UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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MEETING

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TUESDAY
MARCH 29, 2016

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The Advisory Committee met in the Auditorium, 355 E Street, S.W., Washington, D.C., at 8:45 a.m., Keith Payne, Moderator, presiding.

MEMBERS PRESENT:

BETSY BOOREN, North American Meat Institute
KURT BRANDT, United Food and Commercial Workers International Union
MICHAEL CRUPAIN, Consumer Reports
PATRICIA CURTIS, Auburn University
SHERIKA HARVEY, Mississippi Department of Agriculture
SHERRI JENKINS, JBS, USA, LLC
ALICE JOHNSON, Butterball, LLC
JOHN MARCY, University of Arkansas
KRZYSZTOF MAZURCZAK, Illinois Department of Agriculture
RANDALL PHEBUS, Kansas State University
TANYA ROBERTS, Center for Foodborne Illness Research and Prevention
MICHAEL RYBOLT, Hillshire Brands Company
MANPREET SINGH, Purdue University

EX OFFICIO MEMBERS PRESENT:

MARGUERITE PAPPAIOANOU, Centers for Disease Control and Prevention
STAN PAINTER, National Joint Council of Food Inspection Locals

ALSO PRESENT:

PHILIP DERFLER, Deputy Administrator, Office of the Administrator, Food Safety Service
KEITH PAYNE, Deputy Director, Outreach and Partnership Division, Office of Outreach, Employee Education and Training, Food Safety and Inspection Service, Moderator
NATASHA WILLIAMS, Designated Federal Official

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

(8:44 a.m.)

MR. PAYNE: Good morning everyone. My name is Keith Payne, I'm with the Outreach and Partnership Division within the Food Safety and Inspection Services Office of Outreach, Employee Education and Training.

I'll be the moderator for this National Advisory Committee on Meat and Poultry Inspection Public Meeting today and tomorrow.

What I'd like to do first is turn over the meeting to Deputy Administrator of the Food Safety and Inspection Services, Mr. Philip Derfler, who will give the formal welcome and opening remarks. So with that said, I'll turn it over to Mr. Derfler.

MR. DERFLER: Hi. Good morning everybody and welcome to this meeting, the National Advisory Committee on Meat and Poultry Inspection.

Al Almanza, Deputy Undersecretary and Acting Administrator asked me to convey his apologies for not being able to be here. He really

wishes he could be here to welcome you in person, but his travel schedule didn't allow it.

On his behalf, I wanted to say that we're really looking forward to getting your advice and recommendations on the two important topics that we're going to be presenting to you today.

But before we do that, we want to review the progress that we've made on recommendations that we've gotten from this Committee over the years.

I know at various times over the years there's been members of the Committee who felt that the issues that we were presenting to the Committee were not really that important to the Agency. I hope that what you're going to hear in the follow-up presentations will put those concerns to rest. The work of this Committee is really important to FSIS.

This Committee has been called upon since 2008 to address some of the most important issues that FSIS was facing at the time. And quite frankly, continues to face each one of them today.

The advice that we receive from this Advisory Committee has played a pivotal role in getting the Agency to the point where it is now.

So what I want to do is I want to briefly describe each of the issues that you're going to hear about and tell you a little about why it's important. One of the most important issues we're going to discuss today is International Equivalence.

In fact, Mr. Almanza recently testified in front of Congress and he was asked, what is the most important issue that the Agency is dealing with. And what he said was that the need, the most important issue was the need to ensure that countries, foreign countries that had achieved equivalence, maintain equivalence.

And today you're going to hear about what we've been lately, from Jane Doherty, who is the head of our office of International Coordination.

After that you're going to hear from the Economic Research Service. They were here at the

last meeting and they talked about their cost calculation model. And today Dr. Sandra Hoffman will talk to you about what she and the ERS have done since they heard from you last time.

As you know, the National Residue Program has made significant changes after consulting with this Committee. Today Rita Kishore, at the Office of Public Health Science, will talk to you about recent developments in the Residue Program.

Todd Reed, who's going to talk about releasing specific types of data.

When we came to this Committee, one of the main recommendations was that we go to the National Academy of Sciences for recommendations about how we go about releasing specific data. We did that.

The input that we got from them was very important, and today you're going to hear how we're carrying through on the basis of the information that we got from them.

There's two other issues that we're

going to talk about that are both very important to us. One is the safe handling label and changes that we should be making in the safe handling label. And Chris Bernstein is going to talk about that.

We're also going to talk about public health regulations and how we are using them. We've talked to this Committee about them.

There's been some significant advances as of late, in our use of the public health regulations. And you're going to hear about that today from Chris Alvares.

Captain Kis Robertson Hale is going to give you a presentation about chicken livers and about the role that they're playing in spreading Salmonella and Campylobacter.

This is not an issue in which we're going to seek your recommendations, but it's an emerging issue that we think is important enough that we wanted to bring it to your attention and give you information about this.

That will bring us to the two main issues that we're going to make presentations to

you today.

First Kristina Barlow will talk about FSIS's best practice guidance for controlling Listeria monocytogenes in retail delicatessens. And how this guidance is currently being used by retail delis.

This issue is very important to us. In 2003 FSIS put out a final rule on Listeria monocytogenes in post-lethality exposed products.

Since we did that, at that time deli meats was a major source of Listeria monocytogenes. Since that time, the product emerging from plant, deli meats emerging from plants, has stopped being a problem.

We recently did a risk assessment that showed that 80 percent of the illnesses, from Listeria monocytogenes involving deli meats, were deli meats that were sliced at retail. Which causes us to be particularly concerned about what's going on at retail.

And so therefore we're seeking your advice on how we should proceed with respect to that

issue. And Ms. Barlow will make a presentation on it.

And then finally, Mark Wheeler is going to talk about products that are not ready-to-eat, but that appear to be ready-to-eat. Meat and poultry products that have these characteristics.

The products have been a problem for us for 18 years. And we're now considering, what new direction we should strike out for. Whether the actions that we've been taking have been appropriate or not. And so we'll be seeking your advice on that.

So obviously we have a very full agenda today, so I'm going to stop. I just wanted to thank you all for agreeing to participate in the Committee.

We know your time is really valuable. We know you all have other lives that are really, really significant.

And we really appreciate your willingness to take out time and spend it with us and help us protect the meat and poultry supply in

the public health. So thank you very much.

MR. PAYNE: Thank you, Mr. Derfler, for that opening. Now we'll turn over to the charges to the Committee, and the rules of order or housekeeping measures.

First of all, we have our staff from the Outreach and Partnership Division here to assist you. A couple of whom, or a few of whom, you're already familiar with.

And I'd like to introduce everyone on that staff. We have Ms. Natasha Williams in the back here. Dr. Jane Johnson, Ms. Diane Jones, Ms. Bee Herbert, who is out at the registration desk, Ms. Elaine Height, who is at that desk with her. Dr. Robert Boyle, in the back here. Ms. Darlene Lee, Commander Jeff Tarrant, in the back here. Ms. Kaitlin Keller, Ms. Evelyn Gomez and Ms. Cho, who is in the back here. And we have Daniel Puzo, who is our director, to my right.

In particular, I would like to recognize Ms. Natasha Williams, the designated federal officer for this Committee, and Dr. Jane

Johnson, for all their due diligence and exceptional work in pulling things together so we can have this meeting here today and tomorrow.

If you have any questions, please feel free to ask them. Any of the folks I've mentioned from our staff, they can assist you.

There are restrooms on this floor. The best thing I would suggest, if you don't know where they are, is to ask our staff here for directions to them.

There are restaurants, when it comes time for lunch. We do have a listing of eateries in the area. So again, please ask them for assistance.

Outside here to the right of our tabletop display, toward the end, you'll see a break area. There's an ATM machine, there's a cold drink vending machine if you need cold drinks as well.

Now let's turn to the introduction of the Committee Members, who are seated around the table. And we'll start to my left.

When you introduce yourself for this, please engage the microphone. There's a green button that lights up. Speak into it, state your name and affiliation and then you can turn, hit that green button again to disengage the microphone.

So let's start to my left here. Just for the record, starting with Mr. Derfler, around the table here.

MR. DERFLER: I'm some guy that passed the rule.

MEMBER MARCY: John Marcy, I'm a Professor at the University of Arkansas, poultry processing specialist.

MEMBER CURTIS: I'm Pat Curtis at Auburn University.

DR. JOHNSON: Alice Johnson, Butterball.

MEMBER MAZURCZAK: Krzysztof Mazurczak, Illinois Department of Agriculture, State Inspection Program.

MEMBER CRUPAIN: Michael Crupain. Last time I was here I was in consumer reports, now

I'm a medical director at the Dr. Oz Show.

MEMBER ROBERTS: I'm Tanya Roberts, Chair of the Board of Directors of the Center of Foodborne Illness Research and Prevention and Consumer Group. But I worked at the ERS USDA on economic cost of foodborne illness, et cetera.

MEMBER PHEBUS: I'm Randy Phebus, Professor at the Food Science Institute of Kansas State University.

MEMBER JENKINS: Sherri Jenkins with JBS.

MEMBER BRANDT: Kurt Brandt. I'm with the United Food and Commercial Workers International Union. We represent about 1.3 million workers in meat packing, food processing poultry and retail.

MEMBER BOOREN: Betsy Booren, North American Meat Institute.

MEMBER SINGH: Manpreet Singh, Purdue University.

MEMBER RYBOLT: Michael Rybolt, Hillshire Brands, which is now holding all its

subsidiary in Tyson Foods.

MR. PAYNE: Thank you. And we have spaces or spots for Ms. Sherika Harvey from the Mississippi Department of Agriculture and Dr. Dustin Oedekoven from South Dakota.

I understand Dr. Oedekoven is on his way here. So hopefully we will see Ms. Harvey as well.

Just for some housekeeping measures -- Ah, I think we have Ms. Sherika Harvey coming. Great timing. And, Ms. Harvey, for the record, if you want to state your name and affiliation by just pressing the green button on the microphone.

MEMBER HARVEY: Good morning. Can everyone hear me?

PARTICIPANT: Yes.

MEMBER HARVEY: Okay. Sorry for my tardiness. Sherika Harvey, Consumer Safety Inspector at the Mississippi Department of Agriculture and Commerce.

MR. PAYNE: Thank you very much. Okay, just for some housekeeping measures. Cells, please check them. Either mute them or turn them

off so we don't have any disruptions during the meeting.

And let me circle back to the microphones, this is very important. During the discussion, during our meeting, when you need to speak, please state your name and affiliation. Hit the button on the microphone so the green light is on. And after you ask your question or state your comment, then hit the button again.

I know this may sound redundant, but this is very important for the official record. The transcripts.

Mr. James Salandro, to my right here, he's with Neal Gross. And this helps him keep track of the dialogue so he doesn't haven't to ask who stated what for the record.

So we have an orderly flow of discussion, for members, when you want to make a comment or raise a question, as we did during the last meeting, raise your tent card. And this helps me keep track of the line, the order of questions. And when we will get to you, I'll announce your

name, then you can put your tent card down.

Anyone in the public who would like to make a comment, there's a sign-up sheet at the registration desk. Please, if you'd like to make a comment, you can put your name and affiliation down and when we get to the public comment period, we will certainly call upon you in the order.

Before I forget, I'd like to introduce an ex officio member of the Committee, Dr. Marguerite Pappaioanou from the U.S. Centers for Disease Control and Prevention. Dr. Pappaioanou is here today. If you'd like to standup or raise your hand? There you go.

And then we have, from the association, Mr. Stan Painter. Whose president at the National Joint Council of Food Inspection Locals, Mr. Painter.

All right, well thank you very much. That concludes our housekeeping measures and we'll move on now to the next portion of our meeting. These are the Panel Updates.

I'd like to introduce Mr. Daniel Puzo.

The Director of the Outreach and Partnership Division who will moderate these panel updates. Mr. Puzo.

MR. PUZO: Good morning everyone and welcome. To those of you from out of town, welcome to Washington on this chilly morning.

We are going to have a full presentation. This is our third year doing these updates. And don't be alarmed at the number of people up here.

We've actually timed this to make sure we get it in. That it fits the schedule. But kept that in mind when we get to the comments and question periods. I might have to hurry us along to stay on time. Which is important.

Also, we will take questions after each presenter, rather than waiting till the end of the entire Panel. So we'll get started right away with the International Equivalence Update with Jane Doherty International Coordination Executive. Jane.

MS. DOHERTY: Thank you very much and

good morning everybody. It's a pleasure to be back with all of you and to talk to you about our International Equivalence Program here at FSIS.

I have the privilege of leading the Office of International Coordination. But I certainly would not take credit for running our International Equivalence Program. This is truly and Agency effort.

And several offices are involved. Several offices are working on a daily basis with my team and in the Office of International Coordination.

And I could not do this work, the amount of work that is involved in putting the International Equivalence Program that is respected as FSIS is. It takes a great deal of effort in our Agency.

So I want to acknowledge and to recognize my colleagues who work with me on a daily basis to make this happen. Assistant Administrator Dan Engeljohn, who leads our Office of Policy and Program Development.

Assistant Administrator Carl Mayes. Who is here from our Audits and Investigation and Enforcement Team.

And also Assistant Administrator David Goldman. From our Office of Public Health Sciences. Who together, we work together to ensure that our programs are always science based credible and that we are holding countries to requirements that are equivalent to ours.

And as you heard, our Deputy Undersecretary understands the importance of maintaining and continuing to strive that those countries continue to meet standards as we improve our own programs.

So when FSIS came to you several years ago, we presented our international program to you for review, there were three areas of concentration that we wanted to focus on.

Those are document analysis, making sure that countries have a government infrastructure in place to be able to maintain and to run an equivalence program. And that their

national meat inspection system has the enforcement tools necessary to enforce their rules and regulations.

Onsite audits. So that we send our experts over and check what their government has put on paper, but we ensure that for ourselves, we look at their programs and make sure that their criteria that they have described to us, and that they're working on, that they are in fact, we can validate that those programs are in place and what they have told us is in fact true.

And then of course our point of entry reinspection. Is very, very important to ensure that product that is sent to this country is in fact tested and verified that they are continuing to meet FSIS rules, regulations and standards.

So those concepts and the concept of equivalence is very, very important to our international program.

As you know, FSIS is very different from some of our other agencies in the federal government who accept products from other

countries. A country cannot export a meat, poultry or processed egg product to the United States, unless they have an equivalence determination from FSIS.

But there were three questions that we came to and asked you about. Was one, should we be looking at changes to our international equivalence program?

Two is, the regulatory information and the compliance history from these countries, how does that work into our determinations and our ongoing program and what are we finding at port of entries? Are we finding that some countries have more violations then others, and how should that factor into our international program?

And three, how often should we be visiting some of these countries, based on those results of the data that we're able to comply and how do we use that to determine whether a country is continuing to meet those requirements.

So those are the three questions that we came to for guidance on. And the

recommendations that you provided to us is that in fact, yes, our three tier approach to equivalence was right.

Document review is essential as a primary step. And then FSIS needs to go to these countries and validate in fact what is happening and are these countries doing as they tell us that they are doing.

And three, that we're checking at the ports and ensuring that those products that are coming in are meeting our levels of protection.

So you were very clear to us that the structure and the road that we were on was the correct one.

You also directed our Agency to use its resources wisely and to look at the relative risks and the historical compliance with these countries.

And every country system is different. They don't all run their programs the way we do. And under the concept of equivalence, they don't have to. But they certainly have an obligations

document in how they're meeting our levels of protection.

They may do it differently, but they have fundamental requirements to meet our levels of protection. And so what we need to do is figure out, are those countries methods acceptable to meet our standards.

And then finally you also recognized that we needed to be standardized across the board. We could not have one set of rules from one country and another, depending on their infrastructure. We had to standardize that process.

And so we've been spending a lot of extra time on our questionnaire. To ensure that across the board, countries are meeting and working on their infrastructure and reporting to us, in what we call the self-reporting tool. Which is a questionnaire that countries have to fill out to begin an equivalence determination and to maintain an equivalence determination.

So it's a questionnaire where we ask a lot of questions about their rules and regulations.

As we change our rules and regulations, we also require those countries to explain what they're doing to continue to meet those standards.

We don't want to have an equivalence determination and someone, it's not a stagnant process by any means. Once you have an equivalence determination, you're just getting started with FSIS.

It is a working relationship that we have with these countries. And as our standards continue to become more protective, so must they. And they must explain to us how they are doing that.

So we continue to implement your requirements every day. We are working to improve our self-reporting tool. We continue to do out systems audits. And we're continuing to do our port of entry reinspection procedures on a daily basis.

We have developed a performance based approach to address the risks and the historical compliance. And we have developed our self-reporting tool. And all of this was

published in our Federal Register in 2013.

But wanted to give you an update today on what have we been doing since last year's presentation. So we have released our International Equivalence Directive. We are making some fine-tuning changes to it.

But those are the rules and regulations that we follow when we receive a request from a country on what it is that we have to do, as an Agency, to work with that country to determine whether or not their program is equivalent to ours.

We have, since last November, we put out an ongoing equivalence directive that explains what the rules and procedures are for FSIS employees, with regards to maintaining an equivalence determination. So what is required of our policy office, what is required of my office, our field operations office and our auditing team.

So what are we working on together, as well as our public health sciences office. So what are we doing and how are we working to ensure that these countries continue to meet our standards.

