HACCP, reviews of data and the plants should have at least -- .

MR. ENGELJOHN: I'm going to start with the questions. Question number one, what constitutes scientific sufficiency to support use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard?

Question number two, what constitutes scientifically appropriate methods for incorporating regional variations when developing performance standards? Seasonal variations?

Question number three, take a look at what you have. We switched some words around. It should say "Quantitative standards appear to have more technical challenges associated with them than do qualitative standards." It's written in the opposite way.

Number three should say "Quantitative standards appear to have more technical challenges associated with them than do qualitative standards." What special considerations need to be attended to in the development of quantitative baseline data? What special considerations need to be attended to in using quantitative baseline data for the development of quantitative performance standards? Just so you remember, we have qualitative standards -- .

Question number four, what are key scientific considerations that need to be attended to when developing risk assessments for application to development of performance standards? What are the key scientific considerations that need to be attended to when using risk assessments in the development of performance standards?

(Pause.)

MS. WACHSMUTH: Katie?

MS. SWANSON: Katie Swanson, Pillsbury. Just a point of clarification. Are we supposed to be directing our discussions specifically at performance standards for raw product or for raw ground product?

MS. WACHSMUTH: This, as Phil mentioned in the beginning of his talk, we will eventually look at all of the performance standards, a micro-criteria that FSIS is using. But the focus right now is on the salmonella testing and the HACCP which is only for raw product.

MR. ENGELJOHN: But in the opening paragraph where it describes the background which specifically says, "Raw, ground product classes." I think the Agency's goal was to first look at that because we believe that there is a concern primarily with the raw ground salmonella performance standards.

Ultimately we will work towards addressing all of the performance standards for raw product, but I think

initially, the emphasis needs to be on raw ground.

MS. SWANSON: Thank's Dan. I appreciated that, but there is more criticism also about performance standards for ground meat.

MS. WACHSMUTH: Dane?

MR. BERNARD: Thank you. Dane Bernard. The first question, I find a little confusing because looking at supporting "use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard." I'm not sure exactly what measurement against a performance standard has to do with the objective we're striving for because the performance standard itself, as it says in the second line of the introduction is to verify the adequacy of HACCP systems. So shouldn't question one refer to "support use of an indicator organism in lieu of a specific pathogen" for verifying the accuracy of HACCP systems?

It seems to me that to -- if you don't change that -- . Okay. So you will be using an indicator organism against a performance standard which I assume would still be salmonella. That doesn't make any sense.

MS. WACHSMUTH: Dan?

MR. ENGELJOHN: This is Engeljohn from FSIS. I would say that we as an Agency are looking at all issues related to the performance standards. We know that we have

interest by the industry in using indicator organisms where possible, if a pathogen is there at low numbers and, the utility of using a pathogen may not always be what is necessary.

I think that we are open to the issue of is there another way of dealing with reduction in foodborne illness related to meat products by looking at something other than just a pathogen? Is there a way to have an indicator organism to do that? That could in fact be the case. We're not saying the issue is squarely on does there have to be a pathogenic -- . We're opening that up to comment.

MR. BERNARD: So we're recognizing that it's open for discussion. I'm still confused about whether the question really is having -- into the Agency's desires --

MS. WACHSMUTH: Okay. The author of the question? Would you like to clarify that.

MS. HULEBAK: This is Karen Hulebak from FSIS. What I might suggest, Dane, is that the Committee, to the extent that anyone else shares your confusion, and you might undertake to do it yourself, would be to come up with some alternative constructions. In the course of that discussion, you might flesh out other issues that the Committee thinks needs to be addressed.

But I think it's kind of an evasive answer to your question. But I think maybe you put your finger on some

other concerns, some other issues, that might need to be addressed here. I think Dan's answer was a fair answer and -- .

MS. WACHSMUTH: I think the concern is about salmonella performance standards and the evaluation of that. If we were to use another performance standard or indicator I would think we would want to address how that performs, if you will, against the standard that we were discussing.

MR. BERNARD: Dane Bernard again. I was confused but --

MS. WACHSMUTH: John Kvenberg?

MR. KVENBERG: Thank you, Madame Chairman. I have a Center Director who says if you're not confused you simply don't understand the problem --

However, I was taking notes at Phil Derfler's presentation, it was an excellent presentation. My notes say that the performance standards -- not specific -- determination. So maybe for clarification purposes -- close to what I assume you're really asking here; the performance standard will be measured against performance over time and not specific lot information that's helpful. To me that would mean HACCP systems were a subset of the SSOP's. That's initially what I thought I heard expressed. Thank you.

MS. WACHSMUTH: Okay. -- was introducing

salmonella performance standards. Alot of discussion around question one. I think at this point, Karen had a good idea. We'll take any other constructs that anyone wants to suggest and consider those back at the Agency before we get to the subcommittee level? David?

MR. ACHESON: I think -- this is Dave Acheson. I think Dane's consternations rubbed off slightly in my direction.

(Laughter.)

MS. WACHSMUTH: We have enough of them.

MR. ACHESON: I do feel negative vibes from my area.

(Laughter.)

My understanding is in what the Agency is looking for is to address the question of whether the indicator organism acts as a surrogate in salmonella. But if it does it needs to at least meet the performance standards, the standards currently contained by salmonella. Is that correct?

MS. WACHSMUTH: That's also my interpretation, yes. Back to a little bit of procedure, I have a note that maybe not everyone on the Advisory Committee realizes that we're talking today to set the ground work for what happened in the subcommittee. We're here to specifically answer the questions that you have and state other -- anything else

that they think is appropriate that will come back to this full committee.

So right now we're just setting the ground work for what is to come. It's hopefully something black and white that you can react to and react more specifically for the next meeting. Swami?

MR. SWAMINATHAN: Yes. My question is does USDA have the generic E. coli data -- single samples that have shown in -- .

MS. WACHSMUTH: No. The companies collect generic E,coli data as a surrogate for fecal contamination during processing and slaughter only. So companies have slaughter generic E. coli data.

We do have generic E.coli data generated in the baseline studies that was one of the microcriteria that we measured in those baselines.

MR. SWAMINATHAN: Salmonella -- samples on the baseline studies?

MS. WACHSMUTH: Quite. Those were the samples that we used to establish the -- , the committees that Phil mentioned. The slaughter -- we're talking about the grinding. The slaughter baselines were a full year. The grinding baselines were set at different intervals, months.

MR. SWAMINATHAN: Could the committee have access to those data?

MS. WACHSMUTH: Each of the baselines -- in fact, we can supply the committee with that, we should. We have a summary for each baseline.

MR. SWAMINATHAN: Another point of confusion is -- the last speaker's presentation, he mentioned about using salmonella itself as an indicator organism. So we've got two levels of indicator organisms.

MS. WACHSMUTH: You are absolutely right. I think it was stated in a way that control measures that would address or control salmonella would be expected to control other indicator organisms. So that's an accurate implication. Bob?

MR. BUCHANAN: Bob Buchanan, FDA. One question I have is, is FSIS considering modifying the performance standards with regard to raw ground products, in particularly. Does that mean that we should focus our efforts into -- . Are we to -- products -- the use of the salmonella performance standards for all products? With ground products, there were some assumptions that we should be looking at -- operations?

MS. WACHSMUTH: Dan?

MR. ENGELJOHN: This is Dan Engeljohn with FSIS. I would say the Agency's initial interest is, in fact, looking at the ground product performance standards first before we start looking at modifying the slaughter

performance standards.

But there may be situations where in order to, as you say, there are so many assumptions made, we should be looking it. Because, as an example, the Agency does not test the slaughter operations which also -- . So that there is one assumption that may need clarification.

Our initial focus in terms of how we want to move forward would be to start on the ground products -- to start.

MS. WACHSMUTH: You know there's another point of clarification for those who are not familiar with the regulation. When an establishment both slaughters and then grinds, they have ground product and not carcasses. Bob?

MR. BUCHANAN: It would be very helpful if you could review the regulations as far as ground product versus slaughter operations.

MS. WACHSMUTH: We provided the Preamble and the discussion was on the performance standards. I think we could certainly provide information on E. coli testing but that's a different issue altogether, and it's not something that FSIS is doing. Since there is an interest we could supply that though so that you'll have something that addresses that.

MR. BUCHANAN: I think it would be very helpful, at least for me, to get something for comparison of

slaughter operations versus grinding. It doesn't have to be extensive, just identifying both of those areas.

MR. ENGELJOHN: I would -- this is Dan Engeljohn again -- I would point out that the reg doesn't have many differences in terms of the criteria that but there are some policy decisions as to when you need to sample and when you don't. And if those are the questions you're asking about, I'm sure we can come up --

MS. WACHSMUTH: Okay. Swami?

MR. SWAMINATHAN: Bala Swaminathan from CDC. I don't want to say that I'm also confused because that's not really it. What I understood this morning was salmonella is an indicator organism as well as the criteria was that salmonella was the indicator of sanitation problems and food-safety conditions in general. Therefore, the focus was salmonella -- well on salmonella so close to the other possible --?

MS. WACHSMUTH: Salmonella is, as Phil Derfler described, is the performance standard under HACCP for an indication that pathogens are being controlled in the --

MR. SWAMINATHAN: Right.

MS. WACHSMUTH: Pathogen reduction, correct.

MR. SWAMINATHAN: Yes.

