UNITED STATES DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE

ON MEAT AND POULTRY INSPECTION MEETING

Washington, D.C.

Tuesday, January 13, 2015

PARTICIPANTS:

Committee Members:

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Consumer Reports

GEORGE WILSON
Wilson and Associates, LLC

KURT BRANDT
United Food and Commercial Workers
International Union

DR. DUSTIN OEDEKOVEN
South Dakota Department of Agriculture

DR. KRZYSZTOF MAZURCZAK
Illinois Department of Agriculture

MICHAEL LINK, JR.
Ohio Department of Agriculture

DR. MANPREET SINGH
Purdue University

DR. RANDALL PHEBUS
Kansas State University

DR. MICHAEL RYBOLT
Hillshire Brands Company

SHERRI JENKINS
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DR. BETSEY BOOREN
North American Meat Institute

DR. ALICE JOHNSON
Butterball, LLC

DR. CAROL LORENZEN
University of Missouri

PARTICIPANTS (CONT'D):

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P R O C E E D I N G S

(8:04 a.m.)

MR. TOBIN: Good morning, everyone. My name is Andrew Tobin. I'm here from our ethics office to conduct your ethics training during a private portion of this meeting and then we'll transition to the public side, and they're the real heavy hitters here to talk to you.

This is sort of just a basic intro, talk a little about the different designations for folks under the ethics rules and all that kind of stuff. If you have questions of me as I go, please just raise your hand, stop me, we can go from there.

A little bit of background about our office, the Office of Ethics services all 100,000 employees at USDA. We handle all 16,000 financial disclosure reports, we have -- we do all our vetting for our 16 Senate confirmed folks, we do a lot of training, a lot of advice, so we sort of have a wide-ranging group.

Our specialists at Services FSIS will be

here soon, but for my background, a practicing attorney, I've been with the USDA for about six and a half years, handle mostly our political staff and our senior career folks and in addition do some of these advisory committee trainings as well, so if you have any questions of me, I'll have my contact information at the end of the slides, but by all means, please, don't hesitate to stop me sort of as we go.

First sort of question -- can you guys see these okay? It's not the ideal set up, I'll talk you through them, but first sort of question is, what is a federal advisory committee? Why are you here? The answer to that is, it's a committee, board, or other similar group, it could be established in one of two ways, it could either be by statute or by the action of the President or any senior agency official, essentially, it can be established one of those two ways.

The purpose is to obtain advice or recommendations on issues or policies within the scope of the Agency's mission. Essentially you're

here because you have valuable insight and expertise that we're looking for, sort of an outside perspective to tell us how our programs are working in the field, what things we can do better, what things are working, what things aren't working. So, you folks are here out of the goodness of your heart to donate your time to us in service of the Department as a whole.

There are about 350 advisory committees USDA-wide, they have sort of a wide variety of issues. Some have been started within the past year, some go back as far as the -- you know, 30 or 40 years. I think this one in particular was started in 1971, so you folks are one of the sort of longest standing advisory committees we have here at the Department.

So, here's the background for why I'm here today. The Government Accountability Office is the Legislative Branch's watchdog group, essentially they do audits, they do investigations of Executive Branch programs, all sorts of programs. Any investigation can be instituted by

a member of Congress. You'll see often those are in the accountability committees, and those folks will sort of institute GAO investigations and that's sort of how we got here today.

Essentially, 2004 the Government Accountability Office did an audit of how Executive Branch programs are running at their advisory committees. What they found was that they weren't doing a good enough job making determinations of status. We'll talk more what that means in a second, but essentially there are three different kinds of categories that folks can be in on advisory committees. It won't make those determinations up front as they were supposed to.

They weren't appropriately applying the ethics rules to those folks once they came on board, and they found that advisory committees were not given a point of contact at the Department if they had any ethics questions. So, essentially they were asked to sort of fly it blind. Basically, there was just sort of a lack of structure, lack of accountability for

Department and Executive Branch programs, and that's why I'm here.

So, essentially there are three possible classifications of the ethics rules. If you serve on an advisory committee, you will fit in one of these three groups, we'll talk about exactly what they mean. The first are full-fledged federal employees, second are representatives of outside groups, and the third category are called Special Government Employees.

First group's relatively straightforward, representatives of outside groups are off there, but a federal employee is relatively straightforward. These are our folks that serve more than 130 days, folks like myself, like Natasha, who are employees of the federal government, we're compensated for our service, we serve more than half the year.

Because we're compensated for our service and we are full-time or part-time federal employees, we are required to abide by a number of different standards, the first are the conflict of

interest standards, these are criminal rules. You'll see them in context, bribery of representation back to the government, of our financial conflict of interest. We have post-employment rules. We have duel compensation rules that say that we can't receive compensation from a source other than our federal positions.

Again, these apply to all federal employees. We're also subject to the standards of ethical conduct, which are a regulatory group of rules that are not criminal in nature but they do apply to all Executive Branch employees. These are the things that cover gifts, attendance at outside events, use of official position, use of official title.

All those sort of things are held under that regulatory regime there, so we have all those different rules as part of why the ethics office exists, is to make sure that our folks are advised properly and they are meeting all their obligations in that regard.

So, the full-time federal employees and

the opposite side of the spectrum are representatives. Our representatives are not federal employees, they're not compensated for their service besides travel and meal expenses. They are here to represent specific interests or outside groups, so essentially when advisory committees are put in place there's a charter that sort of says where the folks will be drawn from. You'll have representatives of particular different issue groups that the Department is interested in hearing from directly. These are our outside interest groups.

They are appointed for the sole purpose of presenting the point of view of the group that they're here to represent, they're usually an outside interest group, a stakeholder group, they come from labor unions, sectors of a particular industry, consumers, basically folks that -- whose full-time position involves being in the effected industry of the Department.

These folks, while they are often experts, you know, have advanced degrees, have a

particular area of expertise, they're not appointed for that purpose on these boards, so have folks -- often our science advisory groups will have folks that are PhDs, that are experts in their particular field, but the reason they're on these advisory committees is to provide a point of view, a biased point of view, not their independent, scientific, or expertise.

Basically, we expect you folks to be biased if you're here as representatives, we want to hear you represent the view of the outside group you're here to represent. So, in this case bias is not a bad thing. The one caveat here as far as identity of these folks, because they come from almost anywhere, what the Obama Administration has said is that these folks that are appointed to advisory committees, representatives cannot be registered lobbyists at the time that they're appointed, which is why you see a lack of lobbyists on these committees, basically because the Obama Administration felt -- you'll see this in the ethics pledge -- that all

political appointees are subject to -- that lobbyists have an outsized role in Washington and one of the main goals of the Administration was to sort of lessen that influence while they were in power here.

So, here why representatives are important to us, essentially they're here to provide an outside perspective that we couldn't get from inside the federal government. We wanted to know how our programs affect participants on the ground, we wanted to eliminate communication barriers that might exist but for the fact that you guys are here in front of us talking to us in Washington. It really does present an opportunity for all our folks to see you face-to-face, hear how our programs are working, you'll have some -- if you look at your agenda, you have some very senior folks talking to you today, which speaks to how important it is to have you here and how important what you have to tell us is.

Like I said, we have a wide variety of advisory committees, they all serve a very

important purpose for us because but for your service, we wouldn't have direct access to sort of what's happening on the ground, with the ultimate goal of helping us improve the products and services that we give to the public, we're here as a result of your tax dollars, want to make sure that those tax dollars, you know, are put into place as best possible -- so that they're used in the best possible way.

So, here's how the ethics rules work for representatives. The goal here is transparency, first and foremost. Representatives are not subject to the conflict of interest rules that I talked about before, those on representation, bribery, conflict of interest. They're also not subject to the standards of ethical conduct, which are the regulatory rules I talked about before, covering gifts, outside employment, things like that.

The reason there is because you're not expected to provide an unbiased opinion, an unbiased service to the government. You're here

to represent the point of view that you've been chosen to represent when you come on board.

That said, these meetings are public -- actually, once this session is over the meetings are public. There are folks in the affected industries that will be interested in hearing what you have to say. They will be closely scrutinizing your participation. So, make sure if there are any particular concerns that you have, that you disclose them to me if you have any questions.

It doesn't come up a lot for you folks because you're sort of working on sort of broad-based policy matters, you're here to provide input, you're not working on particular matters involving specific parties. Those are things like contracts, grants, some of our advisory committees work on those sort of smaller matters, but they're actually handling money and administering those kind of grant programs. In those cases there's a higher potential for conflict of interest because you can see they're actually handling money and

they're going to be giving money out on behalf of the government.

You folks are here to sort of provide us with policy expertise and sort of policy perspectives, therefore that's not a big concern for you folks at all, but be aware of the appearance that your actions have when you're serving here on this advisory board.

Like I said, if you're a representative and you have any concerns, fully and immediately disclose to your designated federal official, which would be Natasha, any potential conflict of interest you see, any concerns you have, we'll be happy to talk you through those if you do have them.

Although it's not required, in some cases we can recommend a recusal or disqualification from a matter that would affect your financial interests or those close to you, you can see how if you're working on a grant matter that affects the interests of your spouse's employer, or if your minor children's stock

interests, business partner, stuff like that, you can see that would be a problem, basically anything where the appearance of your position could call into question your impartiality, those things are problematic, obviously, we want to make sure that the good work you're doing is completely above board and can't be called into question by the folks in the field. So, it's important to us that you let us know.

An example of where we'd recommend disqualification would be let's say a business owner is serving on a committee that was reviewing grants and the employer of her spouse comes forward and submits an actual grant application. You can see that her impartiality in that matter could be called into question and therefore we'd recommend that she recuse herself from taking action on that entirely.

So, those are the first two categories, you have full-fledged federal employees, you have representatives. Third category is sort of a hybrid. These are called Special Government

Employees. These folks are here to provide their independent advice and expertise based on the expert knowledge that they have. They're not here to provide a biased representation of an outside group, they're here to tell us what they think, based on their expert opinion, about the issues that are coming before the advisory committee.

These folks can serve in a number of different contexts. We have hundreds of them across USDA that serve as little as sometimes just a week a year, sometimes a little bit more. They can be compensated by the federal government but they don't necessarily have to. Actually, as a group, these folks came into being during the Kennedy Administration, essentially President Kennedy realized that there was a need to have some sort of outside perspective, it's independent experts that we couldn't hire full-time as federal employees for a number of reasons, whether because they were serving at universities, because the pay wasn't enough, whatever different reason, and the Kennedy Administration essentially created this

hybrid role that would allow folks from the outside to come in and give us their expertise on a part-time basis and the -- so that they could still serve in their full-time roles outside of the government.

These folks are considered to be intermittent employees, meaning they're on duty on the days they serve. They can work no more than 130 days and in that case you're under supervision of a federal employee meaning that their work is reviewed by federal employees, unlike representatives who are here basically to just be a voice of the outside group.

Does anybody have any questions at this point on any of this stuff?

Basic rules for Special Government Employees. What we're concerned about here is the overlap between those two circles where your financial interests or those close to you overlap with your official duties, so the general rule is if a matter comes before the committee that involves your financial interests or the interests

of someone close to you, you should not work on it personally. Relatively straightforward. Same rule exists for our full-time employees.

The important thing to know here is that for Special Government Employees, your interests include not only those of you personally, your personal stock holdings, your personal employer, but those of your spouse and minor children, an employer you have on the outside, or someone you're negotiating for future employment with. So, if you're in sort of the interview stages with an outside organization, the interests of that group are as a Special Government Employee.

Third category is a general partner in a general partnership you may have. And the fourth is the interests of an organization where you are an officer, trustee, or general partner, essentially where you have a fiduciary duty over the outside group, outside organization, say if you're a president of an outside group or nonprofit, the interests of that organization are imputed to you.

So, for SGEs, for you folks we don't have much ethics concerns because when we're talking about particular matters that would trigger a potential recusal or conflict of interest, we're talking about just these sort of narrow issues that could affect a specific party, so essentially we can identify what your work is going to effect. These are sort of the grant proposals I was talking about before, where you can tell who's coming before you asking for a grant, and who would benefit if you gave them that grant. That's what we're talking about, those kind of narrow matters where you can really identify the parties involved and it's not just rulemaking or policy that would affect an entire industry, we're talking about grants and loan applications, talking about contracts, we're talking about litigation, any judicial proceedings before a federal tribunal or administrative law judge, any requests for a ruling or determination, so essentially where you can tell which parties are on both sides. In those cases those are the

things we're worried about, those are the things we would recommend recusal if you had an interest that could be affected by your work in that regard.

So, here's an example: One of the advisory committees that exists in the federal government, in USDA, is the National Urban and Community Forestry Advisory Council, let's call it NUCFAC. This is overseen by the Forest Service. They work on sort of urban forestry projects. If you see parks in urban areas, things like that, a lot of times they are benefitting from NUCFAC grants. Essentially every year they administer about ten grants, I think, there's a number of applications that come into them.

So, they're one of those committees that we're concerned about because oftentimes they're working in the particular arena that they could affect by administering these grants and therefore we make sure they have a full disclosure of sort of whose interests are imputed to them, what stock interest they own personally, so these are the

ones that sort of tend to cause the potential appearance of a conflict of interest, so it's really important that we hit that one.

So, here's an example. Say Jim is a member of that particular council and his wife is the president of City Leaves, Incorporated, which is a group that's going to be submitting a grant for a creative and innovative project program grant, which is one of the grants that NUCFAC administers.

The question is: Can Jim evaluate and score the City Leaves application? And the answer there is obviously no because it involves the interest of his wife's company it would be a direct conflict of interest for him to administer or even to review those grant applications because his wife has a direct stake in it. So, that's relatively straightforward.