Those are spelled out. The directions for FSIS employees in the ongoing equivalence directive.

We've also put out notices with regards to import inspections in our import/export program last November. There were two new directives that came out talking about what our requirements are and what we're looking at from our employees, as far as reinspection of meat, poultry and processed egg products.

Those directives are 9900.2 and 9900.5. Those are our label verification of those imported meat requirements as well as our reinspection procedures.

So they spell out directly what every employee is responsible for in our Agency and how we're going to manage reinspections.

And of course I think most of you are familiar with the fact that we put out our final rule on Siluriformes implementation this year and we are working very, very hard. On March 1st the rule became official and we have started

implementation of that rule.

From the Office of International Coordination and working with the other offices here, we are working so that foreign countries understand that there has been a transition to FSIS, for Siluriformes, and what is required in an equivalence program.

So spending a lot of time educating other countries on our standards, our levels of protection. And if they are to apply for equivalence, what's going to be expected of them from FSIS.

We are also working with our foreign authorities. As we said, we have a self-reporting tool, a questionnaire and this program is, by no means, stagnant.

So every year, at least once a year, they have to re-fill out their self-reporting tool questionnaire, talk to us about changes in their government structures, what rules and regulations they've put in place. And then we have to do an evaluation.

And Dan's team does this in our policy office, of evaluating whether that country continues to meet our levels of protection or not.

And then this year we've had some problems with avian influenza, as many of you may know. And that means that we didn't have the supply of processed egg products in the United States that we've had in years past.

So there's been an interest, from a number of industries, to get product from overseas. But we've had to spend a lot of time educating folks that unless you have an equivalence determination for some of these products, you can't bring those products into the United States.

So we've had a number of countries that were not familiar with the jurisdiction issues between FDA, AMS and FSIS. And we've had to spend a lot of time educating countries that this is FSIS and these are the rules and regulations if you're going to send that product into our country.

So our enforcement team has been spending a lot of time at the ports, doing

investigations. But we also have an obligation to talk to the countries and educate them on what our rules and requirements are. So spending a lot of time on that.

And there have been a lot of issues this year with the explanation of what we require as a government inspector in these facilities.

And what we have always said is that an FSIS inspector, what is acceptable to FSIS is that the government have an inspector, a government inspector, at the end of the line in their establishments. Whether you are in Europe or you are in Asia or you are in Canada, we require a government inspector at the end of the line.

And so we have had, as I said earlier, countries do things differently. We have had to explain and define what is meant by a government inspector.

So we are working on that to clarify that for folks. We have been sending letters to these countries so that they understand what the requirements are, and we are holding them to insure

that they are meeting our requirements as spelled out in the CFR. So those are the things that we are working on currently.

In conclusion, our program continues to be very, very strong and respected internationally. We are spending more and more of our time educating other countries on FSIS requirements and why they are based on science, and helping them to raise their levels of protection as well in foreign countries.

They may not all have equivalence determinations, but they're striving. They understand that that USDA gold seal, if you will, means a lot. And can help them economically, as well as from a regulatory point of view, to be able to promote their products in the future.

Your recommendations have meant, have really been seriously, taken very seriously by our Agency and have been implemented. And I can honestly say are at the heart of our programs.

We meet on a weekly basis to ensure that we are insuring that the self-reporting tool is

adhered to. That countries understand that they have to fill out that questionnaire, they have to do it on a regular basis.

We look at our audits and our audit reports in insuring that we are being very transparent, but our decisions are silenced based. And we are looking at our port of entry violations on a daily basis.

What's coming in from a country, have they had a number of violations, what are we doing about that?

And one thing that's been very, very important this year is that that port entry violation issue, if there are a number of violations from a country, we are always in contact with them, if a violation occurs. But they have an opportunity, within a certain period of time, to respond to us with corrective actions.

If we feel that those corrective actions are insufficient, we have the opportunity to push further and ask for more information. Or, as what happened in the case last year, we go down

ourselves to a special audit, and our investigators go down and look at the situation to address the issue. So countries are taking these very, very seriously.

This past week we've had a problem with one country, that's been in the news, about pesticide residues and using pesticides that are not allowed for use in the United States. And one country, immediately after meetings with FSIS, took action to suspend the use of that pesticide in their country.

So international outreach, communication about our programs, is very, very important.

So you'll see the Deputy Undersecretary and our office going out. Our technical teams from policy and audits and public health science going out and educating other countries about the levels of protection that we have here in the United States.

And we believe that they too had an opportunity to promote food safety, but they need

to work with us on what those levels of protection are.

So we're very proud of our program, we thank you for the recommendations that you've made and any suggestions that you have are continuing to improve this program. So thank you.

MR. PUZO: I don't know if there's a question here. Tanya Roberts?

MEMBER ROBERTS: Yes. Chinese chicken has been in the news a lot. And so I'm wanting to get an update from you and some clarification on, will chicken produced in China be able to be sold in the United States, will it have a label, what about the chicken that's fully processed and it's made largely into chicken nuggets and so it's not really an intact piece of chicken anymore, just what's going on?

MS. DOHERTY: That's a good question, Tanya. Thank you.

As you will recall, FSIS has determined that processed chicken has already have an equivalence determination from FSIS. So China has

had the ability to send processed product to the United States for the last two years.

MEMBER ROBERTS: I thought it had to be of U.S. origin though?

MS. DOHERTY: Of U.S. origins, thank you.

MEMBER ROBERTS: Okay.

MS. DOHERTY: But it has to be from U.S. origin or from another source that has already been approved for slaughter.

MEMBER ROBERTS: Okay.

MS. DOHERTY: So another country who already has an equivalence determination for slaughter as well.

But now we are, we have a second request from China, as you are well aware, for Chinese origin raw chicken to be slaughtered, has an equivalence determination from the United States.

We have gone through this process that we just outlined. We have done the questionnaire with them, we have done our onsite audits. And we have made a determination, based on our review and

our audit reports, that we are ready to move forward with a proposed rule for Chinese slaughtered chicken to move forward.

That will be coming soon, will be proposed. There will be a public comment period, as always. We will take comments received and look at the scientific rationale for those comments in support.

And our final decision on whether or not chicken that is origin from China will be allowed to access the United States will once again, be based on the scientific facts presented to this Agency. So as always, the reason we are credible as an Agency is because our decisions are science based.

So the same will happen with China. And we will continue to make sure science is the heart of that decision.

MEMBER ROBERTS: Okay.

MS. DOHERTY: Thank you.

MR. PUZO: Any other questions for Jane? Well thank you.

MS. DOHERTY: Thank you.

MR. PUZO: We'll move right along to the Economic Research Services Cost Calculation Model for Foodborne Illness. One of the most interesting ones I've ever seen. And here is our sister colleague, Dr. Sandra Hoffman.

DR. HOFFMAN: Thank you for allowing me to be here today. As I think you are aware, the USDA Economic Research Service is a sister agency to FSIS and other agencies within the Department of Agriculture.

We are a research agency, we do research on all areas of food and agriculture in the U.S. We have probably three full-time staff equivalents working on food safety I would say. It varies.

That's what I do full-time as well as Mike Ollinger. And there are others who do projects on food safety.

So one of the projects that has a long history, and Tanya Roberts was really one of the initiators of this history, is working on estimates of the costs of foodborne illnesses in the U.S.

Last year I reported on our most recent iteration of that modeling effort and I'm here to tell you a bit about how, you had some comments on here, to tell you a bit about how we're responding to those.

The cost of illness estimates, are available for FSIS to use. They provide a peer reviewed scientifically sound set of estimates of the pre-case cost of foodborne illness that can be used in regulatory analysis. But it is an FSIS decision whether to use those or others or how they're going to proceed with that.

So last year we posed a, had a set of six questions. The first five that we, I'm going to talk to you about.

The first five of which are really relevant to long run planning. And because of the frequency with which disease incidents estimates arise and because of variability in the economic data that we use in the cost of illness estimates, it seems to make sense to us to do estimates every five years.

It's really not something that can be updated in a sensible way on an annual basis. And we also don't have the staff to do that. But mostly it's simply not sensible to do it.

So questions one through five really go to that long run planning process and we will be taking those into account as we move into that phase of our work.

But Question 6 was about communication. And since our most recent estimates came out in October of 2014, we're really in a communications mode.

And what I want to talk to you about today is the recommendation that we present data, in different ways, to reach different audiences. And we've done quite a bit on that, I think, in the last year.

So one of the things that we've done is to reach audience, the scientific users, and audiences that want to use these materials in teaching.

And the primary thing, the primary

product that we developed to reach those audiences, was a report that is intended to provide materials that can be used in teaching. Either in the academic setting or more importantly, I think, probably in an extension or a public health setting. And then also for scientific users to have a better understanding of how we developed our estimates.

The report does a number of things. It gives a more detailed discussion then we have on our website on how we developed our estimates. It provides comparisons across pathogens and tries to put the relative economic cost of different, of the disease caused by different pathogens, into perspective.

And then in addition, for each pathogen, it contains what I like to think of as kind of a folio or pamphlet for that pathogen. And the pieces of that are the disease outcome tree with the probability of different disease outcomes occurring, the number of illnesses we expect, we model to have occurred in those outcomes.

Like for example, the number of cases, let's see, what do I have up here. Cryptosporidium. Of illness cause by Cryptosporidium that end up not seeing, not being attended by a physician or the percent of hospitalized cases that end up dying. And then the costs associated with that.

In addition, we have a pie chart that shows the distribution of costs across the different outcomes. And then also text that sets the incidents that describes the type of disease that's caused by that pathogen, the incidents relative to other pathogens and its cost relative to other pathogens.

The text in this, like almost all the work in the cost of illness estimates, is really a synthesis. And we draw heavily on materials from CDC, from FDA and from other peer reviewed literature, to develop the text for this.

In addition, we did a number of communications efforts to other audiences. For general policy audiences, we used a vehicle that

USDA economic research services developed for this purpose called charts of note.

And they are weekly broadcasts to a wide list serve of, and also onto our website, of charts that are drawn from research products that we've produced. Along with text describing them.

And they're short and they're intended to get people's attention and just to raise awareness and the educational level about the impact. In this case, the impacts of foodborne illness in the U.S.

And so we did five of those over the course of the past year. To reach that audience.

In addition, looking to general public health education, we worked with the FSIS Office of Communications to develop consumer education materials that draw on the cost of illness estimates.

And then from a more technical perspective, we've also conducted, again, as part of standard economic research service, a process for all of our data products.

We did an internal review of data quality with a focus on factors, such as transparency, accessibility, across a diverse set of software platforms that people may have to deal with and documentation in terms of how well it describes the way the data was developed and the limitations of the data.

So we conducted that internal quality review and developed a plan for addressing any short fallings within that.

And in the next few months, one of the things we'll be doing to address issues that we found in the data review, is to post our, the estimates are currently posted in Excel spreadsheet form, and we will be posting those in a CSV format so that they're an open access type of format.

So that is a summary of what we've done over the past year in terms of communications and I can have questions.

MEMBER BOOREN: Thank you. I have a question getting into some aspects with the data

quality aspect.

How are the changes, and how are you planning for changes, in public health laboratories?

We're hearing more and more the difficulties of doing classic serotyping pathogens coming from human clinical isolates. How are you planning on addressing that as you look at data looking forward to make these estimates?

DR. HOFFMAN: Well let me --

MEMBER BOOREN: Those changes are occurring --

DR. HOFFMAN: Right.

MEMBER BOOREN: -- in how that data I used within the government becomes really critical if the data is not accurate.

DR. HOFFMAN: Right. Right. So I agree that that's an issue and a concern. We take the work of CDC on incidents estimate as a given. So we're really looking to CDC for those incident estimates.

And the laboratory testing capacity

will certainly affect their ability to develop sound incident estimates. So, all right. Yes.

MR. PUZO: Thank you, Sandra. All right, next up is the National Residue Program Update with Rita Kishore. Rita?

MS. KISHORE: Good morning. So as you know, the National Residue Program is an interagency program that is designed by various U.S. agencies, like CDC, FDA, EPA, AMS and is implemented by FSIS.

And the goals of National Residue Program are to provide structured process for identifying and evaluating chemical hazards of concern in food animals.

It tests for prevalence of chemical hazards, veterinary drugs, pesticides, environmental contaminants, hormones in meat, poultry and egg products. And identifies the need for a regulatory follow-up when a chemical hazard is found in meat, poultry and egg products.

So last year we asked the Committee several questions. We had four main questions

that we proposed. That we asked the Committee.

And the questions were, FSIS would like NACMPI to provide a feedback on how FSIS says manages chemical hazards, within the National Residue program.

The second question was, does the Committee agree, how FSIS locates samples across the National Residue Program sampling structure?

Is FSIS looking at the right proportion of samples across domestic versus inspected generated programs?

Is FSIS locating samples across slaughter classes effectively?

The third question was, does the Committee agree with FSIS' emphasis on known versus unknown hazards?

And the fourth question was, how should FSIS consider chemical categories? Should they consider them equally or rank them relative to each other?

So we got the recommendations from you. We have reviewed all those recommendations. As

said by previous speakers, we took them very seriously, the recommendations that you gave us.

We thought that these recommendations fit into five main categories. And what we did is we made an action plan for each one of the recommendations. And then what we are providing to you today is what the results of those action plans are.

So the first recommendation that NACMPI gave us, that FSIS evaluated the data from the state slaughter plants. Not only just from the federal slaughter plants.

And also that we should make sure that small establishments are also sampled, and just not the large establishments that are sampled.

So the action plan that we had was that we would increase the collection rate in the state scheduled sampling program.

And so the result was, or the actions that we took to do that, was that we briefed the meat and poultry state directors. We have a meeting with them. Or the Agency has a meeting

with them.

And our group briefed them and told them the importance of the National Residue Program, why the collection rates should be, why they should collect the samples and how they should, what actions should they take to make this collection of samples higher.

And we are pleased to inform you that the sample collection rate has increased 20 percent between 2014 and 2015.

So the recommendation too was that the Committee recommended that FSIS develop a strategy or effectively communicate an active mission and data collection to others. That this is beyond what we do.

We do publish National Residue Program or what we call as the Blue Book. And then we do publish a Red Book, what we call the results. We publish the violation, the name of the violators.

We have our lab matters, but the Committee recommended that we go above and beyond what we already do to communicate National Residue

Program to the stakeholders.

So the action plan or the action that FSIS took was that we decided that we would explain what the National Residue Program is to our state MPI meetings and the HACCP meetings that happen every month. And that we also would do an outreach to other stakeholders.

So the result was that FSIS discussed the design and structure of the National Residue Program at the state MPI meetings. We explained at the HACCP meetings.

We also went to other federal agencies like EPA and CDC where there was a vast audience that are just, that just do the residues but a vast audience of people over there that we explain the National Residue Program to.

We went to JIFSAN. They were having some classes there. We told them about the National Residue Program, the structure, what we do in the National Residue Program.

And also to some foreign governments. We have given seminars to some foreign or talked

about the National Residue Program to some foreign governments. Some of them are Cong Hoa, Vietnam, Chu Nghia, that we adopted them.

And the other thing that we are planning to do, or we have started doing, is we are developing a brochure of describing the National Residue Program for the general public. And we are in the process of gathering the data that we have gotten from other places. And hopefully we'll have this brochure very, very soon.

So the third recommendation that the Committee gave us was to review the inspector training and to make sure that there's an adequate and consistent implementation of the NRP.

So the action plan was that there is a directive for residues that describes, that tells the inspectors on what samples to take. If they find that there is some kind of pathology that's indicated.

And so we decided, and then they did a KIS testing on it. A quick test that's called a KIS test.

So what we did is we reviewed the results of the KIS test and there was questionnaire that was submitted earlier in 2014. We reviewed the results of those questionnaires.

The bob veal and dairy cows are two slaughter classes where we have the highest violation rates in the inspector generated program.

So we reviewed the results. We found that there are about six pathologies in dairy cows and about four or five pathologies in bob veal that actually are most commonly reported by the inspectors as having a residue violation found and that they get confirmed in the lab.

So the results, what happens is that the KIS testing is done in the lab. The tissue, if the result is positive, the tissue is sent to the lab and the lab does a confirmation. And as you know, that many times, when the testing is done, the lab cannot confirm.

So we kind of looked at the data to see what gets confirmed the most, what pathology is the

one that gets confirmed the most. So that's what we did.

We had four plants that we did the pilot study on. So at this time, we are analyzing the data and, from these four plants, and figuring out if whether hypothesis is correct.

And if this is correct, then we will implement it nationwide. And we hope that the number of KIS positives that the lab reports will be higher than what we are getting right now.

So the number fourth recommendation that the Committee told us was that not only we should prioritize the compounds that are used in the U.S., but also look at all the compounds that are used by foreign countries that export the product to the U.S. So all that, that included the drugs and the pesticides.

So the action plan, what we took from there is that we would do a ranking based ranking for all these compounds. To do so, what we have is about -- the first thing we did is we compiled a list of all the pesticides in the drugs that are

used by various countries and the U.S.

So at this point we have compiled a list of about 430 pesticides and about 318 drugs that are used in various countries.

We have presented the models. We have got a couple models that we have. We presented them to EPA and FDA and asked for their input into whether they think these models are correct.

We have done the ranking based on relative health concern. And we are hoping that very soon we come to a consensus with our various sister agencies and start using these models.