MS. WACHSMUTH: That's the organism. I think Phil outlined the reasons that we selected salmonella, the

methodology, the fact that it was at that time thought and close linked to be the number one cause of foodborne illness and it's on all the species, as well. So that is the particular performance standard that we are going to start with in the analysis by this advisory committee.

MR. SWAMINATHAN: -- we started to make an assumption, now we will further refine the fact that if maybe not salmonella, we may have another indicator. For example, a known pathogen, because salmonella is not causing the problem. So it might be better.

MS. WACHSMUTH: I think you understand perfectly because that in my estimation is what the first sentence is about.

MR. SWAMINATHAN: Now just for clarification, the first sentence of -- it ends with "Standards to measure prevalence." What prevalence? Agents or some prevalence for salmonella? In that first sentence, may have prevalence of what?

MR. DERFLER: Prevalence of salmonella in the species that we're --

MR. SWAMINATHAN: So it refers to reducing salmonella's prevalence but not --

MS. WACHSMUTH: In the first sentence on the page?

MR. SWAMINATHAN: Yes. "FSIS has designed the salmonella performance standard to measure prevalence."

MS. WACHSMUTH: Currently it's a plus/minus test. It's a qualitative test.

MR. SWAMINATHAN: It's own prevalence. Salmonella prevalence?

MS. WACHSMUTH: Correct. Correct.

MR. SWAMINATHAN: To me sufficiency is a loaded word. It's a very important word. When you're dealing with causality from salmonella, especially if you're saying something is causing something else.

It seems to me that we've got to clearly understand exactly what the sufficiency of what the criteria would be to accept sufficiency in lieu of salmonella. We have to include that criteria. So we've got to clear this up if sufficiency is going to be acceptable.

MS. WACHSMUTH: I think this August, Bonnie (phonetic) will -- what is the scientific sufficiency for this decision. Swami?

MR. SWAMINATHAN: Just for clarification purposes and just to clear up things in my mind I would like to go back to the definition of indicator organisms to make sure that all of us are speaking the same language.

In my mind an indicator organism is normally used as an indicator of fecal -- and indicator organisms were never meant to, and can never -- it doesn't sound specific enough to be included in salmonella. Does that -- ?

MS. WACHSMUTH: I think that may be why we have a salmonella performance standard. Bob?

MR. BUCHANAN: Swami, you are correct. There are two -- classes and -- indicator organisms. An indicator organism is an organism that will predict the presence of another. The indicator organism is the mechanism that serves to predict the condition or state that would be associated with the pathogen. For example, the indicator organism could either predict the presence of temperature --, or fecal contamination. There are a number of different things it could, but it is there to really state the -- process, in this case, not -- the presence or actions of specific organisms.

MS. WACHSMUTH: Alison?

MS. O'BRIEN: So further clarification of question one. So I understand we're being asked if we could substitute, for example E. coli for salmonella as part of our performance standard. Inherent in that, I assume, is question three, we might have to meet a qualitative standard. I don't even know why we're considering doing this. What isn't working with the salmonella performance standards that's causing you to ask these questions? Is it qualitative? What is the reason for asking these questions? Why go to indirect instead of direct?

MS. WACHSMUTH: I'd like someone from the

Committee to address that. Dave?

MR. ACHESON: To me the reason to do that would be to determine if an indicator organism will give you guidance on more than one pathogen. Indicator organism X could tell what 0157, Campylobacter, and salmonella are all doing. That would be a big advantage.

MS. WACHSMUTH: Bill?

MR. SPERBER: I think in this case, an indicator organism could be used in the opposite mode -- . In the good old days when we wanted to indicate fecal contamination, we used to indicate organisms to indicate the presence of contamination.

-- reduce that by two logs, day in and day out, we could already conclude that we could reduce -- pathogens by two logs, plus or minus another -- factor because not all our organisms are equally sensitive to all treatments.

But I think in that broad sense, an indicator organism would show compliance with SSOP and it would show compliance with HACCP and it will in a sense predict the absence of contamination of pathogens. At least it would indicate a reduced level of pathogens. It wouldn't be a great measure. It wouldn't say, you've got two percent salmonella instead of seven percent. It would say we were looking at a controlled scientific measure to try to reduce the level of all the pathogens.

MS. WACHSMUTH: Katie.

MS. SWANSON: In addition to that, it can provide adequate information for a processor to use if you have a quantitative indicator and you're hovering around a 10 or 20 program maybe an E. coli would show up to that level of magnitude every now and then. But if all of a sudden it was at 100 per gram or 1,000 per gram then you would really have a light go on saying something is drastically different here today, and you need to do something to correct it.

Compare that to just a simple presence/absence test that doesn't happen very often. But you sit there wondering do you really have processing controls in place or not? You never really know until you get the plus or the minus and then you don't know the magnitude of the -- .

MS. WACHSMUTH: Okay.

A PARTICIPANT: I come back to Alison's question. How far do you want to chase this concept. Why are we looking for a different indicator because as you just said, Katie, we can talk presence/absence, and we can talk about levels, and we can also address at some point, if it goes that way, types (phonetic). -- is it more or less capable of finding a host.

So I guess I'd throw it back to the committee as to what information they're trying to address here? If it

is pathogens, which pathogens, and by what criteria and then, of course, this is the question, the sensitivity and specificity of methods.

So we've had a lot of what I think is excellent discussion, tautologically speaking, but what is our charge from a -- standpoint? What are we trying to accomplish before we can discuss the approach we're going to take to get there? I guess I'd like some clarification on that.

MS. WACHSMUTH: Janice, do you want to answer?

MS. OLIVER: I just want to point out that most people's response to my question have actually said why -- E. coli or whatever, would be appropriate. They all talk about the quantitation. So there are two things. It is assumed if we substitute -- and one if we substitute indicator something. Second, -- quantitative aspects. I want to point out that that's how everybody answered.

MS. WACHSMUTH: Okay. Everyone on my list has spoken already so I'll take it in order of -- Bob?

MR. BUCHANAN: -- two things of clarification. One is I'm not sure what you're asking for when you say the system didn't work. What do you mean by that? In terms of when you're asking -- FSIS -- published -- would be hard to detect the change of salmonella -- . This is just a statistical sampling --

MS. WACHSMUTH: Again for people like Tom Billy

and Phil I think the -- is the same. We believe that the salmonella performance standard is definitely working better -- with the compliance of the plants at this point. The vast majority have met the standard and are meeting it, and seem to be controlling and reducing pathogens.

We're also optimistic that we're seeing more improvement data as well. But we signaled in the regulation that we would revisit, perhaps on the basis of data collected on the compliance for salmonella; we could set lower salmonella numbers at this point since the industry's national average is now possibly lower. We are revisiting the issue. And we also have made the promise that when we do revisit any Micro issue, that we bring it to this committee and that our Microbiology Advisory Committee provide advice and report to the Agency. That's sort of to recap and provide perspective on what you're hearing this morning. Okay. John Kvenberg?

MR. KVENBERG: Thank you, Madame Chair. -- statement that HACCP -- it appears to be working for some -- procedure and discussion here -- result is that just -- industry for maybe determinations -- system. At this point in time -- so I don't understand what that evaluation -- presence or absence of salmonella.

MR. ENGELJOHN: John, I guess I'd like to mention just so that we are clear; in terms of how the USDA

operates, and slaughter establishments themselves, have generic E. coli criteria that they themselves measure, and it really is an indicator of fecal contamination.

So they collect evidence themselves. They maintain their own data. FSIS does not collect E. coli information from slaughter establishments. It is not a reciprocal type of requirement to find numbers. -- E. coli criteria.

MS. WACHSMUTH: Dane?

MR. BERNARD: Thank you. Dane Bernard. Where we started this afternoon's discussions, purposely with question one and the discussion has evolved -- . The answer was -- test for salmonella.

The other part of the question was is it as the rule states that salmonella is -- process control -- . So that's my interpretation of -- and I'm asking for clarification on that question -- .

When, in fact, -- the questions involving -- but once again we're turning to more purposes in standardizing -- as a tool and that is to judge whether the processes of control discussions of whether they merit the application of something like -- .

MS. WACHSMUTH: Okay. Cathy?

MS. DONNELLY: Cathy Donnelly with the University of Vermont. I think the discussion has been helpful in

terms of clarifying where we're trying to go with this. Kaye, I think your comments were particularly helpful in terms of the Agency is pleased with the salmonella performance standard.

But what I haven't heard, and generally when I think in terms of indicator organisms, I'm thinking in terms of providing a margin of safety that takes care of the target pathogen but takes care of other things as well. I haven't heard the margin of safety issue being addressed. Is that part of our consideration.

MS. WACHSMUTH: I think that's the question that the Agency is asking you, the experts. So I believe that the margin of safety is certainly something that you should

discuss. Roberta?

MS. MORALES: The last two comments go to the same point as my question. The question I have is because there is ultimately a public health risk from foodborne pathogens as an outcome of this, do we also then look at how an indicator organism might really change that pathogen outcome -- . Is it the only data that exists -- and is that part of our charge?

MS. WACHSMUTH: Yes. That's part of your charge, and, yes, our goal is to reduce foodborne illness. I was

just looking at the Preamble language and it should also be helpful to all of you in understanding the Agency's thinking. It is so much in line with Phil's talk this morning. David Theno?