Second basic rule, if you work in a matter as a Special Government Employee you are then barred from representing another party back to the federal government on that matter as long

as it exists. So, essentially we're talking about if you deal with a contract, with a grant, with some of those narrow matters I was talking about before, if you deal with those you're essentially prohibited from switching sides on that from going to the party you administered the grant to or gave the grant to and representing back to the federal government in any capacity. So, essentially, you're prohibited from switching sides. It's a pretty narrow prohibition. It also exists for all of our full-time federal employees. Essentially if you work on a contract as a federal employee, you cannot leave the government and then represent that party back to the government on that particular matter.

You're essentially considered to have a conflict of interest there, you have direct knowledge from the government perspective of everything that happened within that matter and therefore you're completely barred from having any contact with the federal government on it once you leave. So, it's one of those rules that applies

both to full-time federal employees and part-time federal employees. It's a criminal rule.

If you ever see anyone sort of indicted for a post-employment violation, it tends to be that kind of thing, they tend to be contracting officers who leave and then try to come back to the government and change the scope with that contract or use their sort of inside knowledge to sweeten the pot for the group that they were working with on the outside.

So, here's sort of a second example. Let's say Jim, the NUCFAC member from the first example, and his fellow council members awarded a one million dollar grant to Arbor Incorporated in 2012. So, they made this award in 2012.

In 2013 or 2014, Arbor's CEO contacts Jim and says, hey, you did some good work on the grant for us while you were on the advisory committee. Could you help us out and contract the Forest Service district rangers to increase the size of our grant? We have some more sort of unseen expenditures we would like to actually add

some more acreage to this deal. Could you contact them, represent our interests?

So, the question is: can Jim do that? The answer in that case is obviously no. He'd be switching sides. He worked on the grant on the advisory committee and then he'd move over to Arbor and represent their interests back. With that particular grant, that's a problem. That's sort of the direct issue that the rule is out there to prohibit. Actually, because he has the inside knowledge that he gained as a member of the advisory council, he can't then use that to benefit a private interest on the outside.

So, that's sort of a relatively narrow scope of a rule, but it's something that does come up occasionally for our folks that work in those kind of matters, either as full-time federal employees or as Special Government Employees.

So, here's sort of the upside of all these rules and the reason why we're here before you start your first meeting in these next couple days. Basically, the Federal Advisory Committee

Act creates committees that are put in place to give us expertise. We need your expertise. We often don't hear directly from our customers, from folks that the policies that we put in place affect. You folks are in a great position to allow us to hear that sort of unvarnished opinion, to hear what you think about what's happening, what you think we could be doing better, how we could help you as members of the public, as members of effected industries.

So, the idea is, we don't want to let the ethical problem -- an ethical problem or even the appearance of one derail the good work you're doing. Essentially, you folks are in public positions, you're here to serve us, you're doing it -- you're sort of volunteering your time to help us when you could be working on the full-time jobs I'm sure you all have and that take a lot of work time.

So, the idea is that we want to make sure that that's not going to derail any of your potential appearance problems here. So, if you

have any questions, please do get in touch with me. We're very easily accessible. There's my phone number, there's my email address. If you need copies of this, I'm happy to send it out afterwards, but if you have any questions at all, if you have sort of just a thought that something that's going on might be a problem, please do get in touch with us. We're happy to talk to you -- talk you through those things. Like I said, you folks are working on such high visibility, high level policy matters that it's not really going to cause any particular conflict of interest concerns from our end, but we're always happy to talk you through things if you see something in your interactions with the federal government in your full- time jobs you have questions about, by all means, please don't hesitate to get in touch with me.

Does anyone have any questions about this right now? Perfect.

Well, then with that, you folks have about a half hour before the real heavy hitters

get here to go grab coffee, use the bathroom, do things like that, but thank you very much for your time, I really do appreciate it. And I hope you guys have a great and fruitful couple days here.

(Applause)

(Recess)

MR. PAYNE: Good morning. My name is Keith Payne. I'm the Deputy Director of the Outreach and Partnership Division within the Office of Outreach, Employee Education, and Training, and I'd like to welcome everyone here to the National Advisory Committee on Meat and Poultry Inspection, public meeting for today and tomorrow. I'll be the moderator throughout this meeting.

What I'd like to do first -- I saw Mr. Phil Derfler, just acknowledge our Deputy Administrator of FSIS here at the meeting. And one of the first items on the agenda is to turn the meeting over to the National Advisory Committee on Meat and Poultry Inspection chair, Mr. Al Almanza, who is the Deputy Undersecretary

for Food Safety and Acting Administrator of the Food Safety and Inspection Service, for the opening remarks. Mr. Almanza?

MR. ALMANZA: Good morning. You all look a little bit crowded there in the middle. Are you all okay there? Yeah, it's like -- and then they put all men, right, squeeze you all in. If you need to we can probably move one of you so you can have a little bit more room. If you all want to sit over here, that's fine.

No, you're good? Hey, maybe it's so cold outside maybe a little heat there.

So, good morning and thank you all for being here and I want to welcome you all for participation in this committee. I know we have quite a few new faces and I certainly appreciate your interest in our food safety mission and your patience with the application and selection process.

This committee is really a valued think tank to the Agency and to the Department. We rely heavily on your discussions, ideas, and

recommendations, so they do influence Agency decisions, in fact, some of the things we're going to cover with this meeting are a result of prior committees. We do take your recommendations to heart and we listen to them. It's even likely that we will come back to you more than once to consult you for your guidance.

The great thing about this committee is that it is comprised of members with such a wide variety of knowledge, from industry to academia to government, the perspectives that all of you bring to the table are invaluable.

I've been talking to a lot of our employees and our stakeholders about our strategic plan in our Agency and for our vision for the Agency and this committee plays a vital role in that plan.

If you take a look at what we want to accomplish for fiscal year 2015, you will see a direct correlation with the activities of this committee and many of our goals. We want to strengthen our collaboration with our stakeholders

to really modernize our approach to food safety and we want to make sure that we are effectively aligning our mission with emergency risks and trends and using sound science to do so. We're looking at all of you to help hold us accountable for reaching those goals.

There are a couple of new issues we want to present to you, which are both very important to us one of which is also a priority for the Economic Research Service. Those will be discussed at greater detail this morning, but I'm looking forward to hearing your thoughts.

I know a lot of these issues we present to you are complex, they aren't easy to solve, and we know that, that's why we want your help.

Over the next couple days we're going to ask you to consider ways we evaluate and manage chemical hazards in the recently revised and improved National Residue Program. This is a valuable program to us. We want to make sure that we are using it in the best way possible.

We'll also ask you to discuss the FSIS

and ERS cost calculation model. One of the economists is Dr. Hoffman from ERS, she will speak to you about that and answer your questions before you break into subcommittees to deliberate.

I encourage you to be open-minded throughout the presentations you'll hear and the discussions that will follow. Your perspectives are unique and diverse, so I suspect that there will be differences in opinion, but because of those differences I think that there will be even greater reward when common ground is reached. Not only that, but the outcome is much smarter and stronger.

So, thank you again for your time and participation. I wish you all a productive meeting and a healthy dialogue. I'm looking forward to you all's recommendations. I also want to thank all the new members as well as the serving members. I know that getting here is a challenge. We're lucky we're having such great weather, sort of. If you're coming from Colorado, this is really -- this is almost like coming to a

resort area I guess, but I do appreciate the time you take away. I know you all have busy schedules. I know that you all have jobs to do, but this is really important to FSIS and certainly to the Department in moving forward. Mike? Thank you.

(Applause)

MR. PAYNE: Thank you, Mr. Almanza for that opening. Now we'll turn to the charge of -- to the committee and the rules of order to run this meeting. First of all, I would like to introduce the staff from the Outreach and Partnership Division who are either in this room or just outside in the reception area.

Ms. Natasha Williams, Dr. Jane Johnson, Ms. Diane Jones, Mrs. Beatrice Herbert, Mrs. Elaine Hite, Dr. Robert Boyle, Commander Jeff Tarrant, Ms. Stephanie Kane, Ms. Seunghee Nam, and Mr. Dan Puzo, our Director.

In particular I would like to recognize Ms. Natasha Williams and Dr. Jane Johnson for all of their extreme hard work and extraordinary

dedication in pulling things together so that we're able to be here today and tomorrow.

(Applause)

MR. PAYNE: While we're on the topic of staff assistance, I would like to take this time to acknowledge our dear colleague, Sally Fernandez. Ms. Fernandez brought forth a tremendous zeal and passion to her work and to her colleagues within our staff and throughout the agency and to the many outside partners that we work with. The work that she put into this committee -- and this very one here that we have today started with her efforts, abruptly ended with her untimely passing last June, which shocked and saddened us all very deeply.

Would you please join me in recognizing Ms. Sally Fernandez with a moment of silence?

(Moment of silence.)

MR. PAYNE: If any of you have questions or need anything, please ask any of us in the Outreach and Partnership Division for assistance. We do work in this building. We know the lay of

the land. We have access to many resources here. Since most of the committee members are new, this is your first time here, let me cover some items that the other returning members may remember from our last meeting.

There are restrooms located on the first floor here and many of you have found them already. Basically, the quickest one is to my right, go out through these doors and at the end of the hallway you'll see the restrooms, turn around to a sharp left. There is another restroom going out this way through the left side -- by the left side of our exhibit -- model -- and then go down the hall, turn a right and then turn a left.

Also, if we go to my left through these doors by our floor model exhibit, there is a break room area that you'll see. There is an ATM machine, there is a cold drink vending machine as well.

For lunch, we do have a number of eating establishments in the area. For each of the committee members, in your binder there is a

listing of these eateries in the area, so if you have any questions, again, please ask any of us.

Now for an introduction of the Committee members and the ex officio members of Committee. For the members around the table here, when you introduce yourself and later during the meeting when you speak, please press the button at the base of your microphone so that the red light is on and that means your microphone is engaged and then when you're done, please press the button again to turn it off.

So, let's start with the introductions starting to my left here around the table with Mr. Almanza, state your name and organization for the record.

MR. ALMANZA: Al Almanza, Deputy Undersecretary for Food Safety.

DR. JOHNSON: Alice Johnson, Senior VP for Food Safety and Animal Care for Butterball, LLC.

DR. BOOREN: Betsy Booren, Vice President of Scientific Affairs, North American

Meat Institute.

MS. JENKINS: Sherri Jenkins, head of technical services with JBS USA in Greeley, Colorado.

DR. CURTIS: Pat Curtis, Director of the Auburn University Food Systems Institute.

MR. SAPP: Brian Sapp, Director of Operations, White Oak Pastures in Bluffton, Georgia.

MR. WILSON: George Wilson, Wilson & Associates, Food Safety consultant.

DR. CRUPAIN: Michael Crupain, Associate Director of Consumer Safety and Sustainability at Consumer Reports.

DR. MAZURCZAK: Kris Mazurczak, Illinois Department of Agriculture, State Director for Meat Inspection Program.

MR. LINK: Michael Link, Assistant Chief with the Division of Meat Inspection at the Ohio Department of Agriculture.

DR. SINGH: Manpreet Singh, Associate Professor of Food Safety at Purdue Food Science.

DR. MARCY: John Marcy, Professor and Poultry Processing Specialist, University of Arkansas.

MR. BRANDT: Kurt Brandt, Assistant to the Director of Packing, Manufacturing, and Food Processing of Poultry of the United Food and Commercial Workers International Union.

DR. RYBOLT: Michael Rybolt, Director of Food Safety and Quality, Hillshire Brand/Tyson Foods.

DR. LORENZEN: Carol Lorenzen, Professor of Meat Science, University of Missouri.

DR. OEDEKOVEN: Good morning. Dustin Oedekoven, South Dakota Animal Industry Board and the State Veterinarian and the Director of the South Dakota Meat Inspection Program.

DR. PHEBUS: Randy Phebus, Professor of Food Safety at Kansas State University.

MR. WALDROP: Chris Waldrop, Director of Food Policy at Consumer Federation of America.

MR. PAYNE: Thank you. And now for the ex officio members of the Committee, we have

invited Dr. Margaret Pappaioano from the U.S. Centers for Disease Control and Prevention. I see that she may not be here -- there she is -- she's raising her hand. We have a seat for you up here, Dr. Pappaioano. She's also CDC's Liaison to the Food and Drug Administration Center for Food Safety and Applied Nutrition.

And speaking of the FDA, we also extended an invite to our ex officio member from the FDA, but I look over, we don't have anyone who has arrived just yet.

And then we have representatives from employee organizations who I would like to recognize here: Dr. Danah Vetter, who is representing the National Association of Federal Veterinarians, Mr. Justin Rhee, representing the Asian-Pacific American Network in Agriculture. I don't think Mr. Rhee has arrived just yet. Mr. Peter Bridgeman representing the Association of Technical and Supervisory Professionals, and I don't see Mr. Bridgeman here yet. And then finally, Mr. Stanley Painter was invited to

represent the National Joint Council of Food Inspection Locals for this meeting, however, unfortunately, he's not able to be here due to a scheduling conflict with another meeting.

So, just a couple more housekeeping measures. Cell phones, please check that you've either put them on mute or turned them off so that we don't have any unnecessary disturbances during the meeting, and then if I may circle back around to the microphones and uses of them, as a reminder, please always use that button before you speak into them, to engage and state your name and organization every time you speak. I know it may become redundant, but the reason why we do that is so we have it for the official record. Mark Mahoney over here with Anderson Reporting, it helps him out to keep track of the dialogue and it will make things much easier in the long run.