And the last recommendation that the Committee gave us was that we use a de minimis level to determine if consumption of chemical present in FSIS regulated products pose a public health risk. So the action plan was that FSIS will determine the de minimis level on chemicals that do not have a tolerance or action levels that EPA or FDA have set.

As you know, that EPA and FDA have the mandate to set the tolerances and the action levels. But there are many, many components for

which EPA has not set any levels. And so FSIS has took it upon themselves, that we will calculate the de minimis levels.

So the result is that we have published a Federal Register Notice. And it's been published.

The comment period will end on March 31st. That is, I think, two days from today. And hopefully we will be, at some point, doing our, calculating the de minimis levels. If everything goes on well.

So those are the five recommendations that we got from NACMPI. And then our action plans and our results. So any questions?

MEMBER HARVEY: The bullet points that you mentioned, that you are considering the data on, did you take into consideration the different regions? Are they in different regions of the country?

MS. KISHORE: The --

MEMBER HARVEY: The four plants?

MS. KISHORE: No. We took the four

highest, the four plants that do the highest, that give the highest violation rates.

MEMBER HARVEY: The highest what?

MS. KISHORE: Highest violation rates. And they have most, they have the most slaughter.

MEMBER HARVEY: Understandable. Thank you.

MEMBER PHEBUS: Randy Phebus, Kansas State University. Can you tell us, relative to Jane mentioning the tool used for the equivalency assessment, are these residue monitoring programs and protocols from other countries part of that tool?

Can you kind of describe that or explain that?

MS. KISHORE: So are you talking about the hazard evaluation we have done or talking about the evaluation that is done by the Agency for the foreign countries?

MEMBER PHEBUS: Well I think both. Yes.

MS. KISHORE: Okay. So for the

evaluation that we are doing for the chemical hazard models, we did work with our equivalence staff and we got the list of all the compounds that are used in various countries from them.

And then we do work with our equivalence staff to evaluate the residue plans, that come from various countries, and we partake in that equivalence process. To make sure that their residue plan provides the same equal protection as the FSIS residue plan does.

MEMBER ROBERTS: Tanya Roberts from CFI. So I heard you mention that you publish the names of the violators?

MS. KISHORE: Yes.

MEMBER ROBERTS: And is that then available on the FSIS website?

MS. KISHORE: Yes, it is.

MEMBER ROBERTS: And is that done annually or as it becomes available or --

MS. KISHORE: As it becomes available. And I think it's weekly. It's every week.

MEMBER ROBERTS: Every week.

MS. KISHORE: Every week or every second week. I'm not a hundred percent sure. But it's done as soon as things happen.

MEMBER ROBERTS: Thank you.

MR. PUZO: Thank you, Rita. Next up, with Establishment Specific Data Release -- yes? Oh, another question?

MR. PAINTER: I have a question for her please? Stan Painter with the National Joint Council Food Inspection Locals. My question, I have a lot of questions, but this last one on de minimis.

De minimis is a term that's used in negotiations. To say it has impact, but the impact is minimal. Now the law changes, the court changes.

So what I'm hearing the Agency say is this. That we're going to have a standard that allows for some whatever. Antibiotics, residue, whatever that's de minimis, but we have no way of testing for that, or do we?

And if the court changes and FLRA rules

in a different way of determining what de minimis means, is the Agency going to change its method and determination of de minimis?

MS. KISHORE: So for the de minimis levels we do have analytical methods for compounds that we are talking about. If we find something -- so lead is a real example for it.

So if they find lead in a product, there is no action level set for lead. There is nobody that's going to go to FDA or EPA to say, hey, set us a tolerance for lead because that's an environment contaminant.

So what we're talking about is if we find a value of lead in meat and poultry, we are going to then figure out, what is it hazardous to human health if the level X is found in meat, is it hazardous to human health, by our calculations, based on the amount of meat a person eats, based on the diet the person has. So that is what we are calculating, that's what we are calling de minimis level.

MR. PAINTER: Okay. Then if it's

hazardous to health, it's not de minimis?

It's kind of like a major amount of surgery. Major is when it's me and minor is when it's someone else.

MS. KISHORE: Okay.

MR. PAINTER: If it has impact and there is an impact to the health, the consumers, it can't be de minimums, can it?

MS. KISHORE: So if it has an impact to the human health, it's above the de minimis level and that product is then, would be considered adulterated.

MR. PAINTER: Okay.

MS. KISHORE: And again, the comment period for this is closing the day after tomorrow. So we would be happy to take any comments that you have on this Federal Register Notice.

MR. PUZO: We're going to let Phil address this, if you don't mind. Phil?

MR. DERFLER: Do you want to say something for --

MR. PAINTER: Yes, I have one other

point then.

MR. DERFLER: Okay.

MR. PAINTER: It seems to me then we would have to have a standard for every residue, chemical, something that would create a hazard in order to determine what was de minimis for each one. Would we not?

MR. DERFLER: This is Phil Derfler from FSIS. So de minimis, under the case law, under the legal case that you alluded to, means it's of no regulatory concern.

A de minimis level is not a safe level. It is usually way below what would be a safe level on the basis of the available toxicological evidence. If it existed.

So the answer is, we're only going to find something de minimis, if on the basis of the available evidence, we can say it's of no regulatory concern.

That's all laid out in the Federal Register document that Ms. Kishore referred to. And if you have comments, we would urge you to

respond to it. But basically it's lower than a safe level.

MR. PUZO: Any other questions? Okay, thank you, Rita. Next up, with Establishment Specific Data Release Plan is Mr. Jeremy Todd Reed. Jeremy?

MR. REED: All right, thank you. Hello, I'm Todd Reed.

And I guess where I want to start with today's presentation is to give some background. Because I know so many members of the Committee this year are new members. And so as I go through the presentation I'll try to get kind of everyone up to speed.

I think my presentation is probably a little different than the last two. It's more on transparency and less on actual technical methods and things that the Agency is doing.

So the title is, Establishment Specific Data Release Plan and FSIS Sampling Update. And so really what I'm going to get to is two different things in this presentation.

One is about our specific establishment, specific data release plan, which I've been providing to the Committee updates for several years. And as you'll see in the presentation, we've been getting recommendations and advice from the Committee in going back and forth.

And also kind of a sampling update. And it's really about an update to you and the Committee of how we're being transparent in providing information and making it available.

And so I apologize to anyone that I get overly simplistic with. So I repeat stuff that you've heard before. But just because we have so many new faces, I do want to try to give a little background as we go along.

All right, so to start, where we're coming from is there have been several federal level policy documents, and I'll get them in a slide in a second, directing FSIS, and the government really, about transparency, open data and data sharing. And those have come down from

administration and from OMB.

And so really this talks about how we're trying to make that happen and operationalized that.

Additionally, when we were being very specific on establishment specific data, and I'll get to define that in the next slide, we eventually went to the National Research Council and they did a study and wrote a report that really laid out recommendations of how we needed to go forward.

And that recommendation really said that this data could provide valuable insights that go beyond the regulatory uses. Beyond which the data were originally collected. And so it really is a quite a benefit.

So policy background that I referred to. All right, so starting in 2009 and in then 2011 and '13 and '14 you can see, and I'm not going to read all the titles to you, you've got the slides or you can see it there, but there have been a lot of different memorandums and documents coming out of the administration and out of OMB. Be

transparent, push more information, push more information provided.

I think one of the lessons that I've learned, and maybe many of you have learned, is that even when a government agency goes down this path, it takes time. I mean, as you'll see on the next slide, and I'll go forward, or in two slides, we started this process in 2010 of going through of asking for advice on how to do this, getting advice from different committees, publishing in the initial Federal Register Notice, getting comments.

And so being transparent providing information, in doing it in the right manner, in doing it responsibly and getting feedback, isn't something you can snap your fingers and do. It really does take a lot of time.

And I think this presentation, beyond a specific content, really helps to lay that out. And for me, that was a real learning experience, I think, of how much effort it takes to get through there.

So to set the groundwork. What is

establishment specific data? So there's really two key factors here when we mean establishment specific data.

Okay, so it's data that FSIS generates. So it's our own data that our inspectors are typing in their data systems that the FSIS is generating somewhere else.

It's not data that industry give to us, it's not data from another government agency, it's data that FSIS is generating. And it's data that bears on specific establishments.

And what I mean by that, it's really data where the observation is identifiable as coming from that establishment. Like we know which establishment it came from. It's very specific. The sampling result goes to this establishment on this day for this test.

What it's not, and I've covered this in previous years but maybe is good is, not PII. Not personally identifiable information.

So any information that we have that we've tied that to our individual inspectors or to

employees that work for the establishments and industry, that data is going to be data we release, right? We have to be responsible with the data we release.

It's not going to be things that are corporate proprietary, right? There's certain information that we have that we work with industry and is provided, but we're not allowed to release that. And that's been ruled upon.

The data, when we do post it, if you see the plan, the draft plan came out before, we're working through the process. The final plan will come out. It's going to outline where the data will be.

It will be data.gov. There will be links to it on our website, so it will be available.

All right, so history. How did we get here?

So we started in 2010. We came to this Committee and we really wanted to talk about how or should we release the data.

The Committee talked about it quite a

bit. But really the main recommendation was, in the two days that this Committee has, and with the next group, there just really wasn't the right mix of time and expertise to make a recommendation.

And they said we should talk to someone else with more expertise and more time to look at the facts and look at the information to see what we should do.

So FSIS, later in 2010, asked the National Research Council, within the National Academies, to conduct a study on this. And we wanted them to example the potential food safety benefits, and other consequences, of making establishment specific data publically available on the internet.

So the National Research Council look at this information, they talked to a lot of people, they did interviews, they gathered everything they could and they wrote a report.

And effectively the report came out and said, what I told you before, is it, yes, the potential consequences for releasing this data is

good. Like there are more benefits than there are potential harms and FSIS should move forward.

But, before they move forward, FSIS should make a plan. And the plan should outline what we're going to do and the steps we're going to do. And we should be very thoughtful and conscious of that, as we go forward.

All right. They did say that public release of establishment specific data, by themselves or in a combination with other privately or publically available data, could yield valuable insights that go beyond the regulatory uses. So I covered this. So it's available.

The available evidence of adverse effects of public release of establishment specific data, by other government agencies, is insufficient to predict specific problems that would be inherent in the release of establishment specific data.

So what does that mean? To really draw that one out. Basically they looked at the negative consequences.

They said, when we look at other government agencies that have released data and we looked at those negative consequences, there is not enough evidence for you to hold that back. There is not enough evidence to think FSIS should not release that data.

So in other words they're saying, releasing it is more benefit than potential consequence from not releasing. And they couldn't find that. But again, we need a carefully designed strategy.

So FSIS actions beyond that. So we came back to NACMPI in 2012 and 2013, based on those findings of previous NACMPI and NRC, and we went ahead and talked about how we developed an internal FSIS meeting in our data coordination workgroup and we developed a strategic plan to guide the release of this data.

That plan we brought to NACMPI back in 2014 for feedback. We made changes to that plan based on the recommendations we got and the feedback we got.

And then in 2015 we provided the updated plan to NACMPI for public comment. And then we released the draft plan via Federal Register Notice. Also for public comment.

So what have we done since then in the last year? So we've got the comment from NACMPI, we got the public comment from the Federal Register Notice, we've gone ahead and we've made updated to the plan based on that feedback, we've drafted our final Federal Register Notice and that's going through the clearance process.

And so I mean, I guess me personally, where I'm at is, I'm hopefully that next year, when this comes around and I come back to the Committee to give an update, I'll be able to say, I'm hoping that the plan has passed, it's publically available, you've seen the Federal Register Notice and this is the progress we've made in posting data sets.

All right, so changing subjects. Slightly. Other data that we're releasing or processes where we release data.

So FSIS, for the first time, has developed a five-year sampling plan. Many of you in this room are aware that we've been doing annual sampling plans every year. We publish those in our website.

As you'll see on the next slide, in 2016 was the same. We published in the annual sampling plan.

But we decided to go ahead and make a longer arrange plan this time and we developed a five-year plan. The final version of that is still going through clearance, but once it's clear we'll get it posted on our website.

And really what we're trying to do is we're trying to outline our focus areas for the next five years. About how we want to address some gaps, we want to close some exceptions in some potential new focus areas.

So we're really trying to give the public and provide transparency of where we're going over the next several years.

As I mentioned, we developed our FY16

sampling plan. It's available on our website, along with the '15 and '14 and probably a couple more before that.

The annual sampling plan provides an overview of our current sampling projects, the number of samples we collected and analyzed in the previous year, FY2015, and the number of samples that we project to collect and analyze in 2016. And provide some information on that.

Annual sampling data. So what I mean by this is, many of you are aware that FSIS produces a lot of quarterly reports in the annual reports on our different sampling projects and we load those to our website. Well, we try to update the data on a timely manner.

But what we've come to realize, internally as an agency, is that repeatedly doing that, on the different sampling projects, is a lot of work, a lot of labor on trying to get them through and cleared and updated.

And so what we're doing, as an agency, is that we're actually automating the process

internally, so that we can produce the data in a more consistent, timely manner. And then once this is up and running, it's going to allow us to post it on the website the same day that you're seeing, in a more frequent, regular basis. And the different sampling programs that we have will be more consistent across them all.

Sampling results. All right, this is a big one that we actually got up and running. It is available on our website.

So starting for, in FY2016, we began computing aggregate sampling results on a regular basis. Quarterly is what we mean by regular basis.

What we mean by aggregate sampling results are prevalence, volume weighted percent positive or percent positive estimates for our different sampling programs. And those are on our websites.

And with those, how many samples we collected, how many positives we found and what those, those rates.

Each product pathogen pair is being

computed separately when possible. And like I said, we plan to update these each quarter and keep publishing them on our website.

And that's it. Any questions? Okay.

MR. PUZO: Thank you, Jeremy. Next up is Chris Bernstein, Director of Food Safety Education with Safe Handling Instructions Update. Christopher?

MR. BERNSTEIN: Thank you very much. It's a pleasure to be here. I'm here to talk about the Safe Handling Instructions Label that you see here on the screen.

Just to recap, that label was first discussed in 1993 and it was established in a rule in 1994. Since then, that label has not had significant revisions. And this presentation today will update you on FSIS efforts to update this label.

FSIS presented on this issue to NACMPI during the January 2014 meeting. As you know, your recommendations were complimentary to stakeholder feedback we had received in 2013.

The Committee recommended that FSIS pursue changes to the existing safe handling instructions label to include modifications and improvements, such as including agency recommended end point temperatures.

A very important note, from your feedback in 2014, was that FSIS should conduct consumer testing before any changes are finalized for the safe handling instructions label.

For this reason, we engaged in a requirements gathering contract to understand what consumers are looking for, related to the safe handling instructions label, in September 2014. And that was done with RTI, a social science research firm.

The first step of the strategic, the first step rather, was a strategic discussion with agency senior staff to understand any potential limitations, regarding updates to the label itself.

This meeting was held in November 2014 and the contractor obtained a valuable guidance on

the history and current status of the safe handling instructions label, potential ideas and issues related to the changes.

This second step was six focus groups with groups of consumers to gather information on what they are looking for, related to instructions on meat and poultry labels. Sessions were held in Oklahoma City, Sacramento and Raleigh, North Carolina, in both English and Spanish.

Groups included in the consumer focus groups were at-risk populations, including older adults and parents of children with children 5 years or younger in the home.

The package took some time to clear OMB and was approved in November 2015. RTI worked quickly and focus groups were completed by the end of December 2015.

Finally, RTI is preparing an analytical report and recommendations for the Agency. The report is analyzing the potential changes to the safe handling instructions level, based on information that we gathered during the senior

leadership strategic planning session and during the focus groups that were just concluded in December.

This report is scheduled for completion this spring. And the preliminary data from the focus groups is just the next topic that I want to cover with you all.

To determine if safe handling, the safe handling instruction label needs to be redesigned, the requirements gathering contract created a no-go -- a go, no-go table for us.

The table in this slide shows if certain conditions were met in each focus group. The general conditions were considered met with four out of the six focus groups that we conducted identified these as significant issues.

There were seven conditions overall that were considered for an updated safe handling instructions label.

So the first condition was if focus groups thought adding a recommendation to use food thermometers would be helpful.

The second was about adding end point temperatures.

The third was about finding the current label hard to understand in some capacity.

The fourth was about believing if useful information was necessarily missing from the label that would help consumers safely handle these products in the future.

The fifth was, if adding additional information would make the label more persuasive to consumers in the handling and cooking of these products.

Sixth was, adding a source to go to for more information. Currently that doesn't exist on the label.

And the seventh was, using the food safe families' icons. Which if you're familiar with the public service advertising campaign that FSIS operates with FDA and CDC. Those are icons for clean, separate, cook and show, which are the four key messages we use in the campaign.

So in the requirements gathering

contract with RTI, we determined that if two or more of these conditions were met, RTI would recommend FSIS consider moving forward with a second round of consumer research to test alternative formats for the safe handling instructions label.

As you can see from the table above, five out of the seven conditions were met. With additional analysis from the focus groups, FSIS is planning to move forward with label development and additional consumer research on this project.

After the next phase of research, FSIS will have a validated label that should meet the needs of modern consumers in the home.

So next steps for this project. We are concluding the requirements gathering contract and are moving into the next phase of research.