MR. THENO: David Theno with Jack in the Box. I want to harken back to something that Dr. Buchanan said earlier. He talked about the difference between -- and indicator organisms. I think that's probably -- function and commercially, indicator organisms are used for lots of things, just as Dr. Buchanan indicated.

-- indicator is fecal contamination and also -- and to be quite honest commercially, most people use several indicators. E. coli, -- forms; you may or may not use salmonella or some, you know, listeria species or some other pathogens as indicators. I guess the question I have is, should there be a better alternative -- . You know, should other indicators be included for just what they are. There's another question. Salmonella -- there's not an indicator, at least in my data set, for salmonella with salmonella. So if you want to do it with salmonella -- . If you want to do this other stuff, use the right indicator organisms. We pretty much understand what those are. I guess that's a statement and not a question.

(Laughter.)

MS. WACHSMUTH: Statements are permitted. I was

thinking about Roberta's comment about public health. That's why we had the FoodNet talk as well this morning because that is what the goal is. So that is where we want the focus. That's why the question on risk assessment is there; so that you can keep that goal. Carol?

MS. MADDOX: My concern is just that the kind of balancing, when we're looking at salmonella being a pathogen. If you use it an indicator organism you're constantly battling -- what particularly comes to mind with the case of ground beef most of which comes from cold counts; where you might have a high prevalence of salmonella because of a particular unhealthy animal that made it into the batch and is reflecting your raw material, not the processing.

So you're kind of, you're always balancing that versus it just being an indicator of fecal contamination which, you know, something like E. coli or botulimon will be in relatively constant numbers throughout a sampling and represent contamination regardless of animal health standards.

MS. WACHSMUTH: You're correct. That's why the generic E. coli is the indicator for fecal contamination, and salmonella as the performance standard is in relation to pathogens -- to salmonella as the pathogen.

I think the way that our lawyer put it in terms of

policy is that the control methods that we use for salmonella would be expected to have an effect on other -- pathogens, as well. It's just not quite the same as the indicator but that's the connection that's made in the regulation. Okay. Oh, it's Bob? Bob?

MR. BUCHANAN: I just wanted to get -- Bob Buchanan. I wanted to get some clarification as to -- the discussion of safety measures -- so that a discussion of -- safety margins and standards will be possible.

MS. WACHSMUTH: Speaking for the Agency which they have allowed me to do it seems. I think that this group should consider anything related to these questions in a scientific sense and my connection to the safety margins was in the context of the risk assessment which might be a part of the consideration number four. Not that I necessarily think risk assessors should make comments on safety margins, but if this committee has something to say in that regard scientifically, this is up to the committee. Bill?

MR. SPERBER: Thank you. Bill Sperber with Cargill. Several of the recent commenters have presented the comments in terms of making it sound like one of the outcomes of this Committee deliberation could be the implementation of some performance standards around indicator organisms in addition to the salmonella performance standard.

I don't read question one that way. Question one says, "The use of an indicator organism in lieu of a specific pathogen." So I would read the request of the Committee, based on question one anyway, that if the committee decided that it would be better to have an indicator organism in salmonella, than the salmonella performance standards would be eliminated. How does the Chair read question one?

MS. WACHSMUTH: The Chair likes the idea of the Committee making some of these judgments. I think one of the Committee's suggestions that we have both the salmonella performance standard and possibly other indicator organisms is something that this Committee should deliberate. So that's really a dual question. I realize that. Okay.

MS. WACHSMUTH: Larry?

MR. BEUCHAT: Larry Beuchat, University of Georgia. The discussion on the margin of safety insofar that to also include and based on an agreement of the infected -- of salmonella in general or the most -- salmonella.

MS. WACHSMUTH: Any other comments from committee members? David?

MR. THENO: David Theno with Jack in the Box. Actually, what is -- about risk, is not so much that you

have to worry about risk for exposures. In essence, performance standards is a measure of the process capability or process performance -- .

Now the leap of faith is that someone who does the best job they can controlling the pathogen reduces risk downstream. But we who -- that risk, at least within the context as I've ever used them, have not considered dose responses and, you know, effective doses and all that kind of stuff. These are raw products.

Consequently, at least up until now, we haven't had a lot of great interventions that could -- process or pathogen elimination, like they do with cooking or any other kind of treatment. So this is kind of, do the best you can do, if you will, you know, and push the process down. And these types of processes are in control. I mean --

MS. WACHSMUTH: Dr. Habtemariam?

MR. HABTEMARIAM: Thank you, Madame Chair. Terminology is very important. People go to war because of terminology. And as I've listened, and realizing what Dr. Buchanan said earlier, we have several different difficulties. Just the word indicator, the way I see or understand it, versus --

What I would suggest -- sufficiency. We need to clearly define as we move forward as to what we really mean by indicator organisms so that we can all agree to read from

the same page. Just a suggestion I wanted to throw out.

The other part of it that seems very relevant that an indicator organism, an indicator system measures a process, -- which is really very relevant. This morning Mr. Derfler said that two very important systems in the process, one was HACCP and performance standards, which are very intertwined, tied together. That is a major single development of what FSIS has done through regulations to address foodborne diseases. And at some point we actually see all four questions are interrelated because after the initial risk assessment you want to know what is the endpoint? What really is the endpoint of this quantitative analysis, -- it's not just looking at these organisms.

So there's some intertwining of these systems. And a very important fundamental thing is that, HACCP as a system, is really what we're looking at to see if it, in fact, mitigates foodborne diseases --

MS. WACHSMUTH: Very well said. Thank you. Larry?

MR. BEUCHAT: Larry Beuchat, University of Georgia. Just to follow up on an earlier comment. There are 20, 25 different serotypes with salmonella. We see maybe -- of them showing up as causing foodborne infections. Certainly others are capable and have the potential of causing illness.

But in our discussion of this entire process is there any way to consider that salmonella serotypes differ -- or do you just want to talk about salmonella --

MS. WACHSMUTH: That's for this committee to determine. Swami?

MR. SWAMINATHAN: My suggestion would be -- Bala Swaminathan from CDC. My suggestion would be for this Committee to steer clear of the question that considering individual salmonella serotypes. As far as this committee is concerned every single -- should be considered pathogenic. How frequently we see specific salmonella is a totally different issue -- issue that we don't --

MS. WACHSMUTH: Okay. Bruce?

MR. TOMPKIN: Bruce Tompkin from ConAgra. Just two items. First, I am still struggling with those numbers and in the case of ground beef because we're very aggressively addressing ground products. Ground beef is very small. There's not a risk of -- until the year 2000. Seventy-five data sets concluded in that time period.

There are 53 samples per data set and that comes off to be almost 4,000 samples and that it was reported last year that 10,406. These data are very important in terms of a two-phase status with regard to controlling listeria, excuse me, salmonella.

(Laughter.)

MS. WACHSMUTH: Bruce, you were gone too long.

MR. TOMPKIN: One week is too much of that.

(Laughter.)

But it's a very important measure of our ability to show progress in terms of meeting the regulatory requirements and how well we're doing in terms of continuous process -- continuous improvement through process control. So I would like to make the request that the data be double-checked, though I actually have confidence in those values.

The other thing is that the questions, four basic questions, are finding themselves in terms of what should be used as a measuring stick or tool. I would suggest that it would be very helpful in terms of reducing the problems of salmonella and in terms of achieving the public health goal and that's where the focus is in the criteria.

It would be interesting to know what should be done to increase compliance to use the regulatory tools necessary, -- or not but to achieve the public health goal, it would be helpful to know how can those who do not meet the criteria, meet the criteria? What information is missing and how could that information best be communicated to those who are in -- ? It's that simple.

MS. WACHSMUTH: I think that's a good point. I think we're trying to analyze this data in as many different ways as the Agency can determine to do that. From that

analysis, hopefully identify things that -- exactly as you've indicated.

That is a little beyond what we're asking of the Committee, but if the Committee has comments to that effect, we can certainly note it. Bob Buchanan? I'm sorry, Bruce?

MR. TOMPKIN: Excuse me. Bruce Tompkin. One reason for making that suggestion is that I did not see that in the National Academy of Sciences project. I don't recall if they were going to test for those factors.

MS. WACHSMUTH: Okay. Bob?

MR. BUCHANAN: Bob Buchanan, Food and Drug. To go back to the questions again. I've been listening to the discussion and just for further clarification.

I'm still unclear what the Agency is looking for in question number four. In questions one, two and three we're dealing with technologically based performance criteria. Is what you're asking in number four, for us to consider what would be needed to -- develop a -- risk assessment based criteria? If you can -- I'm trying to think, to get a better feel for what you're asking for in question number four.

MS. WACHSMUTH: The answer is yes. If you listened to Tom this morning and Phil as well, since our goal ultimately is to reduce and prevent foodborne illness, we're looking at how we would identify mitigations through a

risk assessment or identify appropriate food standards through risk assessment, might be one way of making that relevant to public health outcome.

I don't think that either one suggested that we were there, at this point, but I think it's going to be interesting for this committee to comment on the level that's possible, how it might be done if it is possible. Because ultimately the level of protection internationally, we address in terms of food safety objections.

Arguably, our salmonella performance standard could be considered as a food safety objective -- public health outcome. So I think it's up to this committee to make those kinds of determinations. Obviously, the Agency is interested in thinking about it, or question number four wouldn't be here.

MR. BUCHANAN: Then the question then becomes are you looking for it in a generic fashion or are you specifically looking for recommendations for each -- in terms of what would be needed to provide a performance risk assessment for each of those -- turkey and beef?