So, we have an orderly flow of discussion, for the committee members, when you want to make a comment or raise a question, what we ask for you is to set your tent card up on the

table. I'll keep track of who has set their tent card in the order and call upon you in the order that you read your tent card, and once you speak, you can put it back down.

And then for anyone in the public who would like to make a comment, we do have a sign in sheet at the registration desk out front. If you'd like to make a comment during the comment period of the meeting, please write your name down on that sheet and we'll call upon you in the order in which we have the names.

All right, that's it for all the housekeeping measures and now I would like to move on to the next portion of our meeting and introduce Mr. Michael Watts, Assistant Administrator for the Office of Outreach, Employee Education, and Training, to kick off our next item on the agenda, and that is the panel updates. Mr. Watts?

MR. WATTS: Good morning, everyone. I am Michael Watts, Assistant Administrator for the Office of Outreach, Employee Education, and

Training. As Mr. Almanza has mentioned, we started with a panel update to provide updates on previous topics as well as to address topics and emerging issues.

We'll begin with four updates and then have a question and answer period following that and then we'll have a brief update on emerging issues followed again by questions at that time.

We'll begin our update with Mr. Jeremy Todd Reed who will provide us an update on FSIS establishment.

MR. REED: Thanks and welcome, everybody. All right, so I'm going to give a little background as we go through the slides just because a lot of people are new, I think, on this.

So, this is about the FSIS draft establishment specific data release strategic plan. So, there's been -- I'm not going to read all of the policy documents here that we've got on this slide, but I guess what I would say is that there's been a lot of information coming out from the Administration trying to push transparency in

our government agencies and wanting us to share data, and so we've kind of been working on this project for a long time.

I know for me, I've been here several times before the committee, and for those of you that have been tracking along with is, it seems like it's the project that keeps going, but I'm pretty excited because it seems like we're getting near a point where we're going to start seeing some results.

Before I go on, I guess, we should talk about what we mean by establishment specific data. It really is two key factors, first of all, it's data FSIS generates, so it's data that we generate ourselves, it's not data that we get from another agency or data that we get from the establishment, it's our data. And the second thing is, is that it's data that bears specifically on the establishments. So, it's data that really would reference individual establishments and be specific.

So, this is an update. I guess I would

say we started in 2010 when we actually had our first presentation here within NACMPI, and we talked about it and the committee came back and said, this seems like a great idea, but it's not really in our wheelhouse. We recommend that you go and get someone else to look at it that has a little more expertise and a little more time.

Following that advice we went to the National Research Council with the National Academies and they actually set up a committee and the committee spent a long time thinking about this, talking about this, gathering information. They issued a report. The report advised us to follow ahead. The name or the actual title was "The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment Specific Data" and the report very much recommended us going forward, but it had a couple of key things that it thought we should think about when we do it.

First of all, they said that it could yield valuable insights, that sharing this data,

making it available, could be used for a lot of things beyond the regulatory uses. The committee did look at side effects, both positive and negative, and the committee felt that there was not enough evidence of adverse effects that would prohibit us from doing this, but they did say that before we went forward, they really would like us to come up with a very thought out plan and vet that plan so that as we go forward, we really minimize the risks and we have a good idea of what we're doing.

So, what did we do? So, after we got our report from the committee, the next year we came back here to this committee, to NACMPI, and we talked about what we found, we had a draft plan, we got comments on that plan. Since last year we've then made revisions to our plan based on those comments, we've drafted a Federal Register notice. I am happy to announce -- and if you receive our constituent update, you probably saw -- the draft plan is available on our website now and actually kind of an advance copy of the

Federal Register notice is available on our website. So, we're like right at the very last stages of getting that out and pushing forward, which I think is great.

And then another thing that we did in the report is we talked about which data sets we're going to release, again, based on information and feedback from this committee we started with the E.coli and the ready-to-eat testing data is where we intend to start, you know, based on feedback from the report because the committee concluded that those were adulterants and it was easier to understand what that data was. And we're also going to start with a data set of kind of demographic data about all the establishments so that you can place the establishments in context and the sampling data in context.

We do plan to release the data sets one at a time and we plan to get feedback and we plan to really watch what happens and make adjustments on the fly if we need to. So, it's really an

intent to do it kind of like a slow deliberate process so that we don't make mistakes but we want to follow the plan.

And then I guess the last thing I would like to say, because I covered part of this before, is that as we release data sets we're going to use constituent updates to say which data set is coming out and we did already start to publish some data in the last year, we've started publishing more aggregated data that's available, so either on data.gov and from our website.

And that's it.

MR. WATTS: Thank you, Mr. Reed. We're going to go back now -- and unfortunately, Ms. Malagon is not able to be here this morning -- yes, she's here. Okay, we'll proceed with her update on the safe food handling labels.

MS. MALAGON: Thank you. Good morning. I'm Maria Malagon. I'm the Director for Food Safety Education at the Office of Public Affairs and Consumer Education at the FSIS. This morning I will be presenting about our new research on

safe food handling instructions.

As you know, the safe food labels have been around for about 20 years now. Initially, in 1993 we conducted the first focus groups to test consumers in the development of our first safe food handling instructions.

So, basically, back in 2013 we -- the Agency felt, after some informal discussions with the stakeholders, to restart the process to explore new safe handling instructions for our labels. Basically, our first step in these -- in this new phase was to conduct some gathering of information from stakeholders including academia and some organizations that continue to do business with the Agency, asking for their opinions, if we should proceed in changing or exploring to change the safe food handling instructions.

I think everybody agreed with that and then we presented those results to the Committee back in January last year. The Committee agreed with the stakeholders' assessment that we should

move on in exploring changes to the safe food handling instructions and provide more details in our packages including endpoint temperatures.

However, one of the main advice that both the stakeholders and the committee provided the FSIS was the fact that we needed to consult consumers again as we did back in 1993 in terms of what we should do with the safe food handling instructions, what would work for the consumers.

Due to that we decided to enter in a contract. We put an RFP out back in the summer and we started a contract for these purposes on October 1st when the new fiscal year stated with RTI, a firm from Raleigh, North Carolina, which has extensive experience on food safety topics including safe food handling instructions.

This contract has been named the requirements gathering contract and what we are looking is to see what requirements consumers had in terms of safe food handling instructions. Our first step was conducting a strategic planning session with agency leadership to explore the

history of safe handling instructions, issues, concerns, any potential ideas, any ideas that probably would not work in the field and see the opinions of our agency leaders.

The contractor, and actually, my team, we found this discussion very good. It worked in so many ways for us because we understood the history of the issue better and also we got great insight from the Agency.

Right now, we are on step two, and step two is the actual requirement gathering sessions or focus groups. We asked the contractor to conduct six focus groups in three cities. The cities will be selected based on at least three out of the four geography areas in the United States and should have demographics that are representative of the population. In each city they should conduct one focus group in English, one focus group in Spanish, and one of the important things that we are asking is also to take in account not necessarily it will be like that, but at least try to find some consumers that

are representative for our agencies that reach populations which are, as you know, older adults, pregnant women, parents of children under five, and those with low immune system.

And as you know, getting permission from OMB to do focus groups and other kind of research is kind of a difficult and long process. Taking this in account, we have so much urgency to start this process that the contractor on my team started the OMB package back in October, no matter that we were supposedly in our process to wait until the strategic planning session, but that would have taken too much.

So, we started the package back in October and then we included information after the strategic planning session in November and we had the package ready last month. Currently it's under the OMB process, which includes the Federal Registry Notice. I expect this Federal Registry Notice to go out in the next couple of weeks and hopefully we will be on the short side of the OMB process, hopefully it will be quickly, and we will

get clearance, I expect, in early spring, no later than late spring. So, we should have the results from these focus groups in early summer.

After that we will do a recommendations report. The report will include the results from step one and step two, and if, for example, if by any chance the focus groups show that consumers are interested in seeing changes in the label, which we expect that that will be the case, the report also will have a cost/benefit analysis.

Pretty much the next steps will be for us to receive that report at the end of the fiscal year and we plan to share that report with the public, including the Committee. Also, we will be working on another contract because as we expect that changes will be required for the safe food handling label, we are planning to engage in another contract to start the redesign of the label early in fiscal year 16, so pretty much we will see the FSIS proposing new revisions to the label by next fiscal year.

I hope to continue updating the

Committee on this issue and I am open to any questions.

MR. WATTS: Again, we'll save the questions until the end of the updates. We're very pleased to have Ms. Jane Doherty, our International Coordination Executive who can provide an update at this time on the International Program Status.

MS. DOHERTY: Thank you very much. And good morning to all of you. It is a pleasure to be here with you to talk to you about our international programs here at FSIS. Like many of you, I am new to the Food Safety and Inspection Service, but I have worked with the Food Safety and Inspection Service for many years in my old capacity, so I'll talk about that in a minute, but our office is new.

The Office of International Coordination was created in May of 2014 and the purpose of our office is to represent FSIS abroad and to talk to our foreign government representatives, our counterparts in foreign agencies, to make sure

that they understand our rules and regulations and what is required in order to export to the United States and also my job is also to coordinate amongst the programs within FSIS to make sure that the respective offices are working together and talking to each other and addressing international issues based on the requests that we receive.

But as many of you know, there was a former Office of International Affairs. That office has been realigned so that each part is now matched with its fitting domestic program area. My office makes sure that the international components of equivalence and audits, exports, imports and field operations, are working with their domestic counterpart to mirror those policies, but that we're working together also on the international front to represent FSIS policies and regulations to our foreign partners and also other agencies within the United States as well.

As I said, I'm new to FSIS, but I'm not new to what FSIS has done and how it is received and respected throughout the world for its

programs. Formerly, I worked as the Canitary and Phytosanitary Director at the Office of the U.S. Trade Representative and I had the privilege of representing and working with seven food safety agencies in the United States. My job was to negotiate the free trade agreements with the other countries but always remembering to represent the U.S. food safety system and to make sure that what we negotiated ensured that our rules and regulations would be respected abroad as well as here in the United States.

Prior to joining USTR, I worked for the administrator of the Environmental Protection Agency. I was her special advisor on pesticides and worked on the implementation of the Food Quality Protection Act.

I have a strong regulatory background. I do understand the trade side as well and I'm delighted to be back at one of the strongest regulatory agencies that we have in the United States and to represent them abroad. So, it's a privilege to be here and I know from the

leadership of our office here that international activities are very, very important and it's important that we handle these issues quickly, efficiently, and in a friendly and transparent process as possible.

So, you are very, very important to that and the recommendations that you have made through the years to this part of FSIS is taken very seriously, even though the PowerPoint presentation won't tell you so, but there were three basic questions that you -- I'm going to keep going if that's all right -- there are three basic questions that you all -- we went to you and asked for guidance for back in 2008. The first question is: Should the Agency's three- part approach to an equivalence determination be changed? As you know, there's a concept known as equivalence that is part of the WTO Sanitary and Phytosanitary Agreement and it has been incorporated after 1995 when the WTO went into effect, it was incorporated into our laws and regulations.

And what that concept means is that for

a country to export to the United States they have to meet our levels of protection. So, it doesn't have to be exactly the same, but they have to meet, through their programs, through their regulatory systems, they have to meet our levels of protection.

So, we went to you and we said, what we do now in order to make those determinations is we do a document analysis, we look at their laws and regulations, we look at -- when we conduct onsite audits, we look at their facilities, and then we also look at, when we do re- inspections at the ports, are they complying with those rules and regulations, so there's a three-part approach that we've always considered, and we asked you was that sufficient or should we be looking at other things.

That was the first question. The second question we asked you was: Should regulatory information and compliance history of the foreign countries affect how often we do audits and re-inspection activities at the port? That was

another important question that we asked you to consider. And the third question is: Should the scope and frequency of our audits and our inspections be adjusted based on the capability of that country to comply with our regulatory information and should we be sharing information about our rules and regulations as they change as well?

So, those are the questions that we posed to you back in 2008. And your recommendations were as follows: A, yes, we should maintain that three-part approach to equivalence. It's important to do document reviews. It's very important to be onsite and have our auditors go through those facilities and establishments and make sure that what we've received through the documents are actually being implemented. And, yes, it is very important to inspect and to keep track of the violations, if there are any, at port of entries and to conduct our inspections.

Your second recommendation to us was

that we should be looking at using our resources wisely and focus them on relative risks and the historic compliance of our partners to make sure that those food safety systems truly are meeting our requirements.

And then also when we were collecting information, a recommendation from you was to use our self-reporting tool, which is a questionnaire that I'll go into a little more detail to explain, it's how we conduct the initial inquiry with the country about their laws and regulations.

FSIS took those recommendations and has been working towards implementation of those recommendations since 2009. We continue to rely on the document review. We use our document analysis, our onsite audits, and our port of entry re-inspections to ensure that those countries are meeting our regulatory standards and our levels of protection.

On recommendation two, we determined the scope and frequency of our onsite systems audits and our POE re- inspections through analysis of

the results of our document reviews and to assess how the country is performing.

This is a performance-based approach that you asked us to look at and to implement. It directs our resources to the foreign country's regulatory systems that pose the most significant risks to health compared to others. It makes sure that our international programs are consistent with our domestic programs. And it improves the linkage between the violations in the port of entry re- inspections and the onsite audits. So, it has helped us to more effectively prevent unsafe imports from reaching into our country.