Due to results from the requirements gathering contract, we will work with a new contract to review and re-design the safe handling instructions label. The contract will be awarded, likely in the next several months.

Moving into the next phase of the

re-designed label, FSIS will also work with the social and behavioral science team out of the general services administration.

The SBST team includes leading behavioral scientists and innovators from the across the country, who provide government agencies with new perspectives on developing and maintaining consumer engagement, through understanding human behavior.

That team itself was recently stood up based on a executive order out of the White House in September. That just encourages offices throughout the federal government to incorporate more rigorous behavioral change methodology into how we make decisions in the federal government.

Once the new label is select, FSIS will move to rulemaking. And we should be back at the next meeting to discuss where we are with this project and where the rulemaking is in the status.

So if you do have questions?

MEMBER BOOREN: Betsy Booren, the Meat Institute. More of a comment.

With this information, as it's moving forward and you start initiate rulemaking, I think it would be impactful for the industry, as you do your economic analysis on the rulemaking impact because there will be a significant one, to also consider that you have accurate estimates from what the change of the safe handling label would be to retailers and the change with other labeling, significant labeling changes, ahead for both the retail and food industries.

Having those estimates, that my understanding would change software, it would require new machines for many of the retailers, among other aspects. So making sure you have those accurate estimates, let alone what is needed for, I would say the packaged ready-to-eat industry, as well as whole muscle, will be really critical.

MR. BERNSTEIN: Absolutely.

MEMBER BOOREN: Thank you. Thank you very much.

MR. PUZO: Thank you, Chris. Okay, next up with the Public Health Regulations Update

is Chris Alvares, Director of Data Analysis Integration staff.

MR. ALVARES: Good morning. So I'm going to talk today about the Public Health Regulations Update. This was an issue we brought to the Advisory Committee back in 2013. We've been continuing to work on it and provide updates.

Today we've got a little bit of background for some folks who aren't too familiar with the process or the public health regulations. And also an update for 2016.

And I also wanted to touch base a little bit on some of the related activities and the agencies related to FSA work flows. Because the public health regulations ultimately drive how we determine which FSAs we conduct in certain instances. And so the work flow of that is important to how the public health regulations fit into our overall process.

So back in 2008 we developed a data driven approach to prioritizing a number of our FSAs. Some of the ones that we felt were, what we

call for cause or priority ones to conduct.

That was brought to the National Advisory Committee in 2008. And also to the National Academies of Science. And we published a plan for implementing that in 2010 on our website.

Since then we implemented a new information system. The data, the type of data we collected caused us to kind of go back and reassess how we were approaching that data driven strategy. And came up with a new approach called the Public Health Regulations. Which I'll go into more detail in some subsequent slides.

We also have some updates that have gone on just this past year implementing a new decision making process called the public health risk evaluation. This fits into our overall workflow of assessing inspection data, performing this evaluation based on that, conducting an FSA or taking other action as the evaluators determine is needed.

So this one is, I'll talk about some of the other criteria in a second, but this is an

important one to the Agency because it really does take some of our inspection data. The data that inspectors are recording at plants on a daily basis, and tries to assess where there may be issues that the Agency wants to focus additional resources.

So it's one of the ones, in one of the kind of unique ways that we're taking inspection data, and using it to make decisions about further actions or further evaluations.

There are a number of criteria. So these public health regulations are one of a larger set of criteria that we use to determine when to do public health risk evaluations and potentially FSAs.

We've just issued, in the past year, a directive that updates or really consolidates this list of criteria into one directive. Prior to that it had sort of made its, different criteria had made their way into different directives.

But you can see a full list in the most current one. Which I believe is Directive 5100.4.

But don't quote me on that.

You can see some of the other ones here. Pathogen positives, enforcement actions, recalls. A lot of those are based on single events or sort of larger issues. Whether it's laboratory testing or recalls from our recall actions.

The public health regulations are really the one criteria on this list that focuses on inspection data and really the large volumes of inspection results that we gather on a daily basis.

So how do we develop these public health regulations? We have a criteria that we've laid out in a report that we have on our website. It's at a very high level, a four step process.

We define a set of criteria that we used to select the regulations that we want to evaluate. So those criteria are, you know, it does noncompliance in this regulation, potentially result in a loss of process control, does it indicate a loss of or issues with sanitation, does it indicate an inability of the plant to implement corrective actions. It's those very high level

sort of criteria that we use.

And then we look at our regulations and we sort of evaluate them against those criteria. To really ask the question, does noncompliance in this regulation infer or imply a potential risk?

Now, not every noncompliance is going to meet that criteria, but we think that there can be noncompliances in those regs that rise to that level of maybe public health significance.

And so from that, applying that criteria, we developed a candid list of regulations. We use data to analyze those regulations to various outcomes.

So when we first implement this, we were looking primarily at pathogen outcomes. Were higher noncompliance rates in these regulations, prior to a positive -- well were the regulations higher in plants that had positives, then in ones that didn't?

And really we look at that, assess that by looking at their recent history before that event. We look at the 90 days prior to try and see

if there's any elevated noncompliance prior to that pathogen positive event.

Since then we've expanded that, and I'll talk about that in an upcoming slide. But we use that data to narrow down the list to, not just ones that we sort of qualitatively feel are important regulations, but ones that our data support links to outcomes.

And so we use those, we narrow it down to this final list. And those become our public health regulations for that fiscal year.

Once we've developed that, then we go through and we look at all of the establishments that are noncompliance rates for that set of regs and we define a set of cut points. And we say, essentially if the individual establishment's noncompliance rates, for those regulations rises above this cut point, they will be prioritized for this public health regulation and potentially FSA.

So what happens is, once we develop this list each year, we implement it by evaluating establishments on a monthly basis, calculating

their rates, prioritizing the ones that exceed these cut points and we send those lists out to the districts to act upon. Whether it's conducting a PHRE or taking some other action.

So this public health regulation criterion was launched in 2003. We actually brought this issue, I'm sorry, 2013.

We actually brought this to the National Advisory Committee in January of that year, basically asking the question, we present our methods to the Advisory Committee and we essentially asked, do you agree with our approach, is there anything that we've missed in this process, should we proceed or should we do further work?

Really, the recommendation from the Committee was to proceed with implementing this particular criterion, but did have a number of recommendations for us.

For example, they suggesting adding some of the, at that time, some of the new pathogens that we were beginning to test for. They asked us

to look at some other data, besides pathogen outcomes.

They also really recommended that we focus on sort of a post hoc analysis, looking at the feedback loop. Are the outcomes of the FSAs that are scheduled by this process really supporting or really validating that we've identified the more problematic issues or the more at risk establishments to evaluate.

There was also a recommendation from the Committee to really focus on communication and transparency. Both to industry, as well as to our workforce. So that they know how their inspection activities are really informing larger agency decisions and actions.

We moved forward based on the recommendations with the approach that we had in 2013. We published that on your website. But we have continued to reevaluate and make updates.

Every year we go back to our candidate list of regulations. We evaluate using the most current data and we update the list accordingly.

Some regulations drop off the list, some new ones come on. We really look at what the data is telling us in the most current fiscal year to make those kinds of decisions.

We also at times get new regs that get added to what we're verifying in our systems. And so that can also be incorporated into our annual updates.

We included 90157 STEC in Campylobacter in 2015. We also expanded our outcomes to include enforcement actions. NOIES and suspension actions. And found that to be a significant source of regulations, as well, for this process.

So, to give you all an update on 2016 in particular, the methodology is essentially the same. We haven't made any significant changes this past year.

We had made some minor updates to some of the more technical details about how we determine cut points. Sort of at the, when we're evaluating the NRS.

We have published a report that was

posted in, around July of 2015 on our website that talks a little in detail about some of these changes. But largely the same methodology as we had used in 2015. So it still uses some of our additional pathogen data and enforcement actions.

The FY16 list is a set of 54 regulations, and I should say sub parts to the regulations as well. Thirteen have been added, compared to the prior year list. Forty-one of the FY15 regulations carried over. That's about an 85 percent retention rate from FY15.

We also saw about an 80 percent retention rate when we moved from the FY14 to FY15. So we've done this for a couple years. We're seeing about 80 to 85 of the regs stay the same from year to year. But we do see some new ones get added.

And just to give you some perspective on, without going through a very detailed list of the regulations, which are available on the website and in the report, we did break down the regulations into some of these kinds of themes. These

categories that I talked about a little bit earlier.

Roughly half of them, both in FY15 and FY16, fall into the general category of preventing insanitary conditions. Another quarter or so fall into a general category related to hazard analysis and HACCP plans.

And then the balance of them fall into other categories, such as maintaining adequate records, monitoring critical control points, identifying corrective actions and preventing recurrence.

As I mentioned, we don't just develop these regs each year, but we really have a monthly evaluation process that goes on really continuously since we've implemented this. We evaluate each plant, each month, against their respective cut points.

One of the issues that came to the Advisory Committee, back in 2013, was to look at our cut point process. And the way that we do that is we categorize plants into, originally three,

although we've collapsed that down into two operation types.

So currently we're using a processing only group of establishments and then a combination, which includes slaughter and processing.

Originally we had a slaughter only category. We ended up rolling that into the combination group, just because that group of slaughter only was a fairly small group, relatively speaking. And it just made more sense to simplify the operation types and to group them into one of the two other categories.

You can see the cut points here. So what we do is we look at all of the regulation verifications that inspectors are doing.

When they go out to a plant and they are doing an inspection activity that day, they document in our system, not just the task that they performed, but what regulations they verified, when doing that task.

When there's a noncompliance, they also

identify what regulations specifically were noncompliant out of the ones that they verified.

And so we look at that ratio of, for the public health regs, the number of verifications, or really the number of regs found noncompliant, divided by the number of regulations verified. And we use that to come up with a percent for each establishment, looking at the prior 90 days, and we compare it to these cut points.

As I mentioned, what we do with that data has changed a little bit in the past year.

Originally, when we had implemented this, establishments that were evaluated each month and ended up on the, what we call the four cause FSA list, were sent to districts and districts would review those and plan out their FSA schedules for the upcoming months. And so the outcomes of this decision criteria have led directly to conducting FSAs at various establishments.

In 2015 we made two, I think, important changes to our workflow and our process. One is

that we introduced what we call a public health risk evaluation, or PHRE.

This is conducted, it's essentially a data review, an in-depth data review of available data that the agency has for an establishment. I think we looked at prior FSAs. We look at sampling data, we look at noncompliances.

We have EIAOs who are, I'm going to forget the acronym now, but the evaluation investigation and analysis officers out in the districts who really do in-depth reviews of establishments. They're the ones who are doing FSAs.

Now they're, in addition to that, prior to doing an FSA, we're doing this PHRE evaluation and making a determination about whether an FSA is warranted. Or maybe they're making a determination to move directly to an enforcement action or suspension.

The data may already be there to support taking a more significant action, other than an FSA.

But they may also make a determination that based on the data that informs this public health reg evaluation, that no further action is needed.

There may have been a recent a FSA or there may have been an FSA conducted for another reason. And so it is possible to take no further action as well.

So there are different outcomes that occur as a result of this PHRE. Which is now the event triggered by the public health regulations.

We also updated the FSA methodology itself. Originally it was a really in-depth review. It took roughly, I think on average, about two weeks. And looked at a wide range of activities in the plants.

We focused that down and redesigned it to be completed in approximately a week. It looks more comprehensively at the food safety system of the establishment. And so our approach has changed a little bit in terms of what we're evaluating with the FSA and therefore the outcomes.

I think all of that is really to kind of get to a point here which is that, although we're very committed to conducting ongoing analysis, looking at the feedback of this process, we have had changes in our process that we have to incorporate into our analysis as we go on from year-to-year.

We have looked at data on some of our preliminary work. Suggests that this process is identifying plants that warrant sort of closure in evaluation.

We don't have anything that's ready to publish yet or bring in front of the committee, but we do believe that this process is working. But we also, with the changes to the process, are going back and looking at the PHRE in particular and how that process is informing the overall workflow.

But in addition to that, we are continuing to make updates. In one area in particular is with communications.

The report has been posted. We update the website each year with the 2016 regs. As well

as our analysis report and some of the data supporting that.

You can see specific details about, for example, what regs were found significant in what operation types and for what pathogens. But we bring that all together to come up with our overall FY16 report.

We also post the cut points. And we issue a notice each year, both to our, primarily to our workforce, to inform them about the updates. I know a lot of stakeholders also very interested in those notices and so it helps inform them as well.

We also use other communications, such as constituent updates, to notify about updates to the public health regs.

Last year we implemented a PHIS reports that, for both industry and consumers. So those industry users that have access to PHIS can run this report, they can see what their rates are each month, they can look at the noncompliances that contribute to that and helps them better assess

what's going on in their plant and take their own actions as needed.

It's also available to our inspection workforce, our district offices, for them to run as needed.

This year we have added another layer to that, which is what we call a PHIS early warning report. This informs our in-plant personnel of establishments that have had, what we call sort of elevated rates.

They aren't high enough to exceed the cut point, they aren't high enough to trigger this PHRE workflow, but they are at levels that if they continue increasing, may get to that point.

And so we've added alerts that go out to our workforce to let them know that their establishment is not quite at the cut point, but at an elevated level. And they may want to look at what's been going on in the plant, look at their last 90 days and see if there's anything that may warrant action as well.

Just a quick example of the report with

some information. So in summary, we continue to reevaluate the data and make updates.

We are seeing some overall consistent results from year-to-year in terms of the broad themes and regulations and the carryover. But we do see some changes.

We think that that's informative, we continue to look at that and see what's changing and how. And we're using that to try to assess the effectiveness of this overall process and to make improvements as we can.

We added an alert this year that strengthens our communications out to our inspection workforce in this area.

We've implemented this public health risk evaluation, updated our food safety methodology and we're going to be taking a look at both of those changes in the coming year to really evaluate how affective we've been at prioritizing these establishments.

We are starting, right now, to plan for our FY17 evaluation. So this is the time of year

where we do analysis.

We plan to bring that to our governance and announce the results of that in the July timeframe, or end of June, and implement that at the end of the fiscal year and take effect in October of this next year.

So work is ongoing and we welcome any questions from the Committee. Yes, Sherri?

MEMBER JENKINS: Hi, Sherri Jenkins with JBS. On that alert that you said gets sent out to the IPP, is there also a same alert that goes to the establishment in PHIS too?

MR. ALVARES: There is not yet an alert that goes to establishments, but we have had that request come to us. We are evaluating it.

The alerts have sort of primarily been designed for our inspection workforce, but I don't think it's beyond the capabilities of PHIS to do that. But we do have to kind of assess that. So we are looking at that.

MEMBER JENKINS: Okay.

MR. ALVARES: That request has come in.

MEMBER JENKINS: And then just a second part of that is, in the monthly PHIS meeting or the weekly PHIS meeting, is it encouraged that the IPP discuss that with the establishment?

Meaning if there is an alert that comes out that they would be sharing it if we can't get the alert directly?

MR. ALVARES: The weekly meeting that IPP have with plant management? So I forget the exact details of what the notice recommends, but it does recommend that IPP talk to establishments, when the notice came out, to inform them of updates to the public health regs.

I don't believe that the inspectors are asked to sort of provide weekly updates. I think that we are really encouraging plants to get access to PHIS and look at that, run that report themselves as needed.

But the details of what we ask IPP to do with plants, I'd have to defer to what's in our notice and directive. I think Sheila was next?

MEMBER JENKINS: Sherika.

MR. PUZO: Sherika.

MR. ALVARES: Sherika.

MEMBER HARVEY: Sherika Harvey, Mississippi Department of Agriculture.

To answer your question, IPP personnel are to, are instructed to speak directly to the plants about those alerts and notices that come out.

MR. ALVARES: Thank you.

MEMBER HARVEY: So yes, that is implemented.

MR. ALVARES: Randall?

MEMBER PHEBUS: Randy Phebus, Kansas State University. Do you have any way of correlating how the companies who are running the reports and how well they're doing versus companies that are not and maybe using that as an encouragement tool for improving food safety?

MR. ALVARES: Well, that's an interesting idea. We have not looked particularly at the plants that have PHIS access and whether they're sort of using that data.

We have seen, we have looked at sort of trends in the reports and the PHRE report of the four that are available to industry. That is one of our fasting growing reports in terms of utilization.

So I think there is, for those who are looking at it, who have PHIS access, that's one of the most popular reports. But we haven't tried to correlate that yet to this analysis. That's an interesting idea.

Tanya?

MEMBER ROBERTS: Yes. Tanya Roberts. CFI.

I was kind of puzzled by the Foster Farms outbreak that went on for two years and I was wondering, why in the world couldn't you take action sooner?

I mean it seemed to me as though finding a positive in the plant is enough, isn't it?

MR. ALVARES: So that's a tough question.

MEMBER ROBERTS: I thought it used to

be.

MR. ALVARES: Yes. To answer it in this particular context. I mean positives that the Agency, like STEC and listeria positives are criteria that would trigger an FSA and an in-depth assessment.

The particulars of Foster Farms, I'm not really, I don't know enough of the details to go into here.

MEMBER ROBERTS: Okay.

MR. ALVARES: John?

MEMBER MARCY: John Marcy, University of Arkansas. Since you instituted the public health risk evaluation, do you have any sense of the three outcomes, what percentage those have generated? Whether it's a NOIE or other outcome?