MS. WACHSMUTH: I think again that the committee is going to have to make that determination. If it can be made generically but not specifically -- technical --what they can do.

The charge to the committee as it is in the first

paragraph does, as you said, emphasize the ground product. So that is the product of most interest, not excluding the others. Bill?

MR. SPERBER: Thank you, Madame Chair. Bill Sperber with Cargill. Phil Derfler, as I said in some of the discussion we had this morning about the performance standard, really had nothing to do with process control on a lot by lot basis. Rather it was our monitoring of the overall conditions of this plant or some sort of a 53 day period, are things going well or not?

I think the way the performance standards have been implemented, have set up a basic difficulty for those of you who are in charge of enforcing the food safety and those who are producing food. And that is the performance standards spread over 53 days, one sample a day, doesn't give the processor any way to control the process to meet the standard.

I think indicator organisms are attractive because they are immediate, they're quantitative and they can be used for process control. They fit perfectly into the HACCP system of food safety. I would think all processors would welcome the performance standard based on an indicator organism over which they had some control versus the pathogen performance standards.

I like the idea of using a pathogen performance

standard or some measure that you could have as verification of the food safety objective, as you just said Madam Chair. But I think it is wrong to apply that verification of the food safety objective at the individual processor's plant. This is something that should be done nationally on the food system.

As you're doing the risk, getting more baseline data for salmonella -- whether or not you collect samples at individual plants the results of your analysis should not be directed at any one plant. That is the results should be used to guide further actions to reduce the pathogen levels to -- . But I think it's been a fundamental mistake in the Pathogen Reduction HACCP Act to apply these performance standards at the individual processing plant.

MS. WACHSMUTH: Sounded a little like policy to me. We'll let you get away with it once .

(Laughter.)

MR. SPERBER: Yes. Maybe it's something that needs to be considered by our Executive Committee.

MS. WACHSMUTH: Thank you. Okay. If there are no other questions I think we've set the ground work for what the committee is going to attempt to do with the performance standards in this go around. We need to switch gears and start thinking about Escherichia coli 0157:H7 and blade tenderized products.

Again, we're going to call on our Agency representative from the Office of Policy to present the questions and to give us a little background information. Dan Engeljohn has been working on these policies and this pathogen since the Agency began to do it in 1993 in terms of standards. In a way I guess 0157:H7 may also be considered a performance standard. But we're not going to talk about that in that way today, so take that out of your minds. I'm going to give it over to Dan now. Dan, you can take it from here.

MR. ENGELJOHN: I'm going to walk you through these slides. I have a few slides that I want to use to give you some background and then I'll be happy to answer any specific questions that you have.

For those of you not familiar with the regulatory process I do think it's important to just reemphasize that because this is a special meeting of the Advisory Committee; it is, in fact, a public meeting. All of the transcripts from this meeting as well as any materials that have been made available will be made available to the public. The public has an opportunity to access that information either at the FSIS website or through my office since I handle the docket -- .

So all of these materials will be made part of the docket which is considered to be the announcement in the

Federal Register for this particular meeting of the Advisory Committee. So I would encourage you to look there if you need additional information or want copies of what was presented here. We will be posting that information hopefully within the next few days; everything that's presented here today.

Walking you through then from where we started with E. coli 0157:H7. In 1994 FSIS declared E. coli 0157:H7 to be an adulterant in raw ground beef products. We made this determination within the Federal Meat Inspection Act and determined that if raw ground beef product had E. coli 0157:H7 in it, it would be considered to be adulterated once it was fully processed to destroy the pathogen.

The materials in the handout that you have contained in the packet that's marked number A actually contains the information from the Federal Register document that summarizes the comments that I'm making about the history of E. coli 0157:H7.

In 1997, a subcommittee of this whole committee, the Meat and Poultry Subcommittee, was asked to give a recommendation for cooking temperatures for raw ground beef. In part, this was because of the foodborne issues related to intact steaks. At that time we had concerns about -- products and the FDA came forward with a question to the subcommittee. Specifically, they wanted recommendations as

to the appropriate cooking temperature for the steaks in order to control vegetative enteric pathogens. At that time the definition for an intact beef steak was -- with wholeness or had not been injected, mechanically tenderized or reconstructed.

On the issue of non-intact steaks, the Meat and Poultry Subcommittee at that time said that there was a lack of scientific epidemiologic data to identify any hazard associated with these processes that may compromise the integrity of the surface of the meat, and, therefore, allow penetration of pathogens into the material. So at that time the statement that the Subcommittee made -- to making distinctions about the appropriate cooking temperatures for non-intact steak products.

You also have in your packet, Attachment Number C, a copy of the deliberations of the Subcommittee and the actual statement that was adopted by the full Committee.

In 1999 FSIS issued a policy on beef products that included non-intact beef steaks and roasts contaminated with E. coli 0157:H7. This also is contained within your packet, Attachment Number A. I'll just point out a few of the definitions for those of you who are confused about our distinction between intact versus non-intact. We define intact beef cuts as being cuts of muscle which include steaks, roasts and other intact cuts such as brisket, stew

beef and beef cubes -- as well as thin sliced strips of beef that are used for stir fry in which the meat interior remains protected from pathogens migrating from the exterior surface.

So we defined by Federal Register notice, non-intact meat which includes beef that has been injected with solutions -- or tenderized by -- devices or reconstructed into formed entrees. In addition, non-intact beef included those beef products in which the pathogens may be introduced on the surface by a -- process such as chopping, crumbling, flaking or mincing.

They went on to say that intact cuts of beef that are to be fully processed into non-intact cuts of beef prior to distribution for consumption, had to be treated in the same manner as non-intact cuts of beef since pathogens may be introduced below the surface of these products when being fully processed into non-intact products. -- are an example of this type of a product, of the intact product, that's intended to be used as a non-intact product.

FSIS believes that with the exception of intact cut of muscles that are to be distributed that way, any E. coli 0157:H7 contained in the beef product may not be distributed until it is treated to destroy that pathogen. Otherwise, it will be considered adulterated.

As a consequence of our 1999 Federal Register

notice that came out in January, FSIS hosted a public meeting later that year and received information from Kansas State University. At that time, it was preliminary findings from a dissertation that was being prepared.

In that dissertation, KSU researchers identified that the blade tenderization process would, in fact, translocate surface contamination into the interior of -- cut of beef. Roughly, three or four percent of the surface contamination could be transferred into the interior.

The authors also found that blade tenderization did not significantly affect the safety of the beef steaks when cooked to an internal temperature of 140 degrees fahrenheit or 60 degrees celsius. They looked at a number of different cooking methodologies such as boiling and broiling.

We did receive a copy of that dissertation. Each of you have one within the packet, along with a summary sheet that gives pertinent information about the significant findings of that research.

In 2001, this year, FSIS issued a proposed rule on ready-to-eat products which include intact and non-intact beef steaks and roasts. So from the standpoint of FSIS, we have in place now a proposed regulation on ready-to-eat products which could include blade tenderized products. It has included roast beef products since we've had a

regulation for some time on that and then issued a final regulation on performance standards in March of 1999.

Some of the considerations that FSIS has had though is how do we distinguish non-intact roast with regard to the performance standards? The alternatives that the industry -- want to achieve is a six and one-half log reduction for salmonella which is the target -- for ready-to-eat products.

I'd like to point also that FSIS does not have information on the cooking preferences by consumers with regard to steaks and for roasts. We don't know how many of them cook to an internal temperature nor do we know what the number of that internal temperature is.

We do have information on the D-values for E. coli 0157 in beef and in cured-meat products. The KSU study that was presented identified new D-values for E. coli 0157:H7 in steak products that have been blade tenderized. That information appears to be considerably different than what was known for ground products that have a higher fat content.

It also came out that the National Cattleman's Beef Association has and will distribute packeted information they make available about safe, proper cooking practices for beef products. In that information, very rare is defined as 130 degrees fahrenheit. The information in

the Kansas State study ranges from 120 degrees but the information specifically related to the destruction of E. coli 0157:H7 was specific for temperatures at 140 degrees.

So with this as background material as to how we got to where we are today, FSIS is looking to move forward on this policy with regard to blade tenderized beef products, steaks and roasts specifically. I'll be happy to answer any questions that you have at this time.

MS. WACHSMUTH: Any questions on the background or history of where we are with 0157. Dane?

MR. BERNARD: Thank you Kaye. -- public health history of problems related to this issue. The information that is in that packet relates epidemiology associated with blade tenderized beef steaks. Where are we --

MS. WACHSMUTH: Jeff?

MR. FARRAR: Jeff Farrar. Just for clarification, 0157 is still not considered an adulterant, is that correct?

MR. ENGELJOHN: At this time E. coli 0157:H7 is not considered an adulterant of beef products that are going to be distributed or sold to the consumer as a product. The assumption by the agency there is that the consumer properly handles that product and cooks it sufficiently to make it safe.

To follow-up on that, in a retail store that does

their own grinding from muscle meat to ground beef, the finding of an 0157 positive in that muscle meat would be considered an adulterant if the intention was to fully grind it.

MR. ENGELJOHN: That would be a piece of information that would be used for that determination. Presently the Agency views the best process that if, in fact, that product was going to be -- or ground up, the intention was that it wasn't going to be sold to stores. Our expectation would be that that product would be handled differently by the establishment than the product that was going to be sold to stores.