And on recommendation three, we developed the self-reporting tool, which we refer to in FSIS as the SRT. It is designed to help countries to provide detailed information. A country, first of all, in order to have an equivalence determination from FSIS, has to send a letter to us. We, in turn, send them the SRT, which is a series of questions where we ask them to explain their regulatory system, how is it

built, what are the laws and regulations that are in your system, how do they implement their programs, what type of government oversight do they have, what kind of HACCP plans do they have. It's a series of questions and its how we keep, if you will, a repository of information about that country's infrastructure.

And so we're just not going to have a PowerPoint presentation today, folks, but I'm just going to continue to talk to you if that's okay.

So, we have been working on the SRT and trying to improve the SRT since it was created. We conduct this information annually to look at what we are doing and make sure that those countries are continuing to improve as we improve on our standards here at FSIS. And we have been working towards implementation of a number of international programs that are based on your recommendations and I want to talk to you now about the next steps that we're doing.

So, for the past year what we have been focusing a lot of our energy on improving our

international programs is primarily in the area of directives to make sure that everyone understands what's required under international program and to make sure that we're building the best self-reporting tool possible.

When I came to FSIS, I was surprised, to be honest with you, about how much focus they are doing on improvement. FSIS -- and I'm not saying this because my boss is here -- but FSIS truly is one of the most respected regulatory agencies in the world and these equivalence programs are used as a model at the WTO and for other countries to implement, so I was surprised that the focus -- but knowing that my administration now, I'm not surprised, there's always room for improvement, we're always looking to be better, and so that's why your recommendations have been so important to the program, but there's been a focus on, yeah, we have a good program, but we can be better and we can be stronger and more effective. So, what is it that we need to do next to continue to be a strong program?

So, we've been putting out directives on our initial equivalence, which is the first determination when a country makes a request, they fill out the self-reporting tool, we conduct audits, we inspect their products, we make a determination that that country has met our level of protection. There's an initial equivalence program and we lay out for our staff and for the public, what are the requirements that you have to meet in order to have an initial equivalence determination, but once you have an initial equivalence determination, it doesn't stop there. Your program evolves overseas, our program evolved. How are they making sure that they're meeting and continuing to improve as we are at FSIS on public safety and food safety?

So, on our ongoing equivalence program, we also have a number of requirements that have to be met and directives that are being published for our staff and for the public explaining the components of the ongoing equivalence program.

We're also putting out a number of

documents on international audits, what is required, what the inspectors are going to be looking for, our auditors are going to be looking for, and our imports and exports programs, what are the requirements. So, we have a number of directives on the import and export side as well.

We're going to be putting out directives on granting and refusing inspections, what are the requirements, what are the criteria that we're expecting to be met, the importation of undenatured inedible meet and egg products, import re-inspection issues. And on exports we're looking at directives to put out on our export library, what needs to go into that library on recalled products and how an establishment applies for an application for export.

So, there's a number of clear directives that are coming through on guidance and we're trying to be as transparent as possible. The focus this past year is on making our program transparent, so people know what to expect, they know our standards, and they know what they have

to do to meet them.

So, there's been a major focus on that. Next month, we will be publishing a response to a January 2013 Federal Register Notice that we put out in 2013 to talk about our program. Again, always trying to improve our programs. We sent out -- we asked the public, how do we improve our equivalence determinations in our programs, and we received a number of very, very good comments about that. We'll be responding to those comments next month in our February notice, but lucky for you, you get a sneak preview today, and there are two areas in particular where we found that we needed to make some improvements on our self-reporting tool.

So, what we will be announcing next month is -- two recommendations on -- and two things that we're doing to implement and to maintain our document review process and to improve it, first of all, we've been sending out the self- reporting tool as a Microsoft Word document but that takes time, it's very

cumbersome, and it requires a lot of our time and effort trying to input that data.

So, what we're doing instead is going to have a web-based SRT program within our PHIS system, our Public Health Information System. That's going to help us capture that information on the Foreign Food Safety System. It's going to help us to link documents -- supporting documents from that country to look at their laws and regulations immediately. It will decrease the amount of time it takes us to make a determination and we'll make sure that information is updated on a regular basis by that country, and it will also ensure that we have a secure exchange of information with our partners on a real time basis every day.

There will be fewer and more targeted questions in the SRT. We have heard from a number of countries, my gosh, I had no idea how detailed and how complex it is to obtain an equivalence determination from the United States. We don't apologize for that. Our standards are high and

they have to meet them, but we do realize that we could target our questions and focus them to make it easier.

One thing that is new is that we also have an introduction of a level of advancement questions. That helps us to go back to that performance-based recommendation that you all made to us and countries are going to be evaluated based on whether or not they are able to meet higher standards than just the basic requirements. And there are three categories that we're looking at and as you recommended to us, if those countries are meeting advanced levels of protection that they may not have to be audited as often or we will conduct our inspections, but we won't have to audit as often.

So, if a country is a well-performing country, they'll be audited every three years. If a country is doing an average job, they will be audited every two years. And everyone who is not meeting or just basically meeting our standards will be audited every year. Right now most

countries are being audited every year. We're just not comfortable that anyone has met those higher criteria. It'll be interesting to see when we have these level of advancement questions and the responses that we receive if, in fact, countries are able to move up and we will not have to audit as often as we have to do right now.

But right now we are requiring that they will respond to us on an annual basis at the very least. On May 15th of every year they are expected to send that information back to us.

So, there's a lot going on. The focus has been on transparency and continuous improvement. We're trying very hard to make sure that the recommendations you've made are taken seriously. We understand here at FSIS, and I know from my own background, that strong regulatory programs are critical to global food safety. Your recommendations have been implemented and are at the very heart of FSIS's international programs, and I have to say that I really do complement the leadership at FSIS because they understand that

international is just not a boutique program, it is very, very much a part of our everyday food safety concerns. More and more of our food is being imported into the United States and we need to make sure that food is coming in as safe and meeting our standards.

So, we're spending a lot of time on outreach with other countries, explaining to them our rules and regulations. That's why my office was created, to work with these other countries, make sure they understand and that they're working with our technical experts to implement programs in their own countries where they're meeting similar standards to ours to meet our levels of protection.

We're going to continue to improve our programs. We're going to continue to open those lines of communication, but it is very important that we hold our international partners to the same high standards that you expect from us at FSIS.

So, thank you very much. I'm glad to be

here and I'm very happy to be a part of the FSIS team. Thanks.

(Applause)

MS. WILLIAMS: I just want to interrupt really quickly. We tried to be cutting edge and have the presentation on a network so that people around the nation could see it and the network is not working with us, so we're going to turn it off. Just give us about, I would say a minute or two, to adjust the presentation so that everyone can see it in the room and we'll start our panel again at that time.

(Recess)

MS. WILLIAMS: Thank you again for your patience with the brief interruption. We will begin our presentation at this time.

MR. WATTS: Thank you. We're back in session and on the record and we're very pleased to have, for the Public Health Regulation update, Mr. Chris Alvares, Director of the Data Analysis Integration Staff.

MR. ALVARES: Good morning, everyone.

So, I'm going to be talking today and give you guys an update on our Public Health Regulations. We've actually been to the National Advisory Committee on a couple of occasions and so I'm going to start with a little bit of background just to kind of recap what issues we brought to the Committee in the past, give you an overview of what we've implemented with our FY '13 and '14 Public Health Regulations, give you an update as well on the work we've been doing over the past year to revise that and roll out our FY 2015 Public Health Regs, and then finally talk a little bit more about some other recommendations from the committee about communications. We have a new report out related to the Public Health Regs that's available in PHIS, and then kind of wrap up with some future work and additional things that we continue to look at.

But one thing I do want to try to emphasize, and I think you'll see throughout the talk, is that this is an iterative process. We've gotten a lot of very good feedback from the

Committee over the years. We're taking that to heart and we're working through incorporating that feedback as we go through the process.

We still have work to do and I think you'll see that in some of our future work under consideration, but hopefully you'll also see that we've been able to take some significant steps forward based on the feedback we've gotten.

So, to start, back in 2008, FSIS implemented what we call a set of decision criteria, Public Health Decision Criteria. We brought that concept to NACMPI in 2008. NACMPI reviewed it, gave us a lot of really good feedback. We also, similar to what we did with publishing or moving forward with the FSIS posting establishment level data, we also requested a review by the National Academies and they gave us a report in 2009.

Based on that feedback we moved forward with this set of decision criteria and published -- and really implemented in 2010.

What we published on our website is a

Public Health Decision Criteria report, and the link is here, but it provides just a general -- well, a pretty specific kind of an overview of the decision criteria, how we're implementing them and kind of what our concepts were at the time.

I will say that there are seven decision criteria and those seven are listed here. The decision criteria all are being used to prioritize and schedule food safety assessments within FSIS. These are really in depth assessments at establishments. Some of the times of -- we have a couple different types of FSAs. Some of them are just routinely scheduled and we have other ones that are done more for cause.

The ones you see -- the criteria that you see here are ones that would trigger a "for cause" FSAs. We're seeing events or we're seeing trends that cause concern at the establishment and one of the steps that we take is to send an EIAO to go do an FSA at that plant to really take a closer look at the food safety system.

You can see a lot of these criteria are

related to pathogen positives, salmonella category, food safety recalls, links to illnesses or suppliers to the E.coli positives, but the third one on this list is the one that I'll talk much more in depth in the coming slides.

This is our Public Health Regulation Criterion. It's really different than the other ones that you see on the list because it's the one criterion here that's based on inspection data. It uses the inspection tasks that our workforce is doing and documenting in PHIS every day at plants, it looks at the noncompliance of those, particularly with the implementation of PHIS we're able to look at the regulations that inspectors are verifying when they do these tasks, so when they go to a slaughter plant and they're doing a sanitation task or a slaughter task, they can very specifically check off what regulations they're verifying when they do those tasks. You know, we're using that regulatory verification data from PHIS to drive this PHR Criterion.

So, more specifically on the PHR

Criterion, we have a process -- basically a four-step process. This was part of a process that we brought to NACMPI in early 2013 and just to kind of give a very high-level recap, we have sort of a four-step process.

We went through the regulations that inspectors can verify through inspection activities and we defined a set of what we call candidate regulations. These are regulations that, based on our Agency's subject matter knowledge, our understanding of non-compliances associated with these regulations, they represent the set of regs that have the potential for -- noncompliance in these regs has the potential for identifying a food safety -- issue of food safety concern.

So, these aren't the final list, but this is a candidate set of regs that we kind of preselected to say, these regs have the potential, when they're noncompliant, to have adverse -- or set the stage for some adverse outcomes such as pathogen positives or illnesses.

We then went through -- actually, I guess maybe I'm actually talking about the second step on this process. The way that we select those criteria is what I have in this first box and we have basically four criterion related to how we made that selection process. I don't have the criterion listed here but we do have a report on our website that defines them, but essentially, is noncompliance likely to create insanitary conditions, is it likely to be indicative of loss of process control, those sorts of criterion were used to evaluate the regulations and select that candidate set to start with.

Then in this third box that I have here, we have sort of an analysis step where we're taking this candidate set of regulations, we're analyzing the data, the noncompliances, and we're comparing it to the set of outcomes that we see nationwide. So, we're looking at things like when we first implemented this for our FY '13/'14 list, our criteria -- our PHR Criterion, we looked at salmonella positives, we looked at E.coli

positives, and we looked at LM positives across the whole kind of landscape of establishments and really looked at, are these regulations more likely to have higher noncompliances in the group of establishments that have pathogen positives than in the group of establishments that don't. So, we're really looking at sort of an indicator of potential outcomes here.

And more specifically, we look at the noncompliances in the 90 days prior to that positive, so we're trying to really look at what's going on in the plant in the time period leading up to these positive events.

And then, finally, once we've used that data analysis to narrow down the candidate list to really a final list to use in the criterion, we have to develop cut points, and we use those cut points as we implement this PHR Criterion. The way that essentially works is that we go and we apply the use of these regs, we analyze each plant individually on a month-by-month basis, we compare it to a threshold, a cut point, if you will, and

if the plant exceeds that cut point, then they're prioritized on a list for FSAs and that's sent out to the districts to plan their FSA scheduling activity.

So, as I mentioned, we've been going through a couple of iterations. We did present this particular approach to the PHR Criterion to NACMPI in January of 2013. We did get a lot of very good feedback from the Advisory Committee through their report. For example, they suggested that as we move forward with this we continue to look at additional pathogens. At the time that we moved forward with the first iteration, we didn't have a whole lot of nano 157 data, we didn't really have much campy data and so we couldn't incorporate those into our first version. But that's something that we were looking to add and looking forward to with future analyses, future iterations.

We also got advice from the Committee to look for other outcomes besides just pathogen outcomes, and so we've been able to do that this

year and I can update the group on that work.

And then there's some additional recommendations that the committee also advised us on, one was to continue to kind of strengthen that feedback loop, to continue to evaluate this criterion annually, to make updates as needed, to let the data inform the list that's being used, and so that's part of what we've incorporated in the FY '15 iteration.

And then finally I'll talk at the very end about communications. Communication was a big discussion topic at the January 2013 meeting and we've taken some steps this year to increase our communication to the field, increase our -- the information transparency to the establishments as well.

So, going into the details of the criterion, I do want to just kind of reiterate that the methodology hasn't fundamentally changed from our original proposal and our original approach that we brought to the advisory committee in 2013. We have made some changes. We did, in

looking at our candidate regs this past year, we did add 14 new regs to the candidate list. This was partly because of changes to or additions to what was being verified. I asked that we had some additional regs that could be considered.

We did -- as I mentioned, we did incorporate and look at outcomes related to nano 157 positives and to campy. So, those were added to the outcome analysis to narrow down that candidate list. And then finally we added enforcement actions, and in particular, NOIES. These are Notices of Intended Enforcement and Suspensions. These outcomes were also added to the analysis of regulations for FY '15.