MR. ALVARES: Unfortunately I don't have any data to share here. We implemented that around summer of last year and I think we do need to be looking at that.

I know the districts are looking at that pretty regularly. I don't have any data myself to

share today. Sorry. Do we have --

MR. PUZO: Do you have other questions?

MR. ALVARES: Yes?

MR. PUZO: Okay, thank you.

MR. ALVARES: Okay, thank you.

MR. PUZO: Thank you, Chris. Okay, our final presentation is on Chicken Livers, a Review of Risks by Captain Kis Hale with the applied epidemiology staff.

CAPT ROBERTSON HALE: Good morning everyone. I'm the deputy director of the applied epidemiology staff. And I'm really happy to have the opportunity to talk to you about an emerging food safety issue that I consider pretty important, as well as the folks in my staff.

So in the interest of time I'm going to skip over the overview and just jump right into the background.

In recent years, FSIS has investigated several outbreaks attributable to chicken livers. An investigation into these outbreaks have revealed certain patterns and etiology exposure

settings in cooking practices.

And these patterns suggest that these incidents aren't isolated, but rather indicative of a larger systemic problem. These outbreaks have also shown persistence, with the most recent occurring in just this past January.

As a result, OPHS is becoming increasing concerned about the risk associated with this product type.

To better understand the factors accounting for these outbreaks, OPHS conducted a review of outbreak data, scientific literature and FSIS science programs and policies, to better understand this issue.

In this presentation, evidence will be shared for informational purposes with two general aims in mind. Mainly just to put this out there for experts in and outside of the Agency and hopefully stimulate some conversations around what we could be doing to address this issue.

And two, eliciting feedback from the Committee on additional questions we might want to

probe, as we strategize further.

So chicken livers belong to a group of poultry organs collectively referred to as giblets, along with gizzards and hearts. Consumers commonly eat chicken liver in the form of pate, but many also prepare and eat chopped liver.

Although increasingly, chicken livers are finding their way to the mainstream. This product is still closely associated with certain ethnic traditions in niche communities.

In 2011 to 2015, six chicken liver outbreaks were reported to FSIS. Four characteristics standout as common among them.

The vast majority, or 83 percent, involved Campylobacter. The same proportion involved restaurants or institutions as exposure settings.

Eight-three percent involved chicken liver pate. And undercooking was identified as a factor in all six.

In addition, most were relatively small

and localized, involving only a single state, with fewer than ten case patients.

The exception was a large scale outbreak comprised of a 190 Salmonella Heidelberg infections linked to chopped liver that was packaged such that it appeared ready-to-eat when it was actually not ready-to-eat. In total, 220 illness and 36 hospitalizations were associated with all six reported outbreaks.

For the same time period, five additional outbreaks were captured in CDC NORS database. And like the others, common features include Campylobacter, restaurants, chicken liver pate and undercooking. Forty-three illness and two hospitalizations were associated with these outbreaks.

So over a five-year period we're talking about a total of 11 outbreaks linked to chicken livers in the United States.

A review of published reports found that we're not hardly unique in this particular phenomena. Australia, New Zealand and the UK have

documented similar outbreaks in recent years.

So we've talked about restaurants, but what kind of restaurants? Most have been rather small, high-end establishments that tout the use of locally grown organic ingredients and cater to diners seeking an eclectic perhaps European inspired dining experience.

Another affected group includes residents in assisted living facilities serving the Jewish community and other ethnic groups. And two other groups include participants in gourmet potluck events and the alternative health community.

An example of that I'll highlight a little bit later on this topic.

Given that most of the outbreaks that we've seen involve campy, we shall hear national trends in Campylobacter illness from 2006 to 2014. As you can see, in 2009 illnesses started to show an increase and then a leveling off between 2011 to 2014. It's during this plateau when most of the chicken liver outbreaks have occurred.

There are two points worth mentioning here. Due to a number of factors, including the difficulties in subtyping in this pathogen, using conventional technics like PFGE, relatively few campy illnesses are every linked to a recognized outbreak.

So with this it's rather remarkable that not only have we seen 11 campy outbreaks in the last five years, but also that of all the Campylobacter outbreaks we've seen, that haven't involved co-infections with Salmonella, all of them have been linked to chicken livers. And so that makes it likely that what we're really seeing is just a tip of a larger iceberg.

So in addition to what we know about outbreaks, there's also evidence that campy is not just a contaminant that's limited to the surface of chicken liver.

In 1983, Barot and others showed evidence of interior contamination by recovering campy in 20 out of a 117 chicken livers that were first surfaced treated in alcohol.

Later on White and others conducted a similar study in New Zealand and recovered campy in 90 percent of livers that were purchased at retail.

And then in 2009 Cox and others at ARS used a different approach by testing livers that were harvested from necropsy laying hens and they were able to recovery campy in 18 percent.

So both the Barot and White studies found that rates of external contamination were generally higher than internal, which suggest that the environment plays a bigger role in overall pathogen prevalence than does tissue colonization.

That said, the presence of pathogens within the liver tissue has greater implications to the risk associated with undercooking. And I will be elaborating on that next.

Studies have also shown recovery of Salmonella from livers. And in these studies, most of it involves experimentally infected chickens.

So now I'll talk about consumer's bias,

which favors under cooking of chicken livers adding to the risk of, associated with this product type.

So we reviewed social media, blogs and articles in the popular press for evidence of consumer preferences, attitudes and widely used cooking practices. And we found evidence that consumers undercook liver based on three different motivations. Some of which may or may not overlap.

And these include taste preference, health beliefs and low or misinformed risk perception.

First with the taste preference. So in our review of recipes, a number of themes consistently jumped out. Such as cooked to rare or medium rare, cooked until just warm in the middle, cook quickly or cook until still pink or Rosie on the inside.

We also found a quote, seen here to the right. There's nothing, nothing that makes me grumpier than overcooking liver. Which kind of highlights the emotional importance some connoisseurs give to not ruining chicken livers by

cooking them too long.

So all in all, these messages likely lead impressionable food preparers to err on the side of undercooking, at the expense of food safety. Okay.

So the quote here shows the existence of consumers who tout the supposed health benefits of eating, not just undercooked chicken liver, but raw chicken liver. And the author appears to recognize that there are some risks to raw liver, but they apparently also believe that these risks are offset by great advantages to health.

Appreciate as well that they're apparently are a fan of raw milk and that also happens to be another source of Campylobacter.

Supporters of this view maybe a small minority of the public. However, it should be pointed out that in one outbreak that we investigated in 2014, a Washington case patient became ill after consuming pills formed from raw liver, for perceived health benefits.

And finally, there's evidence that many

consumers harbor misinformed opinions about chicken livers that lower their perception of risk. This question was posted on an online message board.

Why is it okay to cook chicken liver or the inwards medium rare, but not the chicken breast?

I understand there are dangers of Salmonella, but doesn't that exist in the innards of the chicken?

So on one hand you have a person that understands and is informed enough to see that there is discrepancy in how we treat chicken livers as compared to other poultry parts, but on the other hand, this person is not informed enough to know the answer to this question themselves. Which means they're vulnerable to misinformation.

And as you can image, the answers that were posted in response to this question span the gambit. There were some reasonably sound answers, but then there were others that were pretty crazy. And patently so-so.

Okay, so what has the Agency done in recently years that address poultry, including giblets?

So as we know, we recently implemented the Salmonella action plan, which includes several initiatives to promote poultry pathogen reduction. Major initiatives include PR/HACCP, changes to the PR/HACCP sampling and associated performance standards, revised compliance guidelines and increased consumer education.

New areas of emphasis also include chicken parts, poultry and pre-harvest controls that are, have been included in our published compliance guidelines.

Despite this relatively large and comprehensive package, the risk associated with chicken livers has not been specifically targeted, until recently.

So to recap some of the conclusions here. Chicken livers are an under recognized source of foodborne illness in the United States.

Consumer risk is heightened by two

factors. Pathogen contamination within liver tissues and preferences, biases and practices that favor undercooking.

But all is not bad, we have not exhausted all options for addressing this issue. There are opportunities for the design of prevention strategies that are targeted to chicken livers.

Over the past few months, OPHS, OPPD, OPACE have been discussing strategies to address this issue. Three major areas for action have been identified.

The first concerns consumer education. I'm happy to say that OPACE has already made some headway in this area by posting advice in the food safety blog concerning the use of meat thermometers when cooking chicken livers. And also asking restaurants or telling consumers to ask restaurants about their cooking practices with respect to pate.

And hopefully we'll continue to explore ways that we can keep similar messaging out there

in the public arena so that consumers can see it.

Outreach to restaurants and others in the hospitality industry is another area we're currently strategizing around. And as with the public, this group may have misconceptions that could be address with education.

And finally, we're considering suitable guidance to the poultry industry that promotes affective risk mitigation strategies.

For instance, studies have shown that freezing is effective in reducing campy in chicken liver and it's possible that additional research could unlock other interventions that producers and processors could use. And in fact, this topic has been submitted for consideration as an Agency research priority.

All right, I would like to thank the team at the applied epidemiology staff for pulling together the information that went into this presentation. I thought they did a great job and welcome any questions or feedback. Thank you.

MEMBER BOOREN: I have a quick question

for you. What is FSIS', oh, Betsy Booren, the Meat Institute. Thanks, Sherri.

What is FSIS' recommendation for end point cooking temperature for chicken livers and does it align with the food code?

CAPT ROBERTSON HALE: Our recommendation right now, it's basically the same for any poultry. That's my understanding, it's 165. So it would be in line with the food code.

MEMBER PHEBUS: When you look at the outbreak data, do you have any indication how much cross contamination in the food service kitchen or the consumer kitchen that's playing a role here?

I got a feeling that the way all of these products are prepared there's a lot of handling and potential for cross contamination and I think we should look at that a little bit more.

CAPT ROBERTSON HALE: It's a good question. I think if it was cross contamination we'd be seeing a lot of other cases or case patients being identified that did not report direct consumption of chicken liver in these outbreaks.

But consistently we see that all of the folks that are being part of these outbreaks have had pate consumption. So that kind of points to that this is a direct exposure and not an indirect exposure.

MR. PUZO: Thank you. Well let's thank all of our presenters today for a great deal of information. We'll break now until 11:00. There is coffee out in the lobby, if those inclined, and see you back in about 14 minutes.

(Whereupon, the above-entitled matter went off the record at 10:48 a.m. and resumed at 11:03 a.m.)

MR. PAYNE: All right, everyone. If we could take our seats, we'll resume our meeting. As a reminder for anyone, if you'd like to make a comment during the comment period this afternoon, please sign up at the registration desk outside.

I do want to make a note here that the National Advisory Committee on Meat and Poultry Inspection received several comments through the public comment process.

We do appreciate the comments from the American Frozen Food Institute, the Safe Food Coalition, and the Association of Food and Drug Officials.

For all the committee members, you have received the printed out comments from the American Frozen Food Institute and the Safe Food Coalition, and the comment from the Association of Food and Drug Officials will be coming to you shortly and it will be distributed to you, so you can have it for your deliberations this afternoon.

Now we'll start looking into the charges, the specific charges for the committee, and we're going to start with the introduction of Ms. Kristina Barlow.

She's a senior microbiologist with the Risk, Innovations, and Management Staff, and she's going to provide an overview on the agency best practices guidance for controlling Listeria monocytogenes in retail delicatessens.

And without further ado, I'll turn this over to Ms. Barlow.

MS. BARLOW: Thank you, happy to be here today to talk about this project. Been a long time coming in our agency. Been working on this project for several years to evaluate Listeria control at retail, develop guidelines, and then see if retailers are following them.

I see several familiar faces here, so thank you for discussing what we feel is a very important topic to our agency and also to public health.

So the guidance document was issued in 2014. We accepted public comments on it. We revised it, reissued it. You should have received a copy of the guidance document in your packet. There's also additional copies out there.

So I'll talk a little bit about the guidance document, give you some background on it, and then also go into some of the preliminary findings that we're seeing from a pilot program that we're doing at retail.

So basically, the guidance document advises retailers of specific steps that they can

take to control Listeria in the retail environment.

And this information is based on a risk assessment, a joint risk assessment that FSIS, FDA and CDC issued describing the risk of illness associated with just different steps that are performed at retail during the handling of meat and poultry products and other products produced at retail. So it's really across the board.

So although this guidance document specifically focuses on meat and poultry products that are sliced at retail, really, it can be applied for any type of product in the deli area.

It also contains information from the FDA Food Code, the scientific literature, and lessons learned from Listeria control in the meat and poultry processing establishments.

So as you know, we've got a long history of driving down Listeria levels and actions that could be taken within the food processing establishments that can also be applied to retail facilities and delis.

So when you think about it, it's really

the same organism. The organism itself doesn't change, and a lot of the same actions that are happening at retail as far as the slicing and the handling of these products before it reaches the consumer.

You know, there are of course some obvious differences. We don't have the same level of control. There's lots of places for cross-contamination. A few carts coming in, people, you know, the customer, lots of areas for cross-contamination at retail you might not have in the FSIS-inspected facilities, but that just adds some extra challenges and those are some things we've covered in the guidelines.

So the guideline also contains a self-assessment tool that retailers can use to determine the practices they can take to address Listeria in the deli area.

So why did we develop this guideline and this Listeria initiative at retail? There is a risk assessment that showed that of the illnesses for deli meat, specifically, about 83 percent were

from those deli meats sliced at retail versus those packaged in federally inspected establishments.

We've also seen that our positive rate from the federally inspected establishments has been low. We've seen a big decrease over the years. We're down to about 0.34 percent from deli meats sliced at retail.

Yet, to hear from CDC shows that the level of listeriosis is plateau or remains about the same and hasn't decreased significantly like it would if all of the contamination is coming from the products that we test at the federally inspected establishments. So that caused us to look further to see what actions we could take to further address listeriosis illness.

So this is an example from FDA outreach materials that they provide on their website of listeriosis harborage that could be found at retail.

So this shows a slicer, one of the ones that typically could be used in FSIS establishments or at retail, and it shows you where Listeria could

form harborage of underneath, I can't really point, but of underneath those blades or the seals.

So that's why it's important to break those equipment down when cleaning to make sure that Listeria doesn't continue to contaminate the product, every product that's sliced as it goes through.

There's one study I think that showed if the slicer was contaminated and you continue to slice a meat product, I think this was a ham product in this case, up to the 14th slice would be contaminated.

So it continues to contaminate the product slice after slice once the slicer becomes contaminated. And that's a big show point that we've seen, so that's one area where we focus.

So as I said, the guidance provides practical recommendations that retailers can use, and they're really separated into four areas which are product handling, cleaning and sanitizing, facility and equipment controls, and employee practices.

And so those are the four main areas that were shown by the risk assessment to impact the level of illness from deli products, and those are the four areas that we focused on with our recommendations and also with our pilot project which I'll be talking about later. You'll see that carried through.

We also remind people that of course some of these are recommendations in this guideline coming from us, but they could be requirements depending on the state or local authorities that are applying the Food Code.

So I'll just very briefly cover some of the recommendations from the guideline. I won't go through all of them, you have that information, also there's most of this presentation on the results from our pilot project that we have so far.

But some of the most important findings were in the product handling area. And the risk assessment found that if deli products are formulated with antimicrobial agents, and those are preservatives like acetic acid or lactic acid

or even something as simple as vinegar, then that has a significant impact on the risk of illness from the product.

So the risk of illness can be decreased by 96 percent, and that was the most significant finding from the risk assessment.

We also recommend promptly returning ready-to-eat products to the refrigerated cases after they're handled, because as long as those deli cases are kept at 41 degrees and below that will slow the growth of Lm.

So that was another significant finding from the risk assessment. That's one thing we've seen, you know, possibly deli cases that aren't maintained at 41 degrees, some states even allow 45 degrees, there's a lot of variation there.

And the key to Listeria control and you'll hear me say this again, is cross-contamination control, keeping Listeria from getting on the product, and then if it's there on the product keeping it from growing, because it's the higher levels of Listeria that most often

cause illness.

So those are the two key components, the cross-contamination and the growing. And so these two product handling guidelines are there to control the growth of Lm.

We also have several that are focused on controlling the cross-contamination, and those are in the cleaning and sanitizing recommendations. And we recommend that retailers develop written sanitation procedures that describe how their equipment including those slicers will be cleaned and sanitized prior to use.

The Food Code recommends that those be cleaned every four hours, and the risk assessment showed that that was an effective level of cleaning.

We also recommend that unsanitary conditions are controlled so that mold and other dirty surfaces aren't present that could lead to cross-contamination, and that construction isn't performed during the slicing of these products.

Listeria can hide down into the dust and

the grout in the tiles on the floor and then back behind the walls, survive for many, many years. So it's important that retailers also realize that they shouldn't be like ripping up floors or doing something else to cause dust to come in.

That should be minimized as much as possible during when the product is being sliced so that Listeria doesn't cross contaminate into it.

So the facility and equipment controls are important. In the retail area you've got a big potential for raw products and ready-to-eat products to come in close proximity to each other.

I'm thinking of an example where you could have a rotisserie chicken being cooked in the same area where you've got deli meat being sliced.

So bringing in those raw products or the raw ground beef in the same area as the ready-to-eat, sometimes in the same deli case, that could cause aerosolization of the Listeria, the air blowing across it, and cross-contamination by employees not changing gloves in between handling raw products. So there's a lot of issues that can

lead to that cross-contamination.