MS. WACHSMUTH: John?

MR. LUCHANSKY: John Luchansky with ARS. Dan, I didn't have time to go through the whole thesis and so forth, but I wonder if you could address the question as to was this study replicated? Does this test a single strain of 0157:H7 and how representative is this strain. What was the sensitivity of the recovery method unless procedures test -- . Do you have any information or clarification on that?

MR. ENGELJOHN: I'm sorry. I don't have that kind of information. There is some information within the dissertation about the methodology used, but I don't have answers to those questions.

MR. LUCHANSKY: You made the statement that the D-values were different compared in common with -- that has to do with strain variation. So you don't know if there was any attempt to move similar strains that were in the literature?

MR. ENGELJOHN: I'm sorry. We don't know the answer to that.

MS. WACHSMUTH: Since this will go to a subcommittee to evaluate the data in the study in more depth. Dan Engeljohn who is likely to be chair of that subcommittee, which is probably obvious to all the members. But it may be possible to have the authors of that committee, or someone present with a research person to interpret and provide information?

A PARTICIPANT: -- take the data at face value --

MS. WACHSMUTH: We need to have a resource for you to get details about the study.

MR. ENGELJOHN: If any of you have specific questions for which we can get answers or be sure that we have the answers to those questions it would be appreciated if you can have them ahead of time.

I do know that the researchers from Kansas City University as well as from the National Cattleman's Beef Association have conducted additional follow-up studies and have compared this to salmonella, not just

E. coli 0157:H7. So they have additional information that we have not yet been given so we're unable to give that to you. The intention is that if it's available over the course of the next few weeks to two months, that they will make that available for you and possibly make that available for subcommittee review. If I could have your questions ahead of time, to be sure of getting answers to you, that would be helpful.

MS. WACHSMUTH: Okay. John?

MR. LUCHANSKY: Thank you. This is a simple one, I think, but let me ask it. Wouldn't the consumer retailer, if tenderizing was conducted in another location, have difficulty in discerning if the meat was -- just by examining it?

In other words, wouldn't it be difficult to handle this stuff without identifying it. Wouldn't it be difficult to identify the prime rib from the tenderized cut?

MR. ENGELJOHN: There is an expectation that it would be difficult to distinguish the intact from the non-intact without some appropriate measures. One of the issues contained in the food code and we do have some information in your packet that includes some of the food code information.

But we do distinguish cooking procedures differently for those two products. One way that a

restaurateur will know if they have an intact or non-intact product will be by labels. FSIS does allow labeling and labels to go on to products to identify it as either intact beef products or as non-intact beef products. We think it's appropriate for them to be labeled.

Now when you go into our consumer hotline, the hotline number that we have available to consumers, that the blade tenderized products continue to be marketed in the supermarkets. We did receive numerous calls from consumers and their concerns were that they felt they did not -- steak products -- there. So that was one of the first indications that we have a distinction in the types of products available.

The design is such that the steaks were blade tenderized in a very specific way. The Agency doesn't have any information as to whether or not that's how or which products are commercial -- together. They, in fact, have more than one HACCP in fact, we have two other HACCP's.

MS. WACHSMUTH: Marguerite?

MS. NEILL: Marguerite Neill. I'd like to go back to something that Jeff Farrar just asked and try to clarify something. Knowing that 0157's presence in ground beef is considered an adulterant; are there procedures available by which suppliers would be expected to determine the ultimate outcome of the intact beef product, specifically whether it

was intended for --

MR. ENGELJOHN: The response I would give to you on that is in the Federally inspected facilities, a component of the HACCP plan developed is that the establishments need to identify to the intended consumer the use of that product.

So within the Federal establishments, if they're purchasing product from a supplier, one way that they could deal with that would be identifying within that mechanism what the product is intended for and might continue to be or to be -- in that facility.

MS. NEILL: Do you Federal establishment what do you mean?

MR. ENGELJOHN: When I say Federally inspected facility, I'm referring specifically to those establishments where these meat products are inspected by the USDA/ FSIS. I would say that in the State inspected facilities that meets the same requirements as the Federal program. That has to -- in terms of -- HACCP plan development.

But for retail operators, for the most part grocery stores with few exceptions, are not Federally inspected by FSIS. They would not have the same kind of -- the HACCP plan -- .

So those establishments that are inspected by FSIS

would have that obligation. Those that are not inspected by FSIS and by the state would not have that requirement.

MS. NEILL: Thank you.

MS. WACHSMUTH: For those in the Committee who don't have the background, Peggy was referring in part to an outbreak that occurred in a restaurant chain where whole muscle meat that is normally to be cooked as a whole muscle meat was ground in the establishment.

This occurred in Milwaukee. There were quite a few illnesses and a death from it of a young child and it made The Post and a lot of other national coverage. So that has brought this whole policy up into another light. That's not exactly the problem we're addressing, but I think the question's very much on point. David?

MR. THENO: Thank you, Madame Chair. David Theno with Jack in the Box. Just to clarify this, Dr. Neill, the internal -- muscle cuts -- 0157 monitoring -- today. In fact, -- 0157 -- will be done on a carcass basis -- prime ribs or -- .

The issue that was discussed in the outbreak, in the grocery stores and in places where the -- were cut up and were trimmed -- into ground beef. So we really -- at this stage.

MR. ENGELJOHN: Just to spell out what Dave just said, the Agency does have its policy on E. coli 0167:H7

spelled out in the Federal Register notices that you have.

We still as an Agency are collecting samples only on ground beef. We have not changed our procedures on what we sample. We haven't changed our policy in this regard to -- products that are going to be sold -- product. Those are questions that some day we may get to this Committee but today the issue would be strictly to those items that are --

MR. THENO: Dave Theno, Jack in the Box. Does that policy apply to products that would be injected with marinades? It's a different -- basically a penetrating issue I'm asking?

MR. ENGELJOHN: I think for purposes of what we would like the committee to look at we'd like to narrow the focus today to the issue. The issue of marinades, injections and those types of things we recognize as being problematic and included them along with other products that are non-intact. But I think right now we have a specific need to move forward on ready-to-eat -- products.

MS. WACHSMUTH: Bruce.

MR. TOMPKIN: Bruce Tompkin from ConAgra. So then one of the charges that the Committee is going to evaluate this topic we need to review the study that we should have when it is made available, and anything else that may come forth as to the likelihood of a -- square centimeter of E. coli 0157 and on the prime cut such as a roast or steak.

And then walk through this whole process as to how this research was done, and try to relate it to what might happen situation in a normal situation.

MS. WACHSMUTH: I think you're pretty accurate on that. I think the best thing we can do right now to clarify those is to go through the charge to the Committee.

MR. ENGELJOHN: I had them on a slide but I'm not sure I -- I've lost computer control.

MS. WACHSMUTH: I think everyone has a copy. In your folder, on your second orange tab you should have the E. coli information that includes a copy of the charge.

MR. ENGELJOHN: Right. Now question number one, is the available information on non-intact products adequate to answer the following questions? That would be the questions two and three below. If, not are there any other reasons to conclude that the translocation of E. coli 0157:H7 that occurs with blade tenderization or similar processes renders traditional cooking -- by that we refer to very, very rare -- of these products inadequate to kill the pathogen?

2. Do non-intact, blade tenderized beef steaks present a greater risk to consumers from E. coli 0157:H7 compared to intact beef steaks if prepared similarly to intact beef steaks? Again, looking at very rare or rare product. If yes, what should be the scientifically

supported cooking process for safe ready-to-eat non-intact blade tenderized beef steaks? If yes, then that would be these products present a greater risk than intact steaks.

Should consumer cooking instructions differ from those for the industry, meaning for retail or other institutions? If no -- meaning that blade tenderized steaks do not present a different risk than the intact steaks -- is the cooking process for intact beef steaks sufficient for non-intact, blade tenderized beef steaks? That cooking process is contained within the packet and is what the Advisory Committee Subcommittee presented to the Agency and to FDA in 1997.

3. Question number three is the same question posed for steaks but is specific to roasts. Do non-intact, blade tenderized beef roasts present a greater risk to consumers from E. coli 0157:H7 compared to intact beef roasts if prepared similarly to intact beef roasts? That would be very rare or rare.

If yes, what should be the scientifically supported cooking process for safe ready-to-eat non-intact blade tenderized beef roasts? If yes, should consumer cooking instructions differ from those for the industry versus retail or institutions? If no, -- if the cooking process for intact beef roasts sufficient for non-intact, blade tenderized beef roasts?

Those are the three questions. Do you need clarification?

MS. WACHSMUTH: I did have a question earlier about epidemiological data implicating these products in illnesses. Dan implied that we had no outbreak data that would indicate if we had an outbreak due to these products. Would the case control study of E. coli 0157:H7 this cases?

MR. LIANG: The short answer is that the question is --

(Laughter.)

I actually don't believe in accepting data at that level of precision. I prefer to -- outbreak -- outbreak or the case control data -- . Of course, the definitive answer is --

MS. WACHSMUTH: I think in the second case control study perhaps that was investigated. It's totally out of order and Caroline seems to either know or have a related question.

CAROLINE: Thank you, Kaye. There are at least two outbreaks linked to E. coli 0157:H7 in what appeared to be intact beef. As soon as I get to it -- the first one is roast beef in July 1990. The second one is a 1995 outbreak, again roast beef.