I think this looks the same so I'm going to skip slide 41. So, what happened with FY '15? Just to give a very high-level recap, we did come up with a new list for FY '15. It has 48 regulations on it. This is an increase from the 33 regulations that were part of the FY '13, FY '14 list. Twenty-one regulations were added this year. All of the ones from the original version,

27 carried over -- 27 of the 33 carried over and so that's roughly 80 percent of the original list is still on the list for FY '15, but you can see there are a significant number of new regulations added.

A big part of that is because we added some new -- we added new outcomes and I think enforcement actions in particular added a lot more regulations to the data analysis part of the step, and so we do have more regulations. That's not unusual. That's not surprising. It's also not surprising to us that some regulations from the prior year dropped off. So, you can see even though 27 out of 33 carried over, that means that six regulations were dropped with the FY '15 iteration.

This was expected. We knew that as we go through this process, some regulations would get added, some would get dropped. This is really -- FY '15 is really our second iteration of this process. We do expect to see this stabilize as we go through further years of analysis and that's

something that we'll be looking at is whether this is stabilizing or whether this level of variability continues. That's something we'll be monitoring, but we do see, I think, some very good progress here.

So, I mentioned some of these changes and I think it kind of bears the question as to what's -- you know, what's really changed in those regulations. I tried to provide a very high-level synopsis here on this slide. I'm going to start with the bottom. We did drop six regulations from last year and I've listed them specifically here, two of them are related to SRMs, one related to removal of U.S. Reject tags, contaminated carcasses is one.

We also went through and looked at the 21 regulations that we added in FY '15. Clearly, these aren't the exact same regulations, but one thing that we did notice was some common themes. So, although the regulations might be changing in terms of the specific paragraph or subparagraph that we're considering this year, we do see

similarities in terms of the subject area of the regulations. So, contamination of carcasses is still -- there are still regulations related to that. There are still regulations related to U.S. Retain tags. There are still regulations related to SRM, so although we're seeing changes at the regulatory level, we are also seeing some level of consistency at sort of the higher level, the themes related to these regulations, and we think that that's an interesting observation this year.

In terms of the cut points themselves, once we've identified these regs, these 48 for FY '15, as we've talked about it at prior NACMPI meetings, our process is to, each month, evaluate establishments against these 48 regulations, calculate a noncompliance rate for each plant and then compare that plant to an overall cut point. The cut point is really derived according to sort of the distribution of noncompliances from similarly or like establishments, peers if you will.

The first version in FY 2013 and 2014

defined three categories of peers or operation types. We had a slaughter category, a processing category, and a combination. These were plants that were doing both slaughter and processing. I mean, you can see the cut points in this second column here of noncompliance that we used.

One change that we made in FY '15 was to combine the slaughter category with the combination. Part of the reason for that was the slaughter category is a much smaller group of establishments than the other two categories. It really was small enough to the point where we thought it just didn't make sense to define it as a separate group and so we've combined it with the combination group for FY '15.

We've looked at outcomes, we've assessed how that might impact establishments that are being selected. We think the impact is very small and so we think we're pretty comfortable with that change.

I will say that one of the recommendations from the advisory committee was to

look at other ways to define peers versus simply operation type. That is still on our to-do list, that is still something we want to consider, but we do see data that really supports that these are distinct groups and that we really should define cut points by operation types, but we continue to consider this an area of further exploration and further analysis.

In terms of communications, this was another big recommendation from the Advisory Committee, particularly communications to the establishments, industry really, in order for them to really respond to this and as part of what we want to see happen, they need to know what these regulations are, how they're being -- what kind of the level of verification is, they need to have information that allows them to see at the regulatory verification level what's going on in their plants in terms of inspection.

We also got very good feedback that we need to get this information in the hands of the inspectors as well. Our first line in the plants,

the supervisors, the district offices, to help them understand when this is coming up on a monthly basis as a plant that's been selected for an FSA, what's the data behind that, what are the noncompliances that are being counted, what are the regulations, even PHR related or maybe even not, but what are the regulations that were most noncompliant in that plant, and so we've taken some good steps to do that.

I mean, I'm really getting to the last point on here, but PHIS reports, we've developed two reports, one for industry, one for our federal workforce. They're essentially -- they're really the same report but we've had to implement two separate reports just the way that we designed or deploy reports in PHIS, but they have the same content in them and I'll show you an example coming up.

We also have been issuing notices each year. We just issued our notice on the FY '15 criterion -- our public health regulations. That has instructions to EIAOs, it has instructions

about meeting with plants to inform them that the regulations have been updated, how can they find information. We have a bunch of information on our website. When we updated with FY '15, we posted a new analysis report on our FSIS website. We've also posted the list of regs. We have both the FY '13/'14 list as well as the FY '15 list on our website now, and we have the cut points also posted.

So, our website has some good reference information for people who just want to gather information about what regs are part of this PHR Criterion, how are the cut points being evaluated, but the PHIS reports really are for the inspectors and for the establishments to be able to see what's going on in individual plants.

So, this next slide I know is probably hard to see and very small and to protect the innocent, I've had to block out some of the blocks here, but you can see the general layout of the report.

This is an example in a screenshot from

a PHIS report. There's a -- besides the kind of introductory information about what plant this report was run for and what time period, you have information about what PHR regs are being verified, how many were found noncompliant, what establishment -- what operation type this is, so that defines what category they're being evaluated against for cut points. We calculate the noncompliance rate for that time period. We present the cut point that they're being compared against. And then there's sort of a status determination, essentially whether they've exceeded that cut point or not.

And then we have another page on the report that can go -- it basically has a list of all of the noncompliances that are cited in that first table of PHRs that were noncompliant, so inspectors, EIAOs, district managers can go and poll this report, look at the actual noncompliances, make some further determinations about maybe when they go in to do the FSA, where do they need to focus attention or they may even

make a determination that based on some of the noncompliances or the pattern that maybe this is one that they may defer to or they may have already just done a recent FSA and they don't feel there's a need to go back.

So, this helps get a lot of information to our workforce and it helps them make determinations about FSA activities.

Going forward, we're already starting to think about FY '16. Here's just a kind of a quick list of things that we're considering. I don't know that we'll get to all of this in the next iteration, but these are on our radar, these are future analyses that we're considering. Certainly, evaluating trends is a very particular interest of mine and of the Agency's. One of the things that we expect from this process is that establishments have a raised awareness of noncompliance in these particular regs and that they're taking steps within their operation, within their business, to prevent noncompliance in those regulations.

So, there may be -- that's one of the things that we anticipate from this criterion is that industry responds just to the fact that we have this list. Now we want to start to look at how they are responding, and we think that we'll see some of that in trends in individual noncompliance with regs particularly as regs get added or removed.

Certainly, if we remove a regulation and noncompliance starts to rise, A, that may be something that we want to think about as far as how this is affecting noncompliance, food safety, inspection activities, but, B, it may very well be an indicator that the next time around the noncompliance rate is raised to a level that it may become significant again and make it back on the list.

And so, we want to start to keep an awareness and keep track of whether there are cyclical patterns with some of these regs, do they drop off and then the next year they come back on and then drop off again, sort of an indicator of

awareness or prioritization in terms of regulatory issues.

We do want to look at some things, as I mentioned, alternatives to the categories that we're using for cut points, evaluating regulatory verification by different types of tasks. So, some of our regulations can be verified under multiple tasks. Right now we're just looking at all the PHR regulations as a whole, but there is a greater level of granularity that we can start to look at in terms of is there a relationship between the reg, the task that they're doing when they verify this regulation.

So, that's all future work. We're already starting to think about FY '16 and starting to do some work in that area. Our timeline, which I don't have on these slides, but we've talked about in past NACMPI committee meetings is to evaluate -- or really to really evaluate annually we really get into that process pretty heavily around January, February, and March, we like to -- our goal is to have an

analysis completed and moving through the agency clearance process in roughly the May/June timeframe and we want to be able, every year, to announce any changes to the regulatory lists July 1st with the goal of implementing those regulations October 1st. So, that's roughly sort of a 90-day advance notice of any changes that are going to be coming and then on a fiscal year we implement those changes.

So, we have updated FY '15. We did just incorporate those in October of this past year. As I mentioned, it does add more outcomes, it did add more regulations, that's part of the annual review process, the feedback loop that we're looking to incorporate into this.

We did see a lot of carryover, which we think is good. We do see some changes that we want to keep monitoring. We've taken some steps to improve communication through new reports. We've posted a new analysis report on the latest findings. And we are preparing, as I mentioned, to start working on the next cycle.

We do very much welcome input, not just from the Advisory Committee, but from our stakeholders all around, whether it's industry, consumers. I think, you know, we do really welcome feedback on that. I think through the Advisory Committee we've received comments but we can also, through various stakeholder meetings and things also get input and comments on that, and we really welcome that.

We've tried to take the feedback into consideration and really incorporate it into our process. As I mentioned, this is a really big activity for us and I think it's going to be a kind of a work in progress as we kind of strengthen it and make it more robust, incorporate -- and make it maybe more sophisticated as we go through annual updates, but we feel like we've made some really good progress. Hopefully, we've gotten that across today and we really look forward to making some improvements as we go forward.

Thanks, everyone.

(Applause)

MR. WATTS: Thank you very much, Mr. Alvares. Now we're going to open the meeting briefly for questions and comments. And then we will have our final update. We'll do our final update after questions.

We would ask that you limit your questions and comments to no more than two minutes and that you engage your mic and first state your name and organization since this proceeding is being recorded.

So, questions and comments on any of the four updates -- safe food handling labels, specific data release strategic plan, international program status, or the public health regulations. Questions or comments?

Please go ahead.

MR. OEDEKOVEN: Dustin Oedekoven, South Dakota Animal Industry Board. My question is for Mr. Reed. Your presentation -- in your presentation you mentioned that only FSIS data is being considered for release. I just wondered if

that includes state inspection information that would be within the PHIS database?

MR. REED: No, not at this time. We're talking about FSIS regulated establishments.

MR. WALDROP: Hi. Chris Waldrop, Consumer Federation. First of all, I wanted to thank the Agency for these updates. It's really helpful, I think, for us to see not only that you're taking our recommendations into consideration as you guys are doing your work, but also to see that the work is continuing and it's not -- you know, we didn't just talk about it two years ago and nothing ever happened to it, so it's helpful to see this, so thank you very much for these updates and I would encourage FSIS to continue them at these meetings. And I'm looking forward to looking at all these proposed rules that you guys are talking about when they're coming out, so that's great.

I did have a question for Jane. In one of your slides you talked about for February 2015, you wanted to post audit reports in a timely

fashion -- that was one of your bullet points -- and I wondered if you had a goal for that, because previous -- in the past, there's often been very long periods of time between when the audits are done and when they're actually posted. Do you have sort of a goal or an intention in terms of that timely fashion?

MS. DOHERTY: Well, that's a very good question and it's one of the areas that we're really working on is on audit reports itself, the content, and one of the questions and concerns that we've heard is that it does take a long time for us to put this together. So, we are working internally now on what are the elements of an audit report that need to be incorporated, what information could be removed from the report, what's essential in that report, and then getting them posted as quickly as possible.

We're talking internally right now about what timeframes look like. I'm not comfortable right now telling you, but I can tell you, it is a major focus that we're looking at, how long --

it's coming directly from the Deputy Undersecretary that we are taking too long to put these reports out and we need to get them done in a more efficient, effective fashion. So, we are working on that, but I couldn't give you a timeframe right now, Chris.

MS. BOOREN: Betsy Booren, the Meat Institute. Question for Jane and Chris. Jane, can you provide some insights on your activities and how that might harmonize with some of the FDA activities? A lot of dual jurisdiction facilities and trying to understand harmonization. And then I have a question or two for Chris as well.

MS. DOHERTY: Sure. Great question, Betsy, and we are spending a lot of our time with the Food and Drug Administration because there is so much overlap on our international programs. We are working with them on a daily basis, to be honest with you, I'm talking to my colleagues over at FDA. We're working with them in other countries, we're doing some joint meetings with them in other countries so that a lot of

countries, to be honest with you, get very confused about our jurisdiction and what falls under FSIS, what falls under APHIS, what falls under FDA.

So, we are making an extra effort to do these meetings as a team, if you will. In the next couple weeks the Canadian government will be coming in and we're sitting down with them and we're doing -- we've planned the agenda where we'll spend half a day on the FSIS rules and regulations and then we'll spend half a day going through FISMA and the implementation of their program and the Canadians will talk to us about those programs where we have joint concerns. Because right now the Canadians have been working with us on some projects and it requires both agencies to work together to address those concerns.

So, we are making an effort to do that. We're also doing that in China. We were recently in China together and as you can imagine, China is a major focus for any food safety regulatory

authority, right, so of course we're spending a lot of our time and effort trying to educate the Chinese on what are our requirements, how do they meet them, and we do that hand in hand with the Food and Drug Administration.

So, oftentimes we tease each other that we only see each other in the Beijing airport and at the conference center, but we are truly spending a lot of time educating them on our rules and regulations and we do that, frankly, on a daily basis with FDA. We spend a lot of time with EPA as well and, of course, APHIS.

Right now, as you may have heard, there's some high path avian influenza requirements and concerns that other countries are very, very concerned. FSIS is working with APHIS and working with our other USDA agencies to make sure that we're addressing those food safety concerns and that we're a part of that team that's talking to the foreign countries.