The employees also play a big role in protecting the product, so we recommend that employees wear gloves. That's not a requirement in every state or locality, although it is recommended by the Food Code.

Also training, training is a very important recommendation, and providing the adequate facilities for hand washing. Some things that we've seen across the board have been, you know, tools in a hand wash sink, for example.

You'll see some examples of these when we further go over the results of the pilot we're performing. So it's important to make sure there's separate hand wash sinks which is a Food Code recommendation.

So many of these you'll see are not new. They do, as I say, come from the Food Code. It's just making sure that they're applied at retail, and the documenting we think is very important that these are occurring.

Okay, so now I'll switch gears a bit and

talk about the pilot projects that we've been working on. And the purpose of this pilot project was to assess whether retailers are aware of the guidelines and they're following them at retail.

So currently we have data from a pre-pilot that we performed the week of December 8th through 15th, where we went to 16 establishments nationwide. Our office of Investigations, Enforcement, and Audit -- I saw Carl sitting back there. His investigators went out to the retail facilities to start performing this evaluation. So we have some preliminary data from our findings so far. So we found that -- what I should say is that the compliance investigators are using a questionnaire to gather data to see whether the retailers are following the guidelines that I just went over, and so we'll talk about what those questions were and what the results were in the following slides.

So from just those 16 establishments we found that a higher percent of the recommendations for facility and equipment controls were being

followed. So pretty, you know, most retailers were following most of the recommendations for the facility and equipment controls.

We saw that a lower percentage were following the recommendations for the product handling and cleaning and sanitizing, but still more retailers were following them than were not. We had about 65 and 63 percent of those recommendations being followed.

So that shows us that we need to do some more work and outreach, and we're looking at additional next steps that we could take based on this information.

We'll also look to see if these findings are carried out through the main pilot where we're looking at many, many more retail facilities than the 16 we initially looked at. So here are some of the data from the pre-pilot project. As you can see, we have the questions laid out here. These are the first part of the product handling questions.

But it's color coded, so the green bars

represent the retailers that followed the recommendations, and the pink bars are the recommendations that were not as likely to be followed.

So you could quickly look across and as you can see, most of them were being followed on a first glance. Not applicable is in yellow.

And so since some of the questions, the answers to the questions were yes and the ideal answer was yes and some were no, this just makes it a little easier to follow.

I won't go through every one of these. You can go through and look at them when you're evaluating this information and I hope you do. But I'll just point out a few.

On this first slide, Number 2, this question was, is physically adulterated product present in the area? And luckily it was a hundred percent no. So that was great news.

We also looked at Question Number 5 where did you observe any opened, ready-to-eat meat or poultry product that isn't date marked, and we

got about 50/50 there.

And date marking is a recommendation in the Food Code, and that is important for Listeria control because the longer the product is kept in the deli case, the longer you have for Listeria to grow at those refrigeration temperatures. So that was a finding that we're looking more closely at.

Question 7, does the deli have records to document temperature of deli cases? And in more cases the answer was no, about 56 percent, than yes. So records might be another area where we would need to focus.

So looking at this next slide, these are also product handling questions. We looked specifically at Question 9. Are all opened, ready-to-eat meat or poultry products covered or wrapped or otherwise protected to prevent cross-contamination? And that's another one where we saw about 50/50.

Question 11. Are the deli ready-to-eat meat or poultry products formulated within antimicrobial agents? So about 70 percent

yes, but about 30 percent no. And that as I said was one of the significant findings of the risk assessment.

So the next slide provides the responses to the cleaning and sanitizing questions. And we saw Number 14, does the deli have written procedures for cleaning? And in most cases the answer was no.

Question 16, is the ready-to-eat equipment, including slicers, cleaned and sanitized every four hours? In most cases, yes, but in about 30 percent of the cases the answer was no.

And then 17. Are there records to verify the equipment is cleaned every four hours? And in about 75 percent there were not records to show that.

The next slide continues the cleaning and sanitizing questions. Question 21 was, are sanitizer types rotated periodically? In most cases they were not. That one can be help keep Listeria from developing resistance from

sanitizers.

We saw that many of the federally inspected establishments use that practice, but currently it's not happening at retail.

Question 23, did you observe the ready-to-eat area being cleaned with a high pressure hose? And in most cases that was no, so that was a good thing.

That's something that we see quite often happening in federally inspected establishments. They take a hose out there and spray down the equipment that causes Listeria to aerosolize and then land on most other things and lead to cross-contamination. So that was something that wasn't occurring as much in the retail deli.

Moving on to the next slide, these are the results for the facility. In most cases, as I said previously, the recommendations were met, so that was good news for these particular questions.

And those are again are, are there

standing water? Are there issues with the ceiling where condensation is dripping down? Is the equipment in good repair? So we've got yes for most of those, so that was good.

And then also for the employee practices most of the time those were followed. So it sounds like in most retail delis, at least in the small group that we looked at, the employees were wearing gloves, changing their aprons as often as necessary. Foot traffic was limited to keep cross-contamination from occurring. That sort of thing.

So here's some summary data looking at the states that we looked at for this pre-pilot. Again as you can see, over in the left hand column we looked at very few retailers for this initial pre-pilot, so only one or two per state.

So it's hard to say how much emphasis to put on this data, but there were differences in the percent of the recommendations that were followed for a specific state. We saw some states with lower percentages of the recommendations that were

followed.

So that could be linked to Food Code adoption in those specific states. We'd have to look further into that. We'll have to see if this is carried out too during the nationwide pilot.

This table shows a breakdown of the data by the type of retail firm. We looked at firms that were part of local or regional chains so that were more likely to be the bigger grocery store, and then also independently owned and operated stores more like the mom and pops, and then the ethnic markets, the two of those.

So the column in yellow is the followed, so you can look across there, and in most cases the local regional chains were more likely to follow the recommendations than the independent stores, and then the ethnic markets. So some of the observations from the pilot study, we saw disposal towels used for drying employee hands only when coming into or leaving the deli area.

They had a hand washing sink but tools were being stored into it. I mentioned that one

earlier. Employee traveled from the ready-to-eat to the raw area without changing or washing hands.

Facility uses a slicer for all their slicing needs including cutting vegetables, then they wiped it down but didn't use sanitizer. So these are just some examples that we saw.

Reusable cloths being used for a variety of products throughout the deli area and not being rinsed or sanitized could lead to cross-contamination.

One product was observed in the deli case with the sell-by date of November, but this was performed in December so it was outside its sell-by date.

Sink located in another adjacent room, so it may not have been available right in the location for employees to wash their hands. Disposal gloves were available but not being used.

Some employees who handled raw products also handled ready-to-eat products. In one case records were kept by the facility but then they were discarded at the end of the week. So

based on the results from this pre-pilot we did start our nationwide pilot. The nationwide pilot started January 25th. We announced this nationwide pilot in this notice. We provided the link here. And so this pilot is to measure the status of their voluntary adoption of these guidelines.

We are not performing sampling during this pilot. We anticipate that it will last about a year while we gather and assess the data, and then we can use the information to determine what best next steps we can take to protect public health based on the results that we're getting from the pilot.

So far we visited, in January and February we visited about a hundred retail facilities as part of it, and we have seen some improvements which is good.

We've seen some of those percentages that I shared with you earlier increase. So we already feel like we're getting the word out and seeing some improvements in actions that the

retailers are taking.

As part of the pilot, the compliance investigators distribute a brochure to the retailers. It's sort of a Cliff Notes version of the guideline to make sure that they're following the steps for Listeria control, and a copy of that's available out on the little table if you'd like to see that.

So that leads me to the questions that we have for you. Basically our question is, what are your recommendations for steps that we should take to ensure better control at retail?

Should we consider additional outreach to retail stores? If so, what sort of outreach should we be doing? What topics should we be considering?

If you don't have any recommendations on specific topics, do you have recommendations of where we could get the information to further develop our outreach?

Also, we're asking for your input on whether we should rely on regulation, state

personnel, the Food Code, or some other means to affect these recommendations.

We have a variety of resources available to us. We share jurisdiction with FDA and the state and local health departments, so how can we work best to affect these recommendations?

Should we work with FDA and the states to make changes to the Food Code requiring sanitizing and temperature control records? We saw that many retailers currently weren't keeping those records at least in the pre-pilot. Should we require certain actions by retail stores through regulations?

So here's some examples of specific actions we've discussed, such as keeping those sanitization records, demonstrating that the slicers and other equipment are cleaned every four hours as recommended in the Food Code.

Keeping records to demonstrate that the deli cases are below 41 degrees to control cross-contamination, the first one is to control the cross-contamination and the second one is to

control the growth of Listeria.

Are there any other considerations, such as cross-contamination due to air flow and aerosolization from the raw product to the ready-to-eat? So do you have any questions?

MR. PAYNE: This is Keith Payne here. Just as a reminder, state your name and affiliation when you ask your question.

MR. PAINTER: Stan Painter with the National Joint Council. Has the agency looked at or thought about the use of fans in processing areas, fully cooked areas, for the control of condensation, and are we controlling condensation with the risk of spreading Listeria?

MS. BARLOW: So thank you. I think that's a really good question, because certainly Listeria could be found in the condensation that's on the overhead ceilings, and when that air conditioning comes on when it's hot in the summertime and you see the droplets of water.

And we've seen this happen in quite a lot in food processing establishments when it comes and

drips down onto the product, and the fear is that the product can become contaminated through that condensation.

So it's something that we would certainly look for as part of the sanitization at retail. Fans can also spread the contamination and I'm sure that, you know, there's the possibility of having the fans running also in the retail area.

So I think, you know, Stan brings up a really good point. There are those lessons learned from what's happening in establishments where we, you know, worked for years to manage that. It's the condensation and the fans, and that's something that we're still struggling with that we can also see, you know, if that same issue is occurring at retail.

MEMBER ROBERTS: Tanya Roberts from CFI. I'm confused as to how much overlap there is between the Food Code and the guidance, because in a number of points you said, well, it wasn't in this particular state's adoption of the Food Code.

So I guess the question is, is one of the problems that -- is the major problem that the states aren't adopting what's already in the Food Code, or is the major problem that there's more in the FSIS guidance than there is currently in the model Food Code?

MS. BARLOW: And then I think that's a really good question too. It's a combination of things, really. Of course the Food Code adoption is voluntary.

MEMBER ROBERTS: Right.

MS. BARLOW: Those states decide whether to adopt it, whether to adopt the most recent version, whether to adopt certain parts of it.

So right now we don't have a really good handle on specifically what parts, what states have adopted. And I hear, you know, that AFDO and others are looking into that and seeing how we can get clearer information on that.

And then there are some recommendations that aren't currently part of the Food Code, like

the antimicrobial one is the big one that I think of right now.

And so at the same time, you know, and there could be reasons why stores might want to adopt that and maybe not. You know, there's natural products out there. People don't want a whole bunch of preservatives always in their products.

So we're looking, discussing at ways, you know, with the Conference for Food Protection, it's also working on a Listeria guideline, and working with our state and local health partners to see what's the best way to address these.

And there's no easy blanket answers unfortunately. You know, we have to work through the process and as always a way, you know, what's going to be important for the retailer and then what parts need to happen to best protect public health.

Randy?

MEMBER PHEBUS: Randy Phebus from Kansas State University. Just for clarification, who put together this, the best practices guideline

document and how was it vetted and reviewed?

MS. BARLOW: Well, we had a committee, a group of employees across the agency. It was developed within FSIS and we worked with our office of compliance, specifically OPHS, to look at the risk assessment and the impacts on listeriosis risk, and also with our Office of Field Operations from the lessons learned from Listeria.

So it was an agency-wide effort. We did seek input from our partners at FDA and CDC. And as I said, it was based on a joint risk assessment that we performed with FSIS, FDA and CDC.

And the guidance document was issued out for a public comment, so when we received comments from the public we received several from retailers who we, you know, updated, revised the document to reflect those.

MEMBER PHEBUS: So what's the process for updating or the plans for updating the guidance document? Is that a major effort or can it be updated?

MS. BARLOW: Oh, yes. All of our guidance documents are works in progress. So certainly we've got this pilot project underway. We will update the guidance document based on information from we receive, and I say we will do that.

Just from our initial pre-pilot we saw that some further information might be needed specifically on the product handling and sanitization, so we plan to bulk up those areas and make sure that it's understandable and easy to follow at the same time.

MEMBER PHEBUS: Just a quick review of the self-assessment portion of it, there's virtually nothing mentioned about drains and how to handle or place or sanitize drains and we all know that's a very high risk aspect of Listeria control.

MS. BARLOW: Yes, I agree. That would be a good one to look at in our further revisions.

MEMBER HARVEY: Sherika Harvey, Mississippi Department of Agriculture. You

mentioned that in the pre-pilot, in the pilot, a group observed the retailers. And I'm assuming that the retailers had pre-knowledge of the group coming in, is that correct?

MS. BARLOW: No, this is performed as part of our FSIS surveillance activities. As part of those we do not provide advance notice to retailers as part of our routine surveillance.

This is something that FSIS has been doing for years, going into retail establishments. It's now become a higher focus for us based on the results from the risk assessment.

So previously, retailers were at a tier 3 status and most of FSIS efforts were focused on warehouses and other areas where we don't have as much regulatory oversight from other agencies. And we've now moved those up to a tier 2.

So we are focusing on retail more and our compliance investigators go into retail as part of their surveillance activities and they look for lots of things like grinding logs.

They look at that under our new

regulation, and also whether the mark of inspection has been applied properly to meat and poultry products. And they've now added looking into the deli for the use control mechanisms more on top of that.

So as part of that process the compliance investigators go to the retail facility, they tell the store manager that they're there, and then they go to the retail area.

MEMBER HARVEY: Okay, great. Thank you.

MR. PAYNE: Just so we don't get too far behind, let's go to Betsy Booren, and then Dustin Oedekoven, Michael Crupain, and John Marcy.

MEMBER BOOREN: Thanks, and I've got two questions and one of them I think we'll need more information for the subgroup. The first one is -- oh, Betsy Booren, Meat Institute. Thanks.

Follows up on Ms. Harvey's question, this was an observation study, correct? Some of the questions that you have data on appears that they engaged with the employees?

For instance, Question Number 21, are sanitizer types rotated periodically? How are you sure that the data you're being collected, you're talking to the right personnel?

I mean, it's supposed to be an observation, but clearly you've had some level of engagement in a series of these questions. And if you're asking perhaps an employee who may not have the notice of that then these results don't accurately reflect it, but more importantly your larger pilot. So that would be one thing.

The other aspect is what exactly does FSIS have jurisdiction in, legally, at the retail? And I think having a summary of that or the CFR regulations for the subgroup as we're considering your recommendations would be very useful.

And I don't expect you to answer that now, but I think if we could get that for this afternoon that would be helpful.

MS. BARLOW: Okay. Yes. I mean, we can get that information certainly for you.

I mean, for surveillance as part of

their duties they're mostly focusing on observations. But the compliance investigators can ask the retailers or someone any questions.

Now they've been instructed as part of their training and the notice to try and limit that as much as possible, but they do have the ability as part of any surveillance activity to interact with the retailers.

So they can ask them questions about that. They're instructed to work with the deli manager or the store manager, but also as part of their training if they can't observe something or they aren't able to ask then they're supposed to put N/A. So we have taken that into account, but we'll continue to think about that also.

And as far as a regulatory authority, according the meat and poultry inspection acts we do have the authority to ensure that meat and poultry products are safe until they reach the consumer.

So our focus has been historically on the food processing establishments, although as I

said we have had our compliance investigators go into warehouses and retail and other facilities, so we have the ability to do that.

But we haven't typically focused on those areas because we haven't had the science in the past to tell us that we should be doing so. So it is a new focus for us, but we do have the regulatory authority as I said to ensure that our products are safe until the consumer consumes them.

MEMBER OEDEKOVEN: Good morning. Dustin Oedekoven, South Dakota Animal Industry Board.

And kind of along those lines, my question was kind of related to one of the questions that was posed to the committee is, should FSIS consider additional outreach to retail stores?

And I wondered if you could describe somewhat the interaction and the outreach that FSIS currently has with retail establishments.

MS. BARLOW: Well, we've got, what we have right now is we have the guidelines. We've given those presentations now at several meetings.

I can't count them all.

You know, over the last few years since we have had this information available, we've made them available for public comment as I said.

Our compliance investigators as part of their job duties do outreach. So their job duties are described in the directive. It was one of the links that I provided. If not, I'll get that to you.

And part of their job is to do the surveillance, but another big job is to do the outreach, so when they're out there they're talking to the retailers. And if they do see some vulnerabilities during their assessment then they'll share that information with the retailer.

And we also recently developed a brochure that I mentioned. We've now got that in a couple of languages, I think, so that's something we're further working on. But there may be additional avenues that are open to us that we haven't considered yet.

I think, Jeff, you --

CDR TARRANT: Yes, I was just going to add to that. We, the agency has also conducted two different webinars. One to the -- hi, Jeff Tarrant.

Yes, the agency has also conducted two different webinars back in January and December, one to our public health partners at the state level and another one to food safety professionals that worked at mostly grocery store chains, retail like 7-Eleven, Publix, Kroger's, where they came on for a big webinar, and we were asking them to disseminate the information along their various associations and lines that way too.