I also have a number of outbreaks that are linked to beef as opposed to ground beef. I think CDC's pretty

particular in their listing whether E. coli 0157:H7 is linked to beef and not ground beef. But I know that we've got at least two links to roast beef.

MS. WACHSMUTH: Thank you. I was aware of at least the one roast beef. I don't think though that the case control study addressed the timing issue for his questions, but we'll see. We'll get some information from him.

MR. KOBAYASHI: Thank you. This is John Kobayashi I just want some clarification on temperatures for rare and very rare?

MR. ENGELJOHN: I'm sorry. I didn't hear.

MR. KOBAYASHI: The temperatures that we're looking at for rare, and very rare.

MR. ENGELJOHN: The Agency is asking for the very rare to be considered to be 130 degrees, and the rare to be 140 degrees. We'll get more clarification.

I will say that in the KSU study, it identified very rare as -- so there's some differences in the Kansas study versus the guidance that's available to retail, but for right now 130 is considered rare.

MS. WACHSMUTH: Frances?

MS. DOWNES: Frances Downes from the Michigan Department of Community Health. I just have a comment on the issue of outbreaks and what this means. I think that we

would only become aware of these if there were an outbreak. It would be almost impossible for consumers to know that they have consumed blade tenderized beef. That would probably never become apparent unless there were an outbreak.

The second, it's my turn to be confused. I'm going to ask for clarification because in the instructions to the committee, the last sentence gives examples of mechanical tenderization and penetrating marination, although you said -- in our discussions. Could you clarify that, please?

MR. ENGELJOHN: Yes. This is Engeljohn with FSIS. I would say that the primary focus is to be on the blade tenderization process. We recognize that the marination and other tenderization such as cubing support may in fact present additional risks, but I think initially -- tenderizing issue. Disregard that --

MS. WACHSMUTH: I think that that was related to the charge of the conclusion in 1997. That may be where the confusion is coming in. But the information, at least the data that we have now is related to blade tenderizing.

MR. ENGELJOHN: I did want to follow-up on something as well which I didn't clarify. One of the reasons why the Agency is interested in this, consumer cooking guidance versus industry guidance, is that we have

traditionally as an Agency provided consumers with additional safety margins in terms of the information that we give them for cooking.

We've traditionally just told the consumers that for beef steaks -- that 145 is sufficient. We haven't gone the extra step at this time to add to that. So I think the question is if there's a need in part that the policy be developed as to what should be given to consumers. But for our consumer information now on beef steaks, traditionally -- 145. The issue is we're looking for a time and temperature much like -- . The question in part should be from a science standard, is there a reason that should be different for consumer information versus the industry which has more process control, and knows more about the products.

MS. WACHSMUTH: Okay. We have two hands up. John Kvenberg.

MR. KVENBERG: Just a quick comment. I appreciate Dr. Engeljohn's comment. I think it would be useful, we've already heard about outbreaks or -- . The problem with the decision I was discussing, is whether or not those foods were classified appropriately based on how they arrived. What happened before they arrived at the table?

MS. WACHSMUTH: That's a good point. Even if consumers were asked they might not be able to make that determination. John Kvenberg?

A PARTICIPANT: -- temperature would have to be timed above a certain temperature --

MR. ENGELJOHN: This is Engeljohn. I think you're bringing up a good point. Again, for consumers, what we have found, is that it is difficult to get them to use thermometers, let alone waiting enough time until the temperature is obtained. We would look for information from this committee that may explain or give information about that "come up" or "come down" time. As an example, the information you have in your packet from the Subcommittee's Report also dealt with the issue of culminated meat patties and talked about the issue of there being an amount of time that it takes to pick up the -- . All that together, then resulted in us having an instantaneous temperature.
So I think that omission would be helpful to us. That if there is an -- temperature that strived be strived for, then we should work out the policy of how we communicate that to the consumer. We do want to try to keep from presenting different information in different formats. With regard to meat and poultry products, many of them are covered by the Food Code -- establishments. The goal is to have one set of instructions or criteria for safety in processing for Federal agencies and hopefully for the consumers if necessary. So that is what the goal is, to provide the appropriate type, scientifically based information that we

can put together.

MS. WACHSMUTH: Dane? Is it Dane sitting behind the microphone? All I saw was a "DA." Okay.

MR. BERNARD: Thank you, Madame Chair. Recognizing there's -- having sat through this debate and looking at number five and -- I recognize that absence of others is not evidence of the absence of questions as to whether we have or not had not outbreaks. There have been some outbreaks of roast beef. The question before us regards blade tenderized and the problems there. I understand that you can't really tell. If you ask the consumers if they have a blade tenderized cut, you probably wouldn't get an answer. And I recognize that. That having been said, my first question is do we have anything in the packet that go to the issue of more and more and more outbreaks related specifically to this?

We were also issued the -- case control study. I was wondering if we might have just a little bit more detail on when we might see that and exactly what type of case control study focuses on specific to this particular question?

MS. WACHSMUTH: Can you answer that Mr. Liang?

MR. LIANG: I'm sorry, Madame Chair. I know that -- phase one obviously, there's this recall case control I believe they're in their second rounds. I don't know

if --

MS. WACHSMUTH: Yes. This would be the second case control. We might be able to get the questionnaire for members and then we can at least see which things they're keying in on through the questionnaire. I've not heard discussions about this. Thank you.

MS. NEILL: I was just going to say don't hold your breath to try to clarify which case control study to acknowledge. There's two completed and published case control studies of sporadic cases of 0157 in the Centers for Disease Control.

There's just no level of address to beef that is pertaining to this problem. There's one case control study that's from the UK that's really just addressing the issues relating to ground beef and -- and this kind of stuff which is not getting at this -- .

The last case control study which is different is the one in Foodnet in which they basically look into the question. I just wouldn't hold our breath that this is likely to give us the answer.

MS. WACHSMUTH: There were two studies, the Ostroff (phonetic) and McDonald, two post -- case control studies. But then there has been one FoodNet case control study and one on the second Foodnet case control study.

The first I think it's published. I know it

identified beef again, visits to farms. There were several things but certainly not at this level.

MR. LIANG: The Foodnet case control study, ----- -- corrected, that there were no positive findings other than the -- ground beef issue. You can still of course, look at that questionnaire to see if they even asked that question and certainly we can look at those studies -- the second page through the second study.

MS. WACHSMUTH: David? I knew I saw that.

MR. ACHESON: It's still upside down. Sorry. That doesn't help. David Acheson. I just want to change gears a little bit. In the packet of information there was some mention of hygienic removal of muscle.

I can see that one potential outcome of the discussion here is blade tenderization can go ahead and maybe there will be some industry move to hygienically remove the muscle or surface treatment. Is there any data out there saying whether that works? How effective it is? Is that a logical solution?

MR. ENGELJOHN: This is Engeljohn with FSIS. All I would say about that is that in the public process of the Federal Register meetings that we've had on 0157:H7; we have raised the issue because industry has told us that they're able to remove the exterior fat layer and some of the muscles on many of the roasts that are typically --

typically those such as the prime rib and the rib roast and those -- roasts and things like that.

We haven't received any information or data that would indicate that there is a different microbial profile on these products, nor do we see that that is how many of the roasts that are prepared are processed, by removal of the exterior surface. But no information on what the microbial profile is for those products that are tenderized --

MR. ACHESON: And what about surface treatments? -- blade tenderization?

MR. ENGELJOHN: Engeljohn again. I'm not aware of any. The information that you have in the file on blade tenderization is really all that we received on the process.

I am expecting that the KSU researchers will be providing additional information shortly, but it's a follow-up to looking at some in particular in relation to 0157 in blade tenderization. I don't know if they've included information about surface contamination.

MS. WACHSMUTH: Dave?

A PARTICIPANT: Thank you, Madame Chairman. Dave Theno, Jack in the Box. Dr. Engeljohn's right. There's a number of studies going on today about this blade tenderization issue.

At the same time, there's a whole lot of research going on today that's just about to be published about surface decontamination of individual cuts and trim. Now this is all brand new research. I expect to see most of it come out -- this evaluation today. So in the next three to nine months, we should have more information on this kind of stuff. It's just an update.

MS WACHSMUTH: Okay. Bob?

MR. BUCHANAN: I guess it's my turn to be confused.

(Laughter.)

MS. WACHSMUTH: Don't say that again.

(Laughter.)

MR. BUCHANAN: I'll try again.

(Laughter.)

I'll just try.

(Laughter.)

MR. BUCHANAN: It's my turn to be confused. If you're asking just straight this question, if a bacteria is present on the surface of a meat product then you destroy that surface, right through the penetrate, probably. If it gets into the surface, is it going to take more cleaning to kill it than it would on the surface? Yes. Probably.

Are you asking that question or are you asking the question is the risk associated with that possibly high

enough to warrant concern? That's a different question. I mean are you looking for just a risk associated with this -- definition of concern or are you asking -- especially if the risk level is relatively a policy decision or are you asking is it physically possible that you could get a bacteria from the outside if you handle steak, when you cut a steak, or whatever ? I'd say that doesn't need a whole lot of scientific evaluation, at least in theory.

MS. WACHSMUTH: Instead of answering you, Bob, I'm going to let you and Dan talk about that during our break which is going to occur right now for 15 minutes and then we'll resume this for another hour. Then we will end these discussions. Thank you all. Good discussion.