MS. BOOREN: Betsy Booren again with the Meat Institute. Chris, two questions and one I

need a clarification on the pathogen positive rate that you gave, the 3.8 higher. What pathogen? Is that LM, is it H7, salmonella? Some clarification there. And then also, as NRs are potentially appealed by establishments I assume that if the appeal is granted that that is being updated efficiently within the system to accurately represent what is going on within the industry.

MR. ALVARES: So, on the first question, with the 3.8, it's not actually a pathogen positive rate, it's the noncompliant -- PHR noncompliance rate. So, what we're seeing in the data analysis is that the noncompliances for these public health regulations are higher in plants that have pathogen positives and it's roughly 3.8 times higher, so that's part of -- that's where that 3.8-fold increase is. It's related to how much higher are the noncompliances in these public health regs in plants with positives than in plants without positives.

MS. BOOREN: And so is that regulatory positives or all pathogen positives?

MR. ALVARES: It's all pathogen positives.

MS. BOOREN: So that would include salmonella?

MR. ALVARES: It would include salmonella.

MS. BOOREN: Thank you.

MR. ALVARES: And then the second question, which I just drew a blank on --

MS. BOOREN: If NRs and other activities are being appealed I assume that the PHIS is being updated accordingly to accurately reflect what is going on within establishments.

MR. ALVARES: Yes. There is an appeals process that's part of PHIS that does -- obviously, some appeals can be reconciled very quickly, some of them can take a fairly significant amount of time, but they are updating PHIS, we do take that into account, and so only noncompliances that are noncompliant at the time that we're evaluating are considered.

MR. WATTS: Thank you very much,

everyone. To have to stay on time, we will end our question and comment period for the first four updates, but be mindful that you may submit your comments or questions for the record in writing, to simply give those to one of the staff and they will be included.

And now we'd like to have our final presentation from the panel, certainly last but not least on a very important and emerging topic, the Upsurge in Raw Consumption of Ethnic/Cultural Meat Products, Mr. Scott Seys.

MR. SEYS: Good morning. My name is Scott Seys and I'm an epidemiologist in our Office of Policy and Program Development and this morning I'm going to give a very brief talk about food borne illnesses due to raw meat and poultry consumption, some of the trends that we've been seeing lately, and this is an informational presentation, so it is meant to raise awareness to this issue and we may be coming back in the future as we move forward to ask more questions and have further discussion.

So, the issue in brief, last year in 2014 we saw that FSIS food borne illness investigations were in covering illnesses associated with raw meat and poultry consumption, that is, individuals consuming uncooked meat and poultry. Scientists from our Office of Policy and Program Development, OPPD, and our Office of Public Health Science, OPHS, did a review going back to 2005 to see how often this issue was coming up.

We uncovered 19 investigations where individuals were engaging in this risky behavior, 11 of those were E.coli 157:H7, six salmonella, one KMP and one hemolytic uremic syndrome where the cause was not determined. Seventeen of those were beef related. One also included lamb and two of those were poultry related.

We tried to take those investigations and categorize them and we came up with three rather broad categories to kind of bucket them or to drop them in. So, the first were those investigations that were due to tasting mixtures

and other cooking mishaps. So, for this we're talking about individuals that are perhaps making meatballs or some other product, mixing in spices but want to taste it to make sure the spice is just right, so they're eating that product before it's cooked to the final product.

We had five outbreaks, all in Wisconsin, related to cannibal sandwiches, also called tiger meat and other terms depending on who's consuming it and where they're consuming it. We'll talk a bit about that in just a second. And then we saw -- we had this kind of third category or third bucket, which were other cultural practices, 2 raw kibbeh investigations that we'll touch on in a bit, and one alternative medicine outbreak where someone was making pills essentially out of raw chicken liver.

So, I want to touch briefly on the cannibal sandwich/tiger meat category. Variable ingredients in this product such as raw beef, raw eggs, and seasonings, typically served on or with crackers or bread. There typically seems to be a

fall and winter seasonality revolving around sometimes NFL football games and we've seen it, as far as the investigations go, in Wisconsin and those are mostly folks with some German ancestry, although it is -- it can be seen with other cultures, other nationalities as well.

I wanted to talk a bit about our raw kibbeh investigations as well. Looks similar on the slide, it's a minced raw meat, typically lamb, goat, or beef, there are minced onions and spices, again, incorporated, some cracked wheat, and again, there are multiple variations depending on where this is seen. The investigations that our joint review uncovered were in the Midwest, Ohio, and Indiana in predominantly Middle Eastern communities.

So, I wanted to talk through, real quickly, some of the policy approaches that we're looking at and we're talking through. There are three that I wanted to talk about, first is risk communication, we want to provide consumers with information about the risks associated with eating

these products, these raw meat and poultry products. And we want to keep in mind, of course, that the same message may not be effective with each different target audience. What might work for someone eating a cannibal sandwich would obviously not be the same for someone that's cooking up meatballs in their kitchen just because they have different motivations for the practices.

We'll talk a bit more about risk communication but also we want to address the hazard as we can at federal establishments and also look at practices at retail.

So, when we talk about risk communication and what we're doing for that approach, when it comes to the tasting and cooking mishaps and some of the culture practices that we've seen, we are working with our Office of Public Affairs and Consumer Education on some messaging to target those behaviors. When it comes to the cannibal sandwich category, the tiger meat category, we do have a multidisciplinary workgroup from across FSIS. We also had student

interns this summer in the Office of Outreach, Employee Education, and Training that created some educational materials. You may have seen December 2014 FSIS blog posting and we're continuing to work with states, with CDC and others on this issue.

As far as federal establishments go, when we're talking about the cannibal sandwich/tiger meat category, we wanted to ensure that establishments producing this product directly at the federal plants are sampled under raw ground beef product sampling programs or the MT43 and we want to ensure that the establishments that are producing this type of product consider their consumer practices in their hazard analysis.

As far as retail practices go, we intend to work with FDA to identify ways to strengthen the recommendations related to intended use statements. We want to work with the -- or continue to work with the Conference for Food Protection pursuing education at retail and considering formation of a committee to evaluate

the effectiveness of consumer warnings. And then, finally, we're considering outreach to a national environmental health association and other groups that are doing the inspections at retail establishments to see if we can pursue some education on that level as well.

So, thank you very much for your time.

(Applause)

MR. WATTS: Thank you very much, Scott. We have time for a couple of questions if there are any from Scott's presentation.

MR. CRUPAIN: Michael Crupain from Consumer Reports. What kind of rates are we talking about of disease or how many people are affected by this kind of practice?

MR. SEYS: It's actually relatively few. For most of these investigations we're seeing a person or two who was infected after eating these products. The exception, I would say, would be the kibbeh or the tiger meats investigations where there may be a few more, you know, up to -- less than 10 still, but more than the kind of single

case that's happening in a larger investigation.

MR. WATTS: Thank you. One last question, Betsy?

DR. BOOREN: As you are investigating -- this is Betsy Booren with the Meat Institute. As you're investigating illnesses with raw meat consumption, how are you working with your other agencies on other raw seafood consumption? There's a lot of sushi eaten that is raw. I mean, it would seem to me if you're (inaudible) work, how is that aligning with those other agencies?

MR. SEYS: Right, and our Office of Public Health Science does take the lead on food borne illness investigations and collaborates heavily with both CDC and FDA when needed when investigating investigations such as this and looking at the questionnaires and evaluating other high risks, such as, as you mentioned, raw seafood, produce, you know, other items like that in ensuring that the epidemiologic investigation was conducted appropriately and that the Agency agrees with those findings. Thank you.

MR. WATTS: Thank you very much. And let's give a round of applause to our panelists for excellent presentations.

(Applause)

MR. WATTS: I'll turn the meeting back to Mr. Keith Payne.

MR. PAYNE: Thank you, Michael. We are now at our break time. Just so we do not run too far behind schedule, let's take about a ten-minute break and reconvene about 10:50. There is coffee outside in the break area and we'll resume promptly at 10:50. Thank you.

(Recess)

MR. PAYNE: We're ready to get started again to go into the charges for our committee and the first charge is FSIS' Evaluation and Management of Chemical Hazards within the National Residue Program. And to present this charge we have Dr. Patty Bennett, who is the Deputy Director of the Science Staff within the Office of Public Health Science as well as Ms. Margaret O'Keefe, chemist, from the same science staff. So, I will

turn this over to Dr. Bennett and Ms. O'Keefe.

DR. BENNETT: Thanks so much, Keith. So, first, before I even get started, I really would like to thank all of you for being here and considering our charge. This has really been a very long time in coming. I've actually been with OPHS for five years and have managed the National Residue Program during that period of time and we have truly grappled with this concept of bringing the work that we do within the National Residue Program to an advisory committee and to actually be standing in front of you and putting forth our charges is really incredibly exciting for me. I mean, we are very excited to see what kind of recommendations that you will have for us once we walk you through the program and the changes that we've made and what we're thinking about going down the road.

And I really would like to thank and recognize everybody in OPHS who's really supported this effort, from the senior management, certainly, to the technical staff. Again, this is

something that we have worked on for many years and have tried to make this happen and so a lot of people put a lot of hard work into having us here today.

I'd also like to thank the staff -- Dan and Keith's staff, one, for listening very patiently and openly to our pitch when we came to them last April/May, and certainly for Natasha and Jane for working with us these last several months so that we could put together the best charge possible.

All right, so that said, I'd like to go ahead and go through my slides. I know you have them already. And in short, to me, the slides really represent three different sections. The first is really talking about what the program is. It is an interagency program, so there's lots of major players. At FSIS we don't do anything in a vacuum, and it is very important to understand the major roles of the major agencies that participate in the National Residue Program.

And then I'd like to walk you through

the significant -- and I can't underscore that enough -- the changes that have happened in the last couple of years. And, again, it takes a village and nothing happens overnight, but what we have accomplished and put into play in the summer of 2012. It's, again, very, very exciting for those of us who are involved in the National Residue Program. So, I want to walk you through those changes and what they mean to the program, what they mean to what we will do in the future, and then finally just to walk you through the charges. And, again, hopefully we have written them in such a way that you will be able to respond to them and give us some very practical advice.

So, very simply, why do we have a National Residue Program? For me, having managed it for so many years, it's really -- a primary reason is, it's just to keep our fingers on the pulse of what's going on in the products that we regulate. How are we doing? When we take these samples, are we finding anything that gives us

pause?

Because we are a regulatory agency, when we do find things or we suspect that there is something going on in terms of a misuse of drugs or a problem with the withdrawal period or some kind of unintended exposure, then we can also take more targeted action. That's also what the program does.

And the third one is this whole part of -- that this is an interagency process, is that we are continuously thinking about how to make this better, that we're paying attention to the chemical hazards that may be in the products that FSIS regulates at a level that when you and I consume these products, that there may be this potential for public health concern.

So, I wanted to -- because this plays into the questions that we asked you, it's just to remind everybody how the program is broken down. So, we really have two parts, one is the domestic portion, and that includes our schedule sampling, so that goes back to the previous slide when I

said we constantly do this kind of surveying of the land. How are we doing? Everything looking okay? Okay, good. And we do this on an annual basis, collecting samples over the slaughter classes that we regulate.

And then with the inspector-generated program, again, that's that more targeted emphasis that we have because we think that a particular production class, perhaps a particular drug that we've been made aware of, or some other kind of chemical hazard -- it doesn't have to be a veterinary drug -- and so that we can take -- have more increased testing perhaps in a certain production class, perhaps against a certain produce, perhaps in a certain area, in a certain plant, just depending on the situations that occur as we go about our day-to-day business.

The import-sampling plan is actually very similar to our domestic program with the exception that this is really a re-inspection. The domestic program is really us laying our eyes and our hands on our products before they go out

the door, whereas with re-inspection, as Jane had walked you through earlier this morning, we have equivalence programs and relationships with our trading partners so they're doing the heavy lifting, akin to our domestic program, and we're kind of verifying that, yup, things are still really good.

And analogous to our domestic program, the normal sampling is just kind of that surveying, re-inspection, things going okay? Okay, good. When they're not going okay, then we start going a little bit deeper and we start doing more sampling.

So, the increased sampling, the intensified sampling reflects situations where we found something and we found something at a level that we need to start holding more product and doing more testing.

So, going back to the concept that this is an interagency program, we work very, very closely with our FDA and EPA partners and there are actually many agencies that come together and

talk to us about chemical hazards. We certainly work with AMS and ARS, CDC is involved, APHIS, I'm probably missing some agencies, but you get the idea. And we operate under certain documents. So, the most important document for us is certainly this memorandum of understanding that we've had in place. The 1985 version is our most recent version, but as this program has actually existed for 47 years in some form or fashion, we have actually had kind of a working relationship with these other agencies for many, many years.

We also meet regularly, so at a very technical level we meet under the auspices of the Interagency Residue Control Group. So, more of the technical people, people at my level, people at Meg's level, where we come together and we go, so how are things going? Anything popping up that we need to be concerned about? Anything that we need to increase testing? How are the results looking? What are the chemicals that we might be thinking about down the road as we continue to think about the upcoming year's sampling plans?

And then annually we also gather, and this is some of our more higher-level, some of our senior management as well come to the table with our surveillance advisory team. And here's where we kind of solidify the upcoming sampling plan for the next fiscal period and so that we all have an understanding of what are we doing in terms of that surveillance that everything's going okay. If we're doing intensified testing, where are we focusing for that year, and even for imports, having our import folks come to the table as well and talk to us about the chemicals or the countries or the products that they might be concerned about so we make sure that we capture everything and that everybody's aware of what we're doing and then of course a look back of how we did the previous year.