MS. BARLOW: We've also been working with FDA. I recently attended two of their meetings with the restaurant partnership and the retail foods partnership to present this information.

But there are certainly other avenues that we could look at, so we appreciate your input on those.

MR. PAYNE: Mr. Crupain?

MEMBER CRUPAIN: So Michael Crupain from the Dr. Oz Show. I think obviously handling and sanitation seems really important, but I'm curious.

On your first slide you say the positive rate from FSIS inspected products is low, but is that still ultimately the source of this Listeria, the meat that's coming out of the inspected plants, or do you think it's coming from somewhere else?

MS. BARLOW: Well, I think that's something that we don't know at this point. It could very well be that that low level of contamination could be bringing in some Listeria that's getting into the deli area.

But generally the science of Listeria is that it's going to be found down in the drains or in the environment. It's a soil-borne organism, really, so it lives in the dirt, survives in the summer and the winter. It comes in on people's shoes, on carts, you know, like I said it could up in the ceiling.

So it's really hard to pinpoint an exact

source. With that low percentage there could be some coming in on the product, but when research that has been performed shows Listeria all over in the retail deli and it forms biofilms, which are like plaque bacteria on your teeth and they're really hard to remove once they get down into the deli area and anywhere, really. So part of it is the constant cleaning and really scrubbing to get rid of it once it gets into the facility. It can be in there, we've seen Listeria survive 10, 20 years once it gets in.

So the answer is it could be a lot of sources, but yes, that could be one. But as I said we've seen the levels go way down with the efforts that industry has made and the policies that have been put in place, but we haven't seen the illness of this taper off.

MR. PAYNE: Okay, we have Dr. Marcy, and then one final question or comment from Dr. Singh before we move on to our next issue.

MEMBER MARCY: John Marcy, University of Arkansas. Just two clarifications on the CDC

data, the 0.24 per 100,000, it states that it plateaued. Was it going up or going down when it plateaued? Do you know?

MS. BARLOW: I mean, I think it's sort of leveled off, but we'll get that information for you. I think we've got more recent --

MEMBER MARCY: Yes, and the second clarification has to do with, I think there's a statement in there that none of the places that you observed were familiar with your guidelines before you observed them.

So when you talk about the follows data later, they're either following or not following that's happenstance, because they weren't familiar with your guidelines before you --

MS. BARLOW: Yes, so that's one of the things that we saw. So we're trying to -- that tells us we need to continue that outreach. You know, since many of those recommendations are already in the Food Code, I think, you know, that's one reason that they were being followed.

But we'd had the guidelines for about two years at that point, and so that just shows us that we continue that outreach. And I think they're getting more and more familiar with it as we continue to give these presentations and we're doing the nationwide pilot.

MEMBER SINGH: Manpreet Singh, Purdue University. Actually, there's two parts to this. One was, in your pilot you had all these retailers around the country. Was there a basis of how you selected those retailers around the country or how their area was divided?

And the second one is, I know you said a follow up to what Betsy had just mentioned that there was a fair level of engagement with the personnel in the retail, so at what level was that engagement? Was it the food safety professional or was it the employee actually performing the task?

MS. BARLOW: Carl, would you? Is Carl back there, still?

MR. MAYS: Hi, I am Carl Mays with the

Office of Investigation, Enforcement, and Audit. When we go out to the retail delis it's just a normal surveillance we do, so we don't target any particular group.

We're broken up into four regions around the United States, so within that region all the investigators look at different places. So it's not, you know, mom and pop or big retail, they go to different places. That's what they're told to do.

The second question I didn't hear.

MEMBER SINGH: The second part for that -- this is Manpreet Singh again from Purdue University. The second part was when you had a, whatever level of engagement you had with the personnel at the retail level, was it with the food safety professional responsible for food safety within the retail facility or was it with the person actually involved in performing the task?

MR. MAYS: So normally what we do is when we go in we contact the store manager and then we go to the deli area. We tell the store manager

and the deli manager that they don't have to be present, but most of the time they will follow the investigators through the whole process to see what's going on.

We observe most of the time. Sometimes we do talk to the people, you know, especially if we're talking about cleaning or something like that and we ask questions like do you have cleaning logs and stuff like that.

So it's kind of a combination but most of it's observation, so we're not actually asking the person in charge. If you're doing something, we're observing it.

MR. PAYNE: Okay. Thank you, Ms. Barlow for that thorough overview of the first issue for this committee.

We'll move on now to the overview of the second issue for this committee to consider and that's the consideration of mandatory labeling features for certain processed, not ready-to-eat meat and poultry products.

And we have Mr. Mark Wheeler who is with

the labeling and program delivery staff. Mr. Wheeler?

MR. WHEELER: Thank you, and good morning to everyone. I'm going to be talking about the considerations in mandatory labeling features for certain processed, not ready-to-eat meat and poultry products.

We'll be going over some background information such as what is the ready-to-eat product, and then talking about some of the recalls that we've had recently regarding not ready-to-eat products.

We'll talk about some issues of concern, and then I'll pose the questions to the National Advisory Committee.

One of the things, you know, to start this discussion we need to lay the groundwork for what is a ready-to-eat product. So determining what a ready-to-eat product is some products are defined by the standards in the regulations as ready-to-eat products.

Other products are expected by the

consumers to be ready-to-eat, and some products may not be ready-to-eat, or they may be ready-to-eat. It just depends on certain features that are in processing that takes place, and the labeling features that how the product may be labeled.

Did this slide move? Wait a second, I think I just talked about this.

And so a ready-to-eat product is a meat or poultry product that's in the form that is edible without additional preparation to achieve safety.

That the product may have additional preparation, but that preparation is to make it taste better or to make it look better, but it's not a safety requirement. These can include both frozen meat and poultry products.

And so by defining a ready-to-eat product is not going to typically have the safe handling instructions as required by the regulations 317.2 with 381.125.

Additionally, a ready-to-eat product is not going to have cooking instructions on it. It may have heating instructions, but they're not,

you know, so there's a distinction there between the heating instructions and cooking instructions.

And so in many cases, the ready-to-eat product labeling is guided by various factors, and so now we're going to look at some examples of labels. And this is what I just talked about is that, you know, your standard of identity for a product. It's either going to be standardized by the regulations or the standard in the food policy book.

And so for this label is a hot dog, it's a beef frank, and the regulations 319.180 defines a frankfurter or a hot dog or wiener as a ready-to-eat product.

And this label is a French liver pate, and its consumer expectations, in the long term production practice, is pates are understood to be ready-to-eat products.

This product here is based on the labeling features. You have nutrition facts is based on eight pieces, 140 grams, which is the ready to be served RACC, or Reference Amount Customarily

Consumed by the consumers. And so based on the labeling features here, these egg rolls are ready-to-eat product.

And this product here, it's, I forget what it, I think it's meatballs. But it has description on the principal display panel indicating that it's simply heat and serve for, you know, from dinners.

Other examples of the terms on the principal display panel would be heat and serve or ready-to-eat and that's indicating that the product is ready-to-eat.

Other information would be heating instructions, as I commented earlier, rather than cooking instructions. It might tell somebody to cook or warm it in the microwave or heat it in the oven.

However, if an establishment produces a meat or poultry product that is not commonly understood to be by the consumers to be a ready-to-eat product, for example, meatballs or a soup or chili or corned beef hash, or if there is

no product standard for the particular product that it be ready-to-eat, then the establishment can decide to send the product into commerce as a not ready-to-eat product even though it was previously prepared as a ready-to-eat product.

And if the plant chooses to classify their previous product as not ready-to-eat, then they must provide assurances through the manufacturing practice, their sanitation practices, and validate the cooking instructions that the product will be safe for consumption. Then FSIS would expect the company's hazard analysis, their HACCP plan to support the contention that the product is not ready-to-eat, such that they have not identified a biological hazard like salmonella, E. coli, Listeria, or staph as hazards reasonably likely to occur that are eliminated by a subsequent heating step. Consequently, the process, the hazard analysis, the HACCP plan, and the decision making documents should be consistent with the manner the company chooses to label and market their product.

This is a particular concern for products that appear ready-to-eat but are not ready-to-eat. Thus, the label must clearly indicate to the consumer that a product is not ready-to-eat and must be fully cooked prior to eating.

Such features include a statement on the principal display panel that the product needs to be cooked, for example, cooked thoroughly, cook and serve. They might have safe handling instructions on the product.

The nutrition would be based on a ready-to-cook reference amount and the product would have cooking instructions. The cooking instructions must not be misleading and be adequately, reflect practical instructions related to the proper use, cooking and handling of the product.

Now we're going to talk about some focus group studies that the agency contracted with. We went with RTI to conduct focus groups to evaluate the consumers' understanding of several labeling

features, including the safe handling of meat and poultry and egg products including the preparation instructions, but these products were not ready-to-eat. And we also looked at the safe cooking instructions for raw meat product.

RTI conducted 11 focus groups in five locations throughout the United States. These included the general population and at-risk populations.

A total of 86 people participated in the groups, and the published document is titled, Consumer Research Assessing the Effectiveness and Application of Public Health Messages Affecting Consumer Behavior Regarding Food Safety.

The findings found that consumers are increasingly relying on prepared meat and poultry products because they are convenient, quick and easy. These recent food outbreaks suggest that some consumers are not properly preparing these products to ensure that the products are safe to eat.

There appears to be confusion as to

whether frozen meat and poultry products are ready-to-eat or not ready-to-eat, and participants did not distinguish between different brands and products unless you have this, you've got people relying on past experience to prepare a product.

And so if they're always cooking something and throwing something in the microwave for two minutes, they continue to do that regardless of what brand it is and what the instructions may say on the label.

Some participants consider all frozen items to be ready-to-eat, and thus not ready-to-eat products may not be properly prepared. Most participants did not know the wattage of their microwave and thus did not make adjustments for the cooking time. They did not use meat thermometers and relied on past experience, and most consumers or participants were confused about the purpose of a rest time.

Thus, a lot of people, they thought that reading the preparation instructions, they believed the instructions were important but they

didn't believe that these were requirements. They just thought that preparation instructions were something to make the, properly prepare the product so you get the best quality product.

I'll just back up a minute. And the same thing goes with the purpose of the rest time. People really didn't understand what the purpose of the rest time was.

They thought, you know, various ideas about, you know, why somebody would let it rest, and thus if they're in a hurry they're going to pull it out of the oven and start slicing it up.

And during this study they offered, RTI offered people icons. And they found this icon here, pictured here, and it's got -- I think it moved a little. At least on my screen it moved.

That this shows an icon and it states, raw chicken-do not microwave, and it shows a picture of it. And most people found that icon to be clear and to the point and understandable.

The reason for the concern is that in 2006 there was a recall of stuffed poultry products

linked to salmonella, and then in 2007 there was another recall for pot pies linked with salmonella and this included both meat pies and poultry product.

And in 2010, there was again a recall for chicken and rice dinners linked with salmonella. And so the concern is not specifically with the stuffed poultry that's gotten a lot of headlines, and I'll show it in the next slide. It's a couple of different types of products here that this problem is occurring.

Following the 2006 recall, FSIS sent a letter to the industry, particularly the industry that's making the stuffed poultry products, the Chicken Kiev, or broccoli stuffed chicken breasts.

And they had the statement. They suggested that these products bear the statement of uncooked, for safety cook to an internal temperature of 165 as measured by the use of a thermometer.

And so this is a product label from one of the products that it's recalled, and you see it's

the chicken breasts stuffed with broccoli and Swiss cheese. And it has an example of that icon that we previously saw, and it also has the statement that the agency recommended for these products that it's raw product and has a minimum internal temperature.

And this is the cooking instructions that were on the back of that chain or product, and so again it's telling people not to microwave it, telling the consumer to put it into the oven at 400 degrees and bake for 25 to 30 minutes. And in spite of all this information there was still illnesses.

And so there's no, you know, in the regulations there's nothing specific in the regulations to require a manufacturer to label their product as raw, to label their product as uncooked or not ready-to-eat. And thus you have the following product, and I'll show you three more labels.

This is a veal steak. It's chopped and formed and it's breaded, and possibly the breading has been sitting in vegetable oil. So the product

is raw, but the exterior may look like it's a ready-to-eat product. But there's nothing on this label to indicate the product is not ready-to-eat and needs to be cooked.

This is a bone-in ham, and again this product is a raw product and there's nothing on the front, the principal display panel, to indicate that. It says keep refrigerated, but it doesn't say that it's raw, it doesn't say that it's not cooked.

And this is a label for herbed Parmesan breaded chicken scallops. Again, a raw product. There's not anything again on here saying the product's not cooked.

And so then the charge that we would like to ask the committee is should FSIS require statements such as raw, uncooked, ready to cook on the labels of raw poultry, or raw product that may appear to be ready-to-eat to convey to these products are not ready-to-eat?

Additionally, should FSIS require that such products bear validated cooking instructions?

And if so, aside from the method of cooking, an endpoint temperature of 165 and instructions to use a thermometer, what other information is needed? And finally, are there other steps that FSIS should consider requiring to prevent illnesses involving these types of products?

And that's -- any questions from the committee?

MR. PAYNE: Okay. I see ten cards going up. First we have Tanya Roberts.

MEMBER ROBERTS: Tanya Roberts from CFI. I have two questions. It occurs to me that in a lot of these processed products that are not ready-to-eat and that they're ready to put in the, they're frozen and then you either microwave them or whatever for lunch or for dinner, do they have a much higher pathogen load than it would be if it was like a fresh chicken cutlet?

Because some of these are preformed product, even the beef ones they might be, have the lean textured beef in them or, so that because they may have a past inspection of the fresh product they

may be put in the required for cooking products. So --

MR. WHEELER: I think it's going to vary depending upon -- I'm not a microbiologist and I don't know about the microbiology of all these various products.

MEMBER ROBERTS: Okay. And you haven't looked at that as part of this project.

MR. WHEELER: Yes. But I think it could vary because, you know, you could have a chicken patty that's breaded or you could have chopped and formed, like the veal --

MEMBER ROBERTS: Right.

MR. WHEELER: -- was chopped and formed. But you could get a veal steak that's --

MEMBER ROBERTS: Sure.

MR. WHEELER: -- a whole muscle that's just been breaded. So it could --

MEMBER ROBERTS: Yes. That could cause considerable confusion too.

MR. WHEELER: Correct.

MEMBER ROBERTS: But then the second

question is, if it's frozen maybe you have increased heat resistance from the salmonella. Because I was reading one paper where they talked about just putting the chicken in the refrigerator for one day increased the heat resistance of the pan-fried chicken the next day. I was really shocked at that.

MR. WHEELER: I'm not a microbiologist. Maybe Dan --

MR. ENGELJOHN: Thank you. Dan Engeljohn with Food Safety and Inspection Service.

Tanya, thank you for the question. So I did want to just touch on the first issue that you asked about with regards to microbiological level or load at the product.

The agency does not test this type of product and so we don't have information as to whether or not this product has a higher or lower level of microbiology in what we would consider to be there on the raw, whole muscle type products, nor does the agency have a current microbiological verification program where we're swabbing the food

contact surfaces or the environment to know whether or not there is higher unsanitary level in the types of operations handling this product.

I can tell you that the agency does have plans to move forward with both types of products. So although it's not directly related to this issue, we certainly would welcome input on that. But there's a vast need for information such as what you're asking about.

On the resistance thing, I don't have a specific answer for you, but I know that we will follow-up to see if we can find additional information to know whether or not that presents additional concerns.

MEMBER ROBERTS: Thank you.

MR. PAYNE: Okay, next we have Pat, then John, and then Betsy.

MEMBER CURTIS: Understand where we're going with the questions that we're asking about the icons and that they understand those, I guess I have a more basic question.

Is there any research that actually

shows what consumers perceive to be ready-to-cook products or not? I mean, we're making certain assumptions that these are the type of products that would need those labels, and you're asking consumers questions about the labels.

Do we ask them any questions about what they perceive to be a ready-to-eat product so that we understand that they agree with our assumptions?

MR. WHEELER: There may have been sort of research back in 2003, or in near-abouts that time frame, but I don't know if they asked that particular question. I'd have to go back and look at that and research. I think RTI might have done that. And I'd have to go back and look at that to refresh my memory on that.

MEMBER CURTIS: It just seems like that would be an important area in determining what products needed the special labeling.

MR. WHEELER: Yes. But I don't think, I don't know. I think we showed them labels and asked them, you know, based on the package do you think this product is ready-to-eat or not

ready-to-eat? But I don't recall us going out there and saying do you think a hot dog is ready-to-eat?

And I know that, you know, years ago when I was young, there was all kinds of debate that could you take a hot dog and eat it. Could you take a hot dog right out of the refrigerator, you know, pull it open and eat it.

And the fellow next door, he used to eat the hot dogs right out of the refrigerator, and it disgusted me. I never thought of eating a raw hot dog, but it is ready-to-eat.

So people have had various opinions about that and I don't know whether we've asked that particular question about, you know, is a hot dog ready-to-eat, is a pate?

I mean, we consider those to be ready-to-eat. A hot dog, at least by the standard of identity it's ready-to-eat, but whether, you know, everyone considers a pate to be ready-to-eat, I don't know.

MEMBER MARCY: John Marcy, University

of Arkansas. I'm glad you have this chain or label in your presentation because it goes along with your question of what you want because it seems like they covered all the points, you know, cooking temperature, use of thermometers.