(Break at 3:05 p.m.)

(Meeting resumed at 3:30 p.m.)

MS. WACHSMUTH: Okay. We have a couple of follow-ups with CDC. Follow-up information.

MR. LIANG: Actually the first case control study asked a number of questions not about ground beef, but about steak and whether it was perceived as being pink or not, as well as roast beef and veal. None of those risk factors in that E. coli case control study is being done under Foodnet.

So, in fact, the second case control study asks even fewer questions about food products because other than ground meat, ground beef -- . So we can present some of

those data from the first Foodnet study as great examples and, as I say, we can provide the questionnaire for the second one. It's unlikely, it's going to shed more light.

Then I guess I also just wanted to point out that usually we're -- of course, we're in the onset, at least at CCR, interviewing cases of their families in control. So for the likelihood that they know what went into the production of the product, actually know how the product was handled as well..

MS. WACHSMUTH: Thanks, Art. Okay. Did Bob and Dan get together?

MR. ENGELJOHN: We did. I'm not sure what the answer is.

(Laughter.)

We discussed the issue of -- we recognize that -- I don't think your question is really asking about the risk. I mean our expectation is that we now have confirmation that there is a --tation of the organism. That where we are is in part we don't know what consumers' handling practices are and whether or not consumers do handle these products similarly to an intact product versus other non-intact products such as ground beef.

That's part of the issue. If in fact, there is a different profile for these non-intact steaks and roasts then what -- should there be a minimum cooking temperature

and so what should that temperature be? That, in part, is based on what is the expected level of an organism to be -- product? So I think it is a mixture of both issues.

MS. WACHSMUTH: Okay. Again I think that this committee can help make those kinds of decisions in terms of what data and what approaches we need to address the problem. And you have the questions that the Agency --if you see a place to do something like risk assessment. I don't know that we're going to have data but the committee can tell us what data they need to make a decision like this. Alison?

MS. O'BRIEN: Alison O'Brien. I have a point of clarification. I'm not entirely clear on what blade tenderized meats are? I can see -- I have a vision of somebody with a large knife hammering a steak. We had some film that we got to view and I saw little needles being poked into meat. Could you give us a quick summary of what the process is?

MR. ENGELJOHN: Yes. I will make an effort to try to get you a video or some additional information that will visually show these processes. But in essence, think of it as a hairbrush, not a hairbrush, but a hairbrush having bristles on it and that being a piece of equipment that's pushed down on to roast or onto a steak so hundreds of little needles that are actually pushed into the product.

It's primary purpose would be to tenderize the product. So it would be very thin needles being pushed in through a product much like a hairbrush would be pushed in.

MS. O'BRIEN: I have a second point. If this is done at say a retail place, a grocery store, is there -- are there generally state regulations to clean that apparatus from roast beef to roast beef or steak to steak?

MR. ENGELJOHN: I don't -- I'm not sure that it actually is used at retail.

MS. O'BRIEN: Is this is a big piece of equipment?

MR. ENGELJOHN: In most cases, a very large piece.

MS. O'BRIEN: A very large piece of equipment.

MR. ENGELJOHN: But I would say that if, in fact, there is a type of technology that again, I think its primary purpose would be for tenderizing the product which gives, obviously, advantages for using the equipment and I would envision that someday if it's not used in retail, it might be in the future.

MS. O'BRIEN: I just want to say, too, that I'm sure or I hope all of you got the films that we sent around. Yes, that was it. That's the one training film we were able to get from our training center.

A PARTICIPANT: And they do clean.

A PARTICIPANT: Did they say --

A PARTICIPANT: clean.

A PARTICIPANT: Okay.

A PARTICIPANT: Is that the point?

A PARTICIPANT: Okay.

A PARTICIPANT: Is that the point?

A PARTICIPANT: Well, yes.

MR. ENGELJOHN: Alison, it would not be sanitized between each use.

MS. O'BRIEN: Okay.

MS. WACHSMUTH: David, can you help us?

MR. THENO: Sure. Yes. This is David Theno with Jack in the Box. The tenderizing marination equipment is not cleaned between individual pieces of meat. In fact, in a meat plant it would be cleaned between species or between different marinations. I think that, or at the end of the day. That's principally how it goes. It's a pretty difficult piece of equipment to clean. You would have to remove pretty much alot of pieces and things but it can be done successfully.

As to the question is it done in retail at all? The answer is yes, they just have scaled down versions. The bigger meat markets at grocery stores typically have tenderizers of some sort to deal with their tougher cuts of meat to make them tender.

MS. WACHSMUTH: Thank you. Okay. Bruce?

MR. TOMPKIN: This is Bruce Tompkin from ConAgra.

I would like to just add that that is all done in a refrigerated room, but that's not what my point was.

I wanted to make sure I clearly understand then what this question is. If these products are being cooked in Federally inspected establishments, time temperatures are already required and that's not an issue. If it's cooked in a food service establishment, presumably the Food Code would apply.

So all we're really trying to do is resolve whether or not the risk is sufficiently high that these products should be labeled so the consumer knows, and particularly there's some cooking procedure on the label that would provide guidance to ensure the safety of the product. If that is the conclusion. Is that correct?

MR. ENGELJOHN: I think John or someone from FDA may be able to speak to the issue of the Food Code. The issue for a non-intact steak is in the Food Code today at 145 degrees for 15 seconds, I believe.

Again, I think the issue presented to the Agency is that this product may, in fact, be sufficiently prepared at a lower temperature for a different period of time. So that's part of the issue here is that 145 for 15 seconds may, in fact, not necessarily be the safety temperature. Maybe something more rigorous would be appropriate.

MS. WACHSMUTH: Frances?

MS. DOWNES: Frances Downes, Michigan Department of Community Health. I also called home at the break and as I recall, we did have a small cluster and I confirmed that with our epidemiologist.

Last week we had a cluster of two to three cases associated with a tenderized steak in a local restaurant chain. If it would be helpful I can submit that, to support that so it can be included in the documents.

MS. WACHSMUTH: Thank you. Catherine?

MS. DONNELLY: I'm going to call on my colleague over there, Jean Kamanzi from the Canadian Food Inspection Agency, because they also have some information in Canada.

MR. KAMANZI: --

MS. WACHSMUTH: Thank you. I think any information, any data, from a study designed to look at that would be extremely helpful to the group in its deliberations. So if Canada would permit us to look at those data, that would be great. Thank you. Okay. Bob?

MR. BUCHANAN: Bob Buchanan, FDA. I'm just -- as I was sitting here listening to Bruce describe clarification of the question being asked I'm reminded of the last session that we had we were asked about surface treatment of oranges in the production of fresh orange juice.

This session is in a similar manner where they are asked to determine whether or not you could -- of the

pathogen within an orange, whether the treatments were effective and whether it occurred as to -- the likelihood of public health concern. I assume that listening to what we're talking about here, the question is being asked in a similar way as to what was asked about orange juice.

MS. WACHSMUTH: Okay. Do you want to make any comment about the conclusions amongst you?

MR. BUCHANAN: The conclusion on the orange juice was that, yes, it was possible to get a determination of the pathogen, at least under laboratory conditions. It was not deemed -- by the this committee to be a likely event in conjunction with, we felt additional precautions would be limited by including microbiological type of testing program in conjunction with the activity. So it was a combination of scientific determination, evaluation of the risks and -- process.

MS. WACHSMUTH: Okay. Nice approach that this committee should consider. John?

MR. KVENBERG: question to -- about the -- what -- processing -- . Am I correct in -- it's not only some type of blade type operation that produces something that looks like cubesteak at the end, but it's also needles that can puncture the intact beef? If so, does that produce a product that consumers will now be able to determine is intact beef or blade tenderized?

MR. ENGELJOHN: For purposes of the discussion today, this is really just a blade tenderization and not the tumbling or restructuring of the steak. So this would be something where a steak or a roast which is blade tenderized would not change in its form so --

MS. WACHSMUTH: Larry?

MR. BEUCHAT: Larry Beuchat. I think, John, you're asking, if you saw the video which I did. That was a needle, not a blade that was tenderizing beef. Are we not to be considering needle tenderized beef but just blade tenderized beef?

MR. ENGELJOHN: I'd have to say I didn't look at the video. Did the process change the structure? You said you couldn't tell if it was still the same?

MR. BEUCHAT: They didn't show us the close-up.

(Laughter.)

But I assume that if one did look closely at it, you would see that the muscle had been disintegrated with the needles. Perhaps Dave can tell us.

MR. THENO: Dave Theno, Jack in the Box. The term needle and blade are interchangeable. In the true tenderizer, actually if you take a look at the bottom of it, they call it needles. It will actually have dual cutting surfaces on it sometimes and there will be a diamond-shaped tip specifically designed to tear the uncut muscle membranes

and the tissue.

Typically when they go through the machine they'll go through -- the belt and you can -- one penetration and if it's a tougher piece of meat it'll go slowly and get a couple -- disrupts the connective tissue structure --

Almost all pure tenderizers have solid needles. The reason is, obviously, you wouldn't want to make any core samples out of them and it would be difficult to clean.

(Laughter.)

So for practical purposes a needle tenderizer is just little spears, if you will.

MS. WACHSMUTH: Have you seen the video, Dave?

MR. THENO: I live the video.

(Laughter.)

MS. WACHSMUTH: And can you tell the difference if you look at a whole cut of meat, whether it has been tenderized or not?