So, another thing that I wanted to convey to you is just to understand jurisdictions. So, of course, FSIS, and I know most of you do understand this, is that we do have jurisdiction in the slaughter plants and that our job is really

to respond to the tolerances that are set by FDA and EPA. And so that's really our relationship relative to analyzing samples, getting the results, and deciding what we're going to do about them.

And so, while we take action against the slaughter plant and go in and say, well, you should be thinking about chemical residues, and look, we found something, what are you going to do about it? How are you going to make sure that this isn't going to happen again? In the meantime, FDA is having conversations with the farmers and the veterinarians, especially if it's a drug that would have been given with the veterinary/client relationship and saying, okay, so who dropped the ball on this? You know, do you understand what withdrawal periods mean? Do you understand that some drugs are not to be given in certain slaughter classes? And let's take a look to the drugs that you might have in the cabinets in your farmhouses.

So, and then we all kind of come

together and hopefully by us looking at it from the slaughter plant vantage point and FDA and EPA looking at it more in the farm side of things that we can resolve whatever issue has come to light.

So, I said earlier that some significant changes happened in 2012, and they really did, and again, it wasn't like they happened overnight. They were many years in coming. But really the most important thing that I will say that happened starting in August is that we introduced multi-analytic methods with a vengeance in our program.

The other significant thing that we did was because we had these multi-analytic methods, we really had an opportunity to change the sampling program that had really probably been pretty staid, pretty solid for maybe five, ten, fifteen years prior to that.

So, the next two slides really walk you through the changes between the two programs. So, prior to 2012, what we would do is we would get together and we would say, okay, we need to test

which slaughter classes, and in this case we decided we were going to do Bob Veal, and then we kind of talked about the different either chemicals or the methods that we would test against that production class.

And because we often were using single acolyte methods or methods that looked at a particular class of antibiotics, we would then collect 300 or so samples, more or less, and analyze those samples against a single method. And, again, sometimes that method would just have one chemical. For instance, Flunixin, Flunixin is a stand- alone, or sulfas, so, we'd look for different types of sulfa chemicals, but still just sulfa drugs and then we report those results out versus what we do now, and what I love about now, because I am a veterinarian and I know what it's like to treat animals and kind of what it takes -- when you think about the husbandry practices of raising animals and caring for them is that now our process is we're looking across the spectrum of chemical hazards, we're looking at many types

of veterinary drugs, not just sulfas, but any kind of drug that might have been used, like an antibiotic, different types of antibiotics, nonsteroidal chemicals, beta agonists.

Again, perfectly okay to use, but certainly as a way for us to say, so what are producers and veterinarians using on our slaughter classes, as well as pesticides. You know, usually we had an either/or prior to 2012. If we tested a sample for pesticides, that was all we would test it for and this time it's kind of the whole kit and caboodle, one sample against several different methods relative to what's applicable to that slaughter class. And as you can see in the right column with the chemicals, many more chemicals.

So, I'm going to go back up. So, prior to 2012, chemicals against a slaughter class. And, again, not against every sample but just in pockets of 300 or 250, and now each sample getting close to 200 chemicals being tested against one sample. And I think that gives us a much better idea of the health of the animal, right, and what

chemical hazards these animals have been exposed to over the period of their life, and that's really our job, what's going on out there and is everything looking okay.

So, I gave you examples about Bob Veal, so really here's kind of the bird's eye picture of what our program now looks like, and this is really the scheduled portion of our program with you have the different slaughter classes, production classes across and down you have the different methods that we test these production classes against. And, you know, not every method applies to every slaughter class. So, if a slaughter class isn't checked, it's because the chemical isn't applicable or the chemicals or the method.

So, to sum up for you, and you will find in your tab five, Natasha has provided two tables, which hopefully give you kind of a quick view of what you'll see on the next two slides, it's really the difference between today and before 2012.

So, now what we look at is that we have 800 samples are allocated for the scheduled program, the surveillance part of our program versus these increments of 300. Now fewer samples are allocated for import though, again, because we are testing against more methods, we're actually looking at more acolytes in a given sample even though we're testing fewer samples. So, we do about 1,500 or we plan for about 1,500 versus -- in years past we planned for about 3,000.

Our inspector-generated sampling program, by enlarge it's unchanged in the sense that we have guidance for our inspectors. They make decisions in the plant whether they will do an implant screen if they suspect something -- needle marks, the animal doesn't look well, they know the producer, they suspect the production class, et cetera -- they will do these implant screens, we call them KIS tests -- I know most of you are aware of this screen -- and then positive results are sent in to our lab for confirmation.

The other part of our program is that -- just so that you understand -- is when you look at our methods -- and, of course, as Jane had said, we try very hard to be transparent and open so our methods are on the website for everybody to see, is that really at this point we are targeting known chemicals. When I say that we are looking for antibiotics, we know specifically the antibiotics that we're looking for or the pesticides that we're looking for. We really are not investing energy at this point for looking for unknown chemicals, so chemicals outside the veterinary drugs or the pesticides or the heavy metals that we're already looking for.

The other thing, too, is that when you look at our schedule program, in years past, we would try and sample all of the slaughter classes that come under our authority, and you know that there are many of those, but what we decided to do in 2012 was when we changed the sampling program to say, look, why don't we focus on the major slaughter classes. I mean, I'm always amazed at

how much the United States produces in terms of meat. I mean, Jane talks about how much we import. I mean, we produce -- I mean, it's amazing, nine billion birds -- nine billion, a hundred million pigs, absolutely amazing, 33 million cows. That's a lot of stuff.

And so, what we thought was instead of going down and spending a lot of energy surveying the ratites and the geese, is that, let's go ahead and put most of our energy into looking at the stuff that most of us eat, because what we can do is, we turn that inspector-generated, that more targeted sampling area into rotating through these more minor species so that we are still looking at them, but not looking at them at the level that we used to in years past.

Also, the major slaughter classes are eligible for the KIS testing. The KIS testing is validated for, again, the major slaughter classes and so our inspectors have the ability to use our KIS screen against these major production classes and then to send the results to our labs for

confirmation.

And then what we had talked about before, and you saw it on the slide where you could see the different methods, is just the types of drugs or chemical hazards that we are looking at these days, so many veterinary drugs -- 60-something, 60-something and counting, 90-something pesticides, we are also now looking more aggressively at heavy metals and trace metals. Again, it's hard to know what is unusual if we don't first know what's normal.

Okay, and now for our charges. Oh, sorry, one more slide. So, then what are we doing as going forward? And even though this is something that I would say we've always done, I think we've become a lot more aggressive and strategic about improving our program, certainly at an interagency level. Again, we've always had a very close relationship with FDA and EPA and the other agencies who are involved in managing our program, but over the last year or so, we've had more dialogue with asking questions about, okay,

so let's talk about the chemical hazards that we should be concerned about and let's figure out a way to prioritize them, right, because we don't have all the resources in the world and not only is there a cost to testing for these chemicals, but there's also an opportunity cost and that if we were putting these resources into our chemical residue program, then perhaps we are not doing something else in the Agency. And so, there's always this give and take, and really, what is the most judicious way that we can use our time, our energy, our money?

We've also been doing a lot more outreach to other stakeholders. Certainly me standing before you today and asking for your input, but I'm also very excited to say that our staffs have gone out and we've been going to conferences. It's absolutely amazing. You probably go, well, of course you should. But we haven't been aggressive about that. And then last year we've been to three -- I think three different situations where we've either presented

posters, we've done a symposia and we've actually done some lectures and stuff, and in the queue we have other opportunities to actually go before IFP, which is really exciting. I've never been to IFP. I'm a veterinarian, why would I go to IFP, but here's an opportunity. There's now an interest in chemical hazards, and so here's an opportunity for us to go, again, out to our colleagues and say, this is the work that we do. And we'd always love to have your input because we always want to do a better job, right?

Okay, so now to our charge. So, really -- and I was explaining this to somebody on my staff last week, and he said, oh, so you want them to grade you, and I said, yes, that's exactly what we want.

So, really what are we looking for? It's really to grade how you think we're doing. And so, in short, if you think our approach is really good, where we're putting our energy, and again, if you look at the table that we provided -- and I don't know, its' somewhere on tab five

and we can certainly talk about it later -- it's the allocation of samples of putting our energy into the schedule portion, the more targeted portion, the import portion of our programs. And then also, of course, if you think that we are not on the right track, why and how do we make that better?

So, going back and being more specific, so, do we have it right? Should we spend most of our energy looking at surveying the major products that we regulate? Is that a good use of our resources? Should we put more into re- inspecting our import sample allocation? And do we have the right mix between how many samples we put in our domestic schedule program, so just kind of surveying the lay of the land versus going after issues where we think or we believe or we already have proof that there's a problem and we're doing more intensified testing?

And then, how are we doing in terms of allocating samples? We made the decision to say, look, we can't survey everything at a level that

really gives us an idea of how well things are going, so let's focus on the big guys, and then let's use our targeted, more ad hoc -- it's not quite the right word -- program to roll in sheep and goats and emus and ratites and things like that?

So, also very important for us is, are we focused on the right kinds of chemical hazards? Do we continue to focus on the known chemical hazards, the ones that we're testing for, the ones that we continue to add to the program, or should we spend some energy looking for the next melamine? You know, we know adulteration happens in our feed, we know the animals get exposed to things. How much resource can we put into chasing down those? Maybe they're rabbits and going down rabbit holes, but maybe not. Maybe it's worth putting some energy into that.

And then also kind of a general -- the way that you saw our program in the slides and it's one sample against many methods, it's always a decision about what you're going to do next.

Are you going to add chemicals to this method? Are you going to add chemicals to that method? Are you going to extend a method to a certain production class? And, again, there's a cost to doing that and when we do that, we're not going to do something else.

And I think at this point I would say, in general, we probably consider the methods equal in terms of our very large -- the most important veterinary drug method that we have versus our pesticide method, we probably consider those methods very equally. Is that a good way to think about those things? Should we put more emphasis on other kinds of chemical hazards that may require us to bring on different methods or perhaps to bring on new methods that continue to look for veterinary drugs and look for pesticides?

And one thing that I will add at this point too is going back to that interagency relationship that we have. We don't operate in a vacuum, I said that before, and when it comes to making decisions on which chemicals to add, this

is something that we talk very heavily with our sister agencies, and everybody's got their own idea of what we should be doing.

You know, EPA has their idea of what we should be focusing on because they have the requirements in their own agency, and we do try and honor that. At the same time, FDA comes to us and they say, okay, but we want you to look at this, this and this. Okay, great, we hear you and then ourselves, because we have very specific products that we regulate, you know, we have to step back and say, well, there's pesticides and there's vet drugs that they want us to look at. Is there anything else that we should be considering that we're going to have to kind of roll into and manage in this system because we can only do so much?

And I think that's it.

(Applause)

MR. PAYNE: Thank you, Dr. Bennett, and now we have a little bit of time for some questions for Dr. Bennett. Mr. Crupain.

MR. CRUPAIN: Hi, Michael Crupain from Consumer Reports. Thanks for the presentation. I have a few questions but I'll try to maybe just ask one or two.

When you do the scheduled sampling, how do you decide how to make that schedule or how representative of the over nine billion animals that get slaughtered is that?

DR. BENNETT: Okay. That's a great question, and forgive me, I could have gone into more detail. So, we actually have an algorithm that we use to allocate samples within certain production classes, and I won't pretend to understand everything in the algorithm though I do have somebody on staff who can walk you through it if you're interested later on this afternoon, but the gist of it is that it is weight -- volume of a plant has a great deal of merit, and so the plants that produce the most volume within a certain class, so the plants that produce the most chickens or the most turkeys or whatever -- cows, dairy cows, they're going to be sampled more

frequently than the plants that slaughter very few of those products. And if you look again at the schedule program, so, what we have said is, here are the nine major slaughter classes, these are the ones that we're going to focus on for our surveillance. We're going to allocate 800 samples, because, again, the reality is nobody samples every animal or carcass that comes through. That's not realistic. And our sampling is meant to be representative of what we regulate, right, so 800 samples far and above the 300 that we usually say is some kind of statistical acceptance -- 800 samples across these different slaughter classes irrespective of their individual or collective volume within the slaughter classes, and that certainly should give us an idea of if we're able to monitor the vet drugs and the pesticides and the heavy metals adequately.

And then, again, if we do find an issue that we're seeing a certain trend, then certainly we can take steps and go, you know what, we're actually finding a problem with Ivermectin and

we're seeing that it's being abused, I think we need to do more intensified testing to kind of understand what's going on in this group. Does that answer your question?

MR. CRUPAIN: Sort of.

DR. BENNETT: Okay, well, ask again then.

MR. CRUPAIN: No, I mean, I'm just going to look into it some more to see how you come up with that. My other question was about the results. There sort of seems to be not that much information provided about -- you've collected an immense amount of data now and it's really actually impressive how you've expanded the program, but there's not really a lot of results published, right?

DR. BENNETT: What do you mean not --

MR. CRUPAIN: What you're finding. So, you'll publish some violation rates, right, quarterly or so?

DR. BENNETT: Right, so, we do have a quarterly report and we do publish the samples

that we collect and the results that we get, but we also have our red and blue book, which has been in existence for 30 years, and the red and blue books actually look across the 12 months of the program, and in those books you can actually find much more detailed information of the number of samples that we collect, how many positives that we get, how many positive results are violative, and then certainly you can have an understanding of those samples then which are negative that we found nothing. In the cheat sheet that I gave you -- in your notebook, if you look at -- and we just gave you two years as kind of a representation, you can see that of all the animal samples that we took for the domestic program in 2011, so, close to 20,000 samples, we actually only found 27 violations versus when we did the more targeted sampling -- so you can see here the two numbers -- the 186,000, so roughly our OFL personnel do close to 200,000 in-plant screens a year. So, of those, 5,000 were positive and sent on to the lab for further confirmation and out of

that we got about 1,000 violations. And if you look over the years with our program, I'd say that we have been pretty consistent whereas we usually find 20, 25 violations with our scheduled -- the surveillance part of the portion. The 1000 is actually lower than it has been. When I first started in OPHS I think it was more like 1,500, 1,600 samples we were finding. I mean, you look down into the 2013, so now we're under the newer methods, again, same thing. So, now this I will tell you, if you didn't pick up on that, we actually have moved ourselves from a calendar to a fiscal year cycle, so one year had to be a little bit short, it was actually fiscal '13 was our first year and it started in January and ended in September. So, when you look at those data you see 19 violations. I kind of, if you extend that out to a full 12 months it would have been about 25 violations. So, again, kind of consistent with our surveillance program. What is interesting is that with the inspector- generated program -- so, we had about 1265 violations found over a

nine-month period. If you extend out and assume they had the same rate of violations, it actually jumped up to close to 1,700 violations, and with import not very high. So, we can certainly provide you with those results if you'd like, if you would find that helpful, not a problem. Over lunch, Meg, Nasser and I, we can make sure that we have --

MS. O'KEEFE: Remember, when we talk about the schedule sample and the inspector generated sample, these are actually different classes of animals, so the schedule sample, they are animals that have passed ante mortem inspection, and are generally healthy appearing, whereas the inspector generated -- the inspector is taking that because he sees something to make him -- so, that also arises in the difference when you look at the number of violations. We expect to find many more violations in the inspector-generated population.

DR. BENNETT: Is that better? Okay, and we'll get you that information for the committee

when you actually convene.

MR. PAYNE: We have Dr. Phebus next and then after Dr. Phebus, Dr. Booren.

DR. PHEBUS: Randy Phebus, Kansas State University. Can you address the sensitivity of the new multi-residue assay test that you're doing compared to the older test? Is it basically the same level of sensitivity for the different elements?

DR. BENNETT: No. It's as different as day and night for the confirmation. And, you know what, I'm not a chemist and I'm not going to pretend to be one, but I do have Dr. Esteban who is in charge of lab services and he can certainly provide more information about the methods if you'd like. Do you want it now or we can do it later? Okay. How are we doing for time, Keith?

MR. PAYNE: We have about ten minutes. Dr. Esteban, can we use the mic, please?

DR. ESTEBAN: Sorry. It's equal or even more sensitive than the ones we used before. So, in my opinion, this technology we're using now is

far, far superior. We switch equipment; we switched the material that we use. It's pretty much bringing FSIS to where the rest of the world was. So, I think it's -- to answer your question -- more sensitive than we had before.

DR. BENNETT: And I think the nice thing that I've learned from hearing about the methods from our labs is that when our methods identify a chemical, they identified the chemical, and, you know, not only are we screening, confirming, but also quantifying when there's a very specific tolerance. And I know we've actually had a lot of questions from producers going, well, it can't be that because we don't use that. I'm just saying what the method called out and if the method called it, then that's what the chemical is, and usually it's an antibiotic issue.

MS. BOOREN: Betsy Booren, the Meat Institute. I'm trying to better understand the inspector-generated samples. Can you give a breakdown, I'd be curious, by establishment, size, or species? I think that would be very

interesting to compare if inspectors are seeing an issue in plant, how does that track with your domestic sampling that the plan's been generated? I think that would be a good indication to see if your sampling plan is fitting where perhaps the riskiest animals may be or establishments? Is that possible to get that analysis?

DR. BENNETT: We can get you that analysis. I will tell you -- so, in general -- and I actually have 2011 data, so we're going to use that as a representative of across the years. But Naser can hopefully get us more detailed information when you're in your meeting.

So, let's see -- so in 2011 we had, again, about 186,000 screens that were done. Of that, 95,000 came from dairy cows, 33,000 from Bob Veal, formula fed 1,500, market swine about 12, 13,000 and then the numbers go down from there. Oh, and beef cow, we had about 18,000 screens that were done.

So, of those screens that were done, again, we had about 5,000 that were positive, and

I can give you the breakdown by the different class. So, for instance, our big one, 95,000 with dairy cows, screens that they did, they actually identified about 3,000 positive screens out of the 95,000 that they did, and that would represent.5 percent of what they did, if I did the math right, and Naser can correct me if I've read his table incorrectly.

But we can provide you with that. The detail of the breakdown by the plants, we can probably easily do it, I think, by large, small, and very small, and to give you some idea. For us when we think about the inspector-generated program, it really is more about by production class. If you don't know, we actually have a regulatory requirement for targeting Bob Veal animals and so our inspectors are required to test that slaughter class at a certain rate, and we certainly do find positives when they're just selecting because it's a regulatory requirement or violations, actually.

The next largest class that we see are

dairy cows, and then it goes from there, I mean, and obviously, from the numbers, and we don't -- well, we offer guidance on what we ask the inspectors to do when they are looking at animals, and really what are we talking about, primarily it's veterinary drug abuse, but certainly if they think that there's been some kind of pesticide exposure.

So, we do provide them guidance in a directive. We don't have any required quota for this kind of testing. We really do rely on their judgment. They're trained. We expect them to know what they're looking for and to test accordingly. And so, again, I mean, then to me that's why it's a nice supplement, as Meg had said earlier, to our scheduled program because with our scheduled program, while we do find violations, again, I think it is representative of the health of our animal production industry, which I think, by and large, for all the animals that we produce, is quite healthy and when there are issues with certain production classes because of really a use

of sometimes it's practices with Bob Veal, the number one violation is neomycin and where is the neomycin coming from? It's coming from the replacer milk. So, they're giving the animals replacer milk, they end up sending them to slaughter, they're going to get called on it for neomycin. That's what we're finding.

And with dairy cows, if you look at our quarterly reports, primarily what are we looking at? We're looking at issues with antibiotic use, cephalaxins, penicillins, genomicins, sulfas, those kinds of things.

And, again, if you look across the years -- I've been doing this for five years -- I'm usually not surprised. Yes, there are changes in -- some changes that we see in antibiotic use, but people are consistently using what they've been using over the last few years.

MR. PAYNE: Okay, we have Dr. Singh and then Mr. Sapp.

DR. SINGH: Thank you. Manpreet Singh from Purdue University. Can you talk about

unintended exposure -- you had mentioned that briefly -- and how that plays into the data which is generated, what percentage of that would it be? And specifically with small and very small processors.

DR. BENNETT: When I am talking about unintended exposure, generally it really is an isolated event. We get a call from a district in our field saying, I think that somebody has used a pesticide that they weren't supposed to use prior to slaughtering the animals, and then, you know, we will come together and look at the situation and obviously if there's proof that they have used this particular chemical, there becomes a determination. Can we test for it? We test for it. If we find a violation, then we certainly take action at that plant level and in sort of the issue that I'm talking about, that really was a real incident. We found violative levels of this particular pesticide. The plant was not using it as intended. Those carcasses were condemned and regulatory action was taken against the plant.

When things happen at a larger level, and again, oftentimes there are interagency issues, for instance, several years ago there was a chemical fire in a barn near a herd -- a cattle herd in Montana. The burned barn went down, several of the animals died immediately of exposure to the smoke, and so we spent several months trying to sort out -- working with EPA and FDA -- what we thought we needed to test because these animals had to have been exposed to things we wouldn't have expected they would have been exposed to, right, this unintended exposure. And so, same situation, we made a decision that, great, these are the chemicals we think that they should have been exposed to, who's going to be able to test them? We develop a sampling plan. The herd was held until we had tested the number of animals that we wanted to. We got the results. We made a decision on the herd prior to releasing it to the owner.

And in that situation, you go, well, FSIS doesn't have jurisdiction on the herd, yes,

that is true, but eventually that herd was going to come to slaughter and we were already saying, we would need to be looking for those chemicals before we were going to allow those animals to come into one of our regulated slaughter plants.

So, those are the kind of situations that I'm talking about. They don't happen very often, but on occasion we are made aware of these situations and when they do happen, you know, you do a quick -- who do you have to call on your bat phone? Ring the agencies, oftentimes it happens at a local level as well, and you have to decide, how far is the exposure, what kind of chemicals are we talking about, how are we going to test for them, how much testing are we going to do, what are we going to do when we get an answer, and go from there.

MR. PAYNE: Okay, Mr. Sapp and then Dr. Curtis and that should round out our questions -- the time we have for questions.

MR. SAPP: Brian Sapp, White Oak Pastures. In your table here, the 5,218 of those

inspector-generated sampling, that was a positive on a screen test, is that correct?

DR. BENNETT: Yes.

MR. SAPP: So, once they're confirmed in the lab, which goes down to 1,000, what are you doing with those other 4,000 tests? Are those tested for an unknown chemical? Or how does that work into the numbers?

DR. BENNETT: Right, so, make sure I answer your question and then come back and ask me, if not. So, let's say they did the 180,000 screen, 5,000 are positive. Those 5,000 are shipped to one of our FSIS laboratories. Then the labs do -- and at this time, we treat them like our scheduled sampling program where they're looked at. We looked at the veterinary drugs, all the different methods that we have for veterinary drugs, and then we report out.

So, of the 5,000, 1,000 were violative. I didn't actually indicate which of those 5,000 were negative or positive, but non-violative, right, but obviously as a regulatory agency, we're

just going to be taking action against the violative ones. So, it's the violative ones that those carcasses are either condemned in whole or in parts and the rest of the animals or carcasses would then be released to go back into commerce because it was, a, a negative result, no harm/no foul, or it was positive, non- violative, again, no harm/no foul.

Does somebody else have another question?

MR. PAYNE: Dr. Curtis?

DR. CURTIS: Yes, Pat Curtis from Auburn University. My question relates to the import and the domestic testing. Are they the same? And how do you determine if you need to test for something different for imported?

DR. BENNETT: That's a great question. So, the one thing about import products is that if a country sends us something that is processed, we're a little bit more limited in the methods that we can use against that product. Obviously, if the product is raw, then all of our methods are

applicable against it. So, that's one part. The other thing is, is that we do have an international staff. They're not -- on our staff they work in policy and actually we do sit down with them on an annual basis and we say, okay, so we've got these 1,300, 1,500 samples that we're going to allocate for the import re-inspection program, what would you like us to do with them? And the import staff actually has their own algorithm that they have established, and again, some of it's based on volume, some of it's based on the country and previous violations that they've founds. Some of the variables for deciding how frequently and what they want to test is based on the types of products that we receive.

And so all those things kind of come together and the import staff goes, great, okay, so we've kind of plugged in all these different variables, we have all this information, and here's a list of what we want tested against the methods that we want.

And then, again, we have another staff

who plugs it into the system and then of course the instructions, directions, whatever you call it, gets sent out to our import folks so they can collect the samples.

When we find violations, it automatically generates more testing against that particular country and then, again, the level of testing at that point is a bit of a judgment call so they can say, great, we know we're going to do more testing, but we're going to limit it to this. If they continue to find more violations, and that does happen on occasion, then, again, FSIS can be much more aggressive about holding a great deal more product and again doing even more testing, and at that point, if we're still finding violations, obviously, the countries are talking to each other because this is something that the countries will have to come back to us and say, gosh, I'm really sorry, this is why it happened, it'll never happen again, and this is what we're going to do to make sure that it doesn't happen again.

So, there's a lot of that going on. But for our purposes, on our staff, it's really saying, here's the samples, getting an understanding of what they think that they need, and then helping them set up the import side of the program and then looking at the data once we get it. Does that help? Okay.

MR. PAYNE: Thank you, Dr. Bennett and Ms. O'Keefe for the coverage of our first issue and the discussion thereafter. So, we're going to move into the overview of our second issue, the FSIS Usage of the Economic Research Service Cost Calculation Model being presented by Dr. Sandra Hoffman from USDA's Economic Research Service, and Mr. Brian Maculloch from FSIS. He's an economist with the Policy Analysis Staff of the Office of Program and Policy Development.

And here we go, Dr. Hoffman, Mr. Maculloch.

DR. HOFFMAN: Well, I want to thank you very much for inviting me to be part of this and for the opportunity to talk with you about the

recently posted ERS Cost of Food Borne Illness Data Product, so you can find that on our website, the USDA Economic Research Service website under "Data Products Cost of Food Borne Illness."

We want to talk to you about a number of things today. The primary thing that we're really hoping to get from you all is to let you know that ERS is planning on updating our cost of illness estimates on a five-year regular basis. I know that we've worked on cost of food borne illness estimates for many years and we're looking forward to trying to get onto a more regular schedule for updating.

And so, part of what I'm really looking forward today is to get more input from you all on a number of questions we'll have to deal with in that updating process. We'd also like to get your input as users into thoughts on how we might improve the way we communicate our results, for you all and for the people that you're interacting with.

So, what I'm going to do is give you a

little bit of background on how the estimates were developed and then I'm going to hand it over to Brian Maculloch, who will walk you through our website, and then I'm going to come back and talk to you about the charges.

So, the new estimates build on many decades of research -- well, not many decades, but a decade and a half of research at ERS on cost of food borne illness estimates. The core substantive analysis has been published in a series of journal articles in the Journal of Food Protection, also the Journal of Food Borne Pathogens and Disease, and that work was specifically designed to extend the existing ERS estimates, even though it was done by myself, Michael