You know, in terms of not having any cooking instruction, just the fact it has a cooking warning for using in microwaves, there is no cooking instruction for using in the microwave. It says do not do this, very clear.

You know, your next thing, there were illnesses. Do you have any information related to the illnesses of how that product was prepared?

MR. WHEELER: No, I don't.

MEMBER MARCY: Does anybody?

MR. WHEELER: I don't know whether the recall staff, epidemiology staff, I don't know what background information they may have gotten on that.

MEMBER MARCY: Okay.

MEMBER BOOREN: Betsy Booren, the Meat Institute. Following very closely to Dr.

Curtis's, when one of the questions the group is considering is requirement statements.

And I think something to consider is that the statement like not ready-to-eat, I know what that term means in the vernacular and what it means within the food industry, but I'm always amazed when consumers could think that that means not safe to eat, as in it's not safe for human consumption.

So again getting to your point on what are words, terms that can be used, I think careful consideration needs to be given of if these are safe and wholesome products that have gone through inspection that we're not scaring our consumers from eating them purely by a label.

The other, my main question is this is a complex food mixed dish item that's primarily meat/poultry, what you've given as examples, but many complex mixed dish food items are also regulated by FDA.

How, do you have any insights or can provide any insights onto this group, because of

the complexity of the food system and inspection and regulation, how is what you're posing, is FDA considering similar types of activities for their not ready-to-eat food products that they're regulating?

I'm just thinking from a standardization type across the food industry. I think that would be helpful information.

MR. WHEELER: I don't know what FDA's anticipating.

MR. PAYNE: Okay. We have Dr. Krzysztof Mazurczak and then Ms. Sherri Jenkins.

MEMBER MAZURCZAK: Krzysztof Mazurczak, Illinois Department of Agriculture, and I would like to comment.

Just today, during previous presentations when talking about revising safe handling instructions, now we're talking about additional requirements for certain types of meat and poultry products.

In June, we have a final rule coming in effect of requiring plants, establishments to list

and validate the cooking instructions on product.

And just looking at examples of pictures with labels of meat products, they become crowded. It's hard to sort it out what kind of information is really important for the consumer, what type of information is expected to be taken very seriously.

So my general comment is that I think we will have to prioritize those messages on the label, and those are really important to protecting public health.

And the second comment is I think what's on occasion is really backfiring in all entities involved with meat inspection is that there's tendency of layering new regulations over existing regulations, and on occasions they are just complicating and preventing the general public from receiving the proper message.

And the last but not least I think that instructions should be very simple and realistic. I would dare all in these to acknowledge who knows how strong their microwave oven is, I mean, the

wattage that they have in their own kitchen. And we've seen those examples that using microwave at 600 watts honestly, I do not know the strength of my own microwave oven. Also what concerns me is instructions for using thermometer. And it's based on the fact not too many people realize that on most common household thermometer there's an indentation point that requires the stem to be pushed at least half inch into the product to get accurate reading, and with like breaded steaks it's impossible.

So to end up, I think let me just to summarize what I was talking about. I hope that we can find a way to prioritize those messages and make them more believable. Thank you.

MEMBER JENKINS: Sherri Jenkins, JBS. I guess on one of the slides I just wanted to state I think we need some clarification. It's one on Page 7 of the handout, and maybe it says 124 on it, where it talks about if you're making a not ready-to-eat product, which means you haven't identified it with the packaging a hazard because

it's going to go through a lethality step, I just want to make sure that we're not saying, since back in 2002, 2003 the Federal Register published that for ground beef, which is non ready-to-eat, it's not intended to be eaten raw, that we have to have the hazard of E. coli O157:H7 in there, and here recently with the non-O157 STECs.

So I just want to make sure that we're not saying that since it's not ready-to-eat, something of that nature, so a list of products or things that would constitute that not ready-to-eat needs further, if we're going to make a statement like this because it kind of goes contradictory to what the current agency thinking has been, unless I'm reading this a little differently.

So I just wanted to make sure that there's some clarification or there's a discussion point in the afternoon group.

MR. ENGELJOHN: So this is Engeljohn. I'll just -- with FSIS. So I'll just clarify that. I do think there's a distinction for raw beef versus these products, which are not raw beef they're

processed products.

But for the raw beef where we have an adulterant determined, labeling cannot be used as a mechanism to not address the hazard. So that's one issue related to beef.

On these products that we're talking about here, none of them have an identified hazard or an adulterant determined, so the pathogens that likely are present in these products are being addressed through a subsequent lethality that the consumer is applying.

So in that particular case there is an expectation that there is a potential contaminant in the product and that the lethality delivered by the end user will in fact make them sick.

So I just wanted to make the distinction that for beef because we've declared O157 to be an adulterant, labeling cannot be a mechanism to undo that hazard.

MEMBER JENKINS: And so with that the rest of the list and what it would pertain to, I think, is very important because I don't think you

want that misinterpreted later on and more questions later.

MR. PAYNE: Looks like we have two more questions and/or comments from Tanya Roberts and then Randall Phebus before we break for lunch.

MEMBER ROBERTS: This is a point of clarification on my earlier question about when a product is declared that it's not safe to eat as, you know, under inspection as a raw product, then it can be sent to be put into a cooked product such as these, or does that mean it can only be in a canned product, and if this is a frozen product that hasn't really yet been cooked but you expect the consumer to cook it, do you make that kind of a differentiation?

MR. ENGELJOHN: So this is Engeljohn. I'll clarify it. No, if a product's been determined to be unfit --

MEMBER ROBERTS: Yes.

MR. ENGELJOHN: -- then it cannot be used for human food purposes.

MEMBER ROBERTS: Oh, any of it.

MR. ENGELJOHN: If it's a, if the determination is that the product can be used but it can only be used in a product that receives a full lethality. Then within the FSIS inspected facilities that may be labeled as for further processing which would indicate that it has to go to another federally inspected facility and made into a ready-to-eat product in that federal facility.

MEMBER ROBERTS: Okay.

MR. ENGELJOHN: So the products we're talking about here are being prepared and handled under we would hope relatively sanitary conditions to reduce the microbial contamination in that product to a level that the manufacturer deems can be made safe by how that product is prepared typically by the consumer.

And so again we don't have standards for any of these products as finished products, nor do we have standards on the sanitary conditions of the facilities.

And so there's this unknown about is the

level of contamination on these products too great for the consumer actually to make them safe? So that is an important question that we ultimately do need to answer.

MEMBER ROBERTS: Thank you.

MEMBER PHEBUS: Randy Phebus, Kansas State University. Back around 2007 when some of the Chicken Kiev and Cordon Bleu type products were involved we did a study, and this is not really related to labeling but I think it has an impact.

We looked at a lot of retail products like this, and they would be stored side by side in the retail case. And the packages and the pictures on the packages, the colors and the schemes on the packages were the same whether it was ready-to-eat or not ready-to-eat, and talking about a very confusing issue for the consumer.

So, you know, in addition to the labeling, there might be some best practices that we could tell processors to make sure these packages look different. The retailers, maybe they could separate them in the retail case so that

they're not so confusing to the consumers.

MR. WHEELER: Okay.

MR. PAYNE: Okay. We'll come to the point now where we'll break for lunch, and if any questions do come up that the committee members think of, bring them up when we reconvene.

We'll try to be back here in an hour at 1:30, so we can move on with our afternoon subcommittee deliberations. You can bring it up during the brief period of time before we break out into two subcommittees.

I want to thank Mr. Wheeler for his thorough overview on the labeling here.

So there is a list of facilities, eateries in the vicinity, in the area. They should be in the binder for the committee members. If not, so you can always ask your staff for some recommendations for a quick bite to eat. So let's see everybody back here at 1:30.

(Whereupon, the above-entitled matter went off the record at 12:26 p.m. and resumed at 1:31 p.m.)

MR. PAYNE: Okay. Good afternoon, everyone. It's 1:30, so let's reconvene for this afternoon's deliberations. While people are taking their seats, I just want to remind everyone those who want to make a comment, please feel free to sign up at the sheet there at the registration desk.

The comments that I mentioned earlier from the American Frozen Foods Institute, the Association of Food and Drug Officials, the Safe Food Coalition, we have copies of those comments available out on the counter for anyone to take. We did distribute them to each of the committee members.

And at our tabletop exhibit across, outside, we do have free resources including these Guidance for Controlling Lm in Retail Delis, both in English and in Spanish for example, so please take copies of these.

We also have our food safety resources brochure. Anything listed there is free of course and we will handle that for you.

So we'll get started now with just for the record to go through the two subcommittees and their respective charges that they are given. Obviously you heard the charges or the issues that were provided right before lunch.

And I will go through just for the record the Subcommittee 1, this subcommittee will focus on the FSIS Best Practices Guidance for Controlling Listeria monocytogenes in Retail Delis.

On that subcommittee we have Dr. Betsy Booren, Dr. Randall Phebus, Dr. Manpreet Singh, Dr. Dustin Oedekoven, and there's Sherri Jenkins, Ms. Sherika Harvey, and Dr. John Marcy.

For Subcommittee 2, which will focus on the Consideration of Mandatory Labeling Features for Certain Processed Not Ready-to-eat Meat and Poultry Products, we have Dr. Michael Crupain, Dr. Alice Johnson, Dr. Krzys Mazurczak, Dr. Michael Rybolt, Dr. Patricia Curtis, Dr. Tanya Roberts, and Mr. Kurt Brandt. That rounds out Subcommittee 2.

Now for Subcommittee 1, let's back up here. Subcommittee 1 will stay here in this auditorium. With Subcommittee 1 we will have the moderator of Ms. Kaitlin Keller from the Outreach and Partnership Division to keep things moving along.

And based on the discussion of some requests I brought down some copies of the Code of Federal Regulations for this subcommittee. If there's any reference that needs to be made to check the CFR, two copies here.

We're also trying to get access to the CDC FoodNet data online. So once we break into the two subcommittees we'll try to get that access for you to that data that you can have.

For Subcommittee 2, you will be with Dr. Robert Boyle there in the back. Dr. Boyle will escort you to Room 6. And I ask for those of you on Subcommittee 2 to take your tent cards with you, because in order to facilitate a free-flowing dialogue but in an orderly manner, Dr. Boyle as well as Ms. Keller will ask you to raise your tent cards

during the discussion.

These two subcommittees are open to the public. You are welcome to go into each one and go back and forth between each one. Public comments are welcome.

So if there any comment, for anybody to make any question or comment, please state your name and affiliation again for the record. We have court reporters in each of the two subcommittee meeting rooms.

So with that said, are there any final questions before we break into the two groups?

Seeing none, we will go ahead and begin our subcommittee deliberations.

(Whereupon, the above-entitled matter went off the record at 1:38 p.m. and resumed at 4:41 p.m.)

MR. PAYNE: So it seems like we had very productive dialogue in both of the Subcommittee sessions and we want to thank our respective Subcommittee Chairs, for Subcommittee 1 it was Ms. Sherika Harvey, for Subcommittee 2 it was Dr.

Michael Crupain.

MEMBER HARVEY: Thank you.

MR. PAYNE: Thank you very much. And for Dr. Crupain and Ms. Harvey are there any other issues? Do you need extra time in the morning to reconvene your Subcommittees?

MEMBER HARVEY: I think we all agreed to leave it where it was, so that's our draft.

MR. PAYNE: Okay, thank you. And I received a negative from Mr. Crupain on meeting earlier. So you are welcome even throughout the night over dinner to think over your draft recommendations, these are draft.

And we do have a hard copy that Ms. Williams has here for the Subcommittee 2's draft recommendations. These are made available to all Committee Members and we will soon have the draft recommendations from Subcommittee 1 to pass out to all Committee Members.

And I want to thank our moderators, Ms. Kaitlin Keller for Subcommittee 1, and Dr. Robert Boyle for Subcommittee 2.

So if you look at tomorrow's agenda, instead of 8:45 we'll convene our meeting, we'll start promptly at 9:00 a.m. I do encourage you to arrive here earlier, as early as 8:30 if you'd like, but definitely we want to start at 9:00 a.m.

And for your binders, you are welcome to leave them in here in this room. It is locked up at night. Obviously, take your personal belongings with you back to the hotel.

Are there any final questions or comments from the Subcommittees regarding the Subcommittees?

(No audible response.)

MR. PAYNE: Okay, I'm seeing none. And so what we'll do, I think we had one commenter who signed up for the public comment session. I think it's Mr. Tony Corbo. Mr. Corbo?

MR. CORBO: Thanks, Keith. Tony Corbo, Food and Water Watch. First of all, I want to thank the Agency for posing two very interesting questions for the Committee to tackle.

I am not going to comment on the work

of the Committee today. We were one of the signatories of the Safe Food Coalition letter that we submitted in advance.

But I do want to comment on the report that Jane Doherty gave earlier today, both comments and questions.

The reason I want to do that is a couple of weeks ago the Deputy Undersecretary for Food Safety, Alfred Almanza, testified before the House Agriculture Committee and one of the members of the Committee asked Mr. Almanza what was the biggest challenge the Agency faced, and Mr. Almanza's response was "Making sure that the countries that export their meat, poultry, and egg products to the United States maintain their equivalency status."

And so I consider that to be, you know, kind of a significant statement because of the fact that we are importing more of our food.

We have had droughts in parts of the country where livestock herds have been liquidated and it's been a long haul trying to repopulate those livestock herds, so we are importing more of our

meat products, and more countries are asking for equivalency determinations.

So among the comments that I would like to make is that a year ago when Ms. Doherty came to the Committee she indicated that one of her goals was to post equivalency audits in a more timely fashion.

And I have noticed that some equivalency audits that were conducted two years ago still don't have reports posted on the FSIS website, so I would like to know what the status is of her work to try to expedite the posting of those reports.

The January 2013 Federal Register Notice that was mentioned earlier called for a 3-tiered rating scheme to be used to assess countries food safety systems, and that 3-tiered grading system would essentially dictate how frequently FSIS would do onsite audits and the types of port of entry inspections the Agency would do.

In 2015 most of the audit reports that

were posted had those ratings. The rating were adequate and a country that received an adequate rating would receive more frequent onsite audits and there would be a greater scrutiny of their products coming in at the ports of entry that was average, which would be a lesser scrutiny of their products, and then well performing where the Agency would not do audits as frequently, upwards of maybe three years.

Late last year all of a sudden the rating system left, it was dropped, and I would like to know what the Agency intends to do in terms of advising the public how frequently they are going to be doing audits of foreign countries now that the rating system is gone.

I found it interesting that there is a discussion going on on the definition of government inspection, and I'd like to know where that discussion is taking place, which countries that seems to be an issue.

I want to thank Tanya Roberts for raising the issue of Chinese poultry. This has

been a 12-year saga that I have been intimately involved with and I have an issue with the audit that was posted on China for its slaughter system because it almost seems that FSIS is granting equivalency just for a couple of provinces in China and not as a country as a whole.

We're not looking at the whole food safety system of China and the Chinese have already indicated that they are going to certify, you know, certain plants that can export their own poultry to the United States.

I find this, you know, kind of intriguing because I have always been told that whenever FSIS does an equivalency determination it is evaluating the country's entire food safety system and now it seems that in China's case we are segmenting that.

I also found it ironic that three days after FSIS posted its audit reports for China there was a story that appeared in an international food press, a food trade press, that quoted the head of China's FDA lamenting that he cannot keep up with

the number of instances of adulterated food in his country, and the picture that was shown on that article was of poultry.

So if somehow there seems to be a disconnect between what FSIS auditors found in China and what the Chinese food safety officials are reporting.

The concern that I have always had with this issue is that it's a beef for chicken swap. This goes back to the 2003 BSE case here in the United States where China stopped importing our beef and China has been very clear that if they are going to take our beef then we're going to have to accept their poultry, seems to be a quid pro quo.

And it's not lost on me that, for example, Cargill all of a sudden is one of the, are two of the plants, two of their plants in China are going to be designated as being able to export their poultry to the United States, and it would not surprise me that Cargill is going to start exporting beef to China once the equivalency determination is made here for Chinese poultry.

On the issue with catfish, part of the Trans Pacific Partnership negotiations involved a letter that was negotiated between USDA and Vietnam where USDA committed to follow all WTO obligations in the implementation of a new catfish inspection program.

And the USDA committed to Vietnam that it would conduct technical meetings with the Vietnamese officials so that Vietnam could comply with the FSIS food safety regulations.

We have sent a technical team to Vietnam, there were 3-day sessions from what I understand, and then lo and behold on March the 18th Vietnam files a protest letter with the World Trade Organization claiming that the new inspection system is going to be too onerous on Vietnam. I would like to know how the Agency is responding to those concerns.

The international program here at FSIS is critical. As I said earlier we are importing more of our food and I do not want to see our standards being diminished for trade

considerations. Thank you.

MR. PAYNE: Thank you, Mr. Corbo, for your specific questions and comments there. Are there any other folks who would like to make a comment?

(No audible response.)

MR. PAYNE: I am seeing none, so I am now looking to Mr. Philip Derfler to officially close the meeting.

MR. DERFLER: Sure.

MR. PAYNE: And he indicates sure, we are adjourning the meeting. So we'll see each other tomorrow morning. We'll start promptly at 9 o'clock.

(Whereupon, the above-entitled matter went off the record at 4:52 p.m.)

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