MR. THENO: A whole cut of meat of roast or a steak that has been tenderized, and particularly with one or two passes, visually you just wouldn't see it. You wouldn't see it a difference unless something was wrong.

If, in fact, it's a piece that needs more tenderizing if you look at it closely on the surface you can actually see the little penetrations in it. But the average person in the supermarket might pick one up and just look at

it and might not know the difference.

MS. WACHSMUTH: Okay. One other thing, Dave, that might be helpful to the committee. In the packet there's a description that begins on page four. This is the study that describes the blades and the process.

MR. ENGELJOHN: Page six is actually a picture. Actually, we're getting this publication electronically, and when I get it will forward it to you.

MS. WACHSMUTH: Larry? Did you have any --

MR. BEUCHAT: No.

MS. WACHSMUTH: Okay. I guess we can go home. Oh no. Not really. The process from here seems to be a little confusing so I thought I would go through what the subcommittees are doing again.

Generally, the Steering Committee, the Executive Committee, puts together subgroups according to topic and tries to maintain the --the balance between the industry, the academic background, the government-regulated concerns, try to balance the subcommittees in that same way.

We also try to keep the groups small because these are almost drafting groups that would come up with a paper, and sometimes they take individual assignments and then meet together as a group and produce a paper that would then come to this committee.

So that's as soon after this meeting as we can get

that Steering Committee together we're going to and make some subcommittee assignments on these two topics that we'll introduce today. Then we will notify those people.

We don't normally have a volunteer system but if you want to send an e-mail or something indicating an interest, we'll certainly take it into consideration. But we will do this as fast as we can because the subcommittees could meet once or maybe even twice before we have another full committee meeting. Then that full committee meeting is going to depend on your schedules.

We have identified August, I'm told for several reasons. One is that there doesn't appear to be a local hotel before September and we do want to meet before the beginning of the new fiscal year. And this might be the hotel. It has a very nice meeting room.

(Laughter.)

MS. WACHSMUTH: Are there any questions about that? About the process at all? Is there anyone who is not on a committee who would to make a comment? I'd be happy to try to explain. I think a good size for a subcommittee is probably around ten people. We don't generally get all ten people at one time. The HACCP subcommittee usually functions with six to eight people who are -- and they produce a product that the subcommittee has to review and those are very lively, friendly discussions. So this will

not be something that is done in subcommittee, and buried in subcommittee, and then just comes out and you endorse it. This will be something that we all discuss. So if you're not selected for a subcommittee, don't be disappointed. You'll definitely have opportunities to assess the products. Any comments from anyone else, or from someone the Steering Committee or the Committee in general. Is there anyone who is not on a Committee who would like to make a comment? Yes, Caroline. Come up to the microphone.

MS. SMITH: I think I can get the microphone to work. I'm Caroline Smith with the Center for Science in the Public Interest. I've been interested to hear the discussions from the newly forming -- committee. It looks like this is a wonderful brain trust of people who have been advising us on microbial food safety issues.

I think the salmonella performance standard which was discussed this morning is a success. It's a success for the public and I think as you go into deliberations and consideration on that standard you should know that. It has significantly reduced salmonella levels on products coming to consumers and I believe that because I have looked at the USDA data documenting that, but also because CSPI tried to test it.

USDA is not sampling in turkey slaughter plants because of a regulatory -- how should we call it? -- lapse

because the baseline data for turkey was not available from some turkey slaughter plants, was not available at the same time that the final rule was being developed. So they've never had sampling in turkey slaughter plants.

So we tried to sample. We didn't use very many samples. We did about 50 samples from five areas in the country. I've talked to Kaye Wachsmuth about how we did those samples and the way we shipped it and how we handled it and the protocols. It was comparable to USDA's enforcement sampling. We couldn't find any salmonella on our 50 samples of turkeys.

We also found very little Campylobacter, which was disappointing to me but, nonetheless, I think an important statement about where the improvements are being made in the industry. We have looked more recently at data from I think it's the University of Maryland, and I talked about it at the National Press Club in November where that data has essentially been confirmed also by data done by a far more scientific source than sampling by CSPI.

But the bottom line is this program has been a success. And when you start to tinker with it you have to recognize that it's -- whatever is done to that program should make it an improvement from a public health standpoint. We're not talking about overturning the system or substituting indicator organisms for pathogens. I think

we need to think in terms of improving the sampling program to better protect consumers.

The other thing is I think you shouldn't confuse the issues of what testing industry should do to improve their HACCP programs and to monitor their HACCP programs. And I've heard a lot of excellent suggestions from the industry which I hope they will take our advice and do that.

But what this program is, it's a regulatory program for FSIS to evaluate how HACCP works in the meat and poultry industry and that program -- it's very important to separate that program from what industry should be doing on its own -- with the government mandate as they are required to do with E. coli --

So Bruce Tompkin, who I always quote whenever I can --

(Laughter.)

-- talked about the fact that he needs to promote continuous improvement and that is what HACCP is designed to do and that's what you all promised us several years ago. So we have seen recommendations for the committee to consider on how to ensure continuous improvement in the HACCP program.

First of all, I agree that lowering salmonella standards. The performance standards that were put in place were based on the baseline data from five, six or even more

years ago. We've seen significant improvement in the industry and that -- if you could lower salmonella -- the salmonella performance standards to what the industry is now achieving I think that would be a significant improvement.

In addition, we would recommend implementing additional testing requirements in the meat and poultry industries, Campylobacter in chicken is one thought, it's more than a thought, we've been advocating it for a number of years now. Listeria testing for ready-to-eat meat products which many of us will be three days in meetings coming up on that topic.

Then testing for additional foods. Let's not forget that we have a HACCP system in place in the seafood industry with no testing requirements. So as you think about that, think also about the need for testing and verification for the government across the board, not just at FSIS but also over at its sister agency, the Food and Drug Administration.

Finally and I'll end quickly, there are a couple of issues dealing with the FSIS policy on blade tenderized meat. I am fascinated that this whole discussion is on cooking again and that cooking is somehow the solution to this problem. I do remember the debates the committee has had on whether to adopt the FDA standard for cooking meat or the USDA standard for cooking meat because, in fact, they're

different.

There's a much better solution and it's one that USDA is fully aware of. The industry did a study several years ago on beef carcass sampling for E. coli 0157:H7. They did it to demonstrate that, in fact, they can control E. coli 0157:H7 coming into the slaughter plants through their slaughter process. And they tested what? Four or five different places during the slaughter process from dehiding all the way up to when it's ready to go into the cooler, or maybe after the cooler. They found significant reductions really -- in the slaughter plant.

Why don't we get a testing system for verification in the beef slaughter industry by requiring them to test at that final point? Let them demonstrate that their slaughter processes are, in fact, controlling 0157:H7 coming into their plants.

Let's not leave it to consumers to know whether this is a blade tenderized piece of meat or not blade tenderized and, therefore, to adjust their cooking temperatures. That communication message is far too complex. I can't get people to do that much research on what they're buying. What they want to know is whether it's safe. I think you guys should be looking far beyond the issue of cooking temperatures for blade tenderized beef and into the issue of how to stop this in the slaughter plant.

Thank you.

MS. WACHSMUTH: Thank you. Any other comments. I don't think we have anyone who called in ahead of time. Dan?

MR. ENGELJOHN: I just would like to make a statement about the public meeting tomorrow and the next two days. I just want to remind the committee that we would welcome your presence at the meetings which will be at this hotel and in this room, I think, tomorrow, Wednesday and Thursday, related to the ready-to-eat meat and poultry performance standards.

Tomorrow is a science-related meeting. We'll have presentations on various aspects of science related to the safety of meat and poultry products.

Then on Wednesday in the morning it will be an overview of the lethality and stabilization performance standards for ready-to-eat meat and poultry products. In the afternoon there will be an overview of the requirements related to listeria sampling, listeria species as well as Listeria monocytogenes.

Then on Thursday morning there will be a presentation on changing the performance standards as well as the removal of Trichina requirements in the current pork regulations. Then the afternoon on Thursday will be devoted to the economic issues related to the ready-to-eat proposal;

mainly related to the issues of using the information from the risk assessment as well as the information we have about illnesses associated with meat and poultry and tying that into a benefits/cost assessment. So we welcome your presence and input during these meetings.

MS. WACHSMUTH: Okay. Dane?

MR. BERNARD: Thank you. Believe it or not I was just curious as to whether we should put some salmonella and Campylobacter into --

(Laughter.)

MS. WACHSMUTH: You just destroyed the credibility of the committee, Dane.

(Laughter.)

After all of those wonderful compliments that you were getting. No. I just want to tell all of you thank you for coming and tell you that I think your questions were extremely insightful and thoughtful. I have high hopes that this committee is going to give us extremely good advice that will protect the public health and will be soundly based in the science as we know it.

I want to thank you for -- and for the Agency and hope that you learn something and help us learn something in the next couple of days, as well. We'll see you again soon. Don't forget to send in your calendars. So we can set up this next meeting. So we'll adjourn, but someone will be

around here until 5:00 in case you have something you want to tell us. Thanks again.

(Whereupon, at 4:00 p.m., the meeting in the above-entitled matter was adjourned.)

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Microbiological Criteria for Foods
Name of Hearing or Event

N/A
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Washington, DC
Place of Hearing

May 7, 2001
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 176, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Marcia Logan, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

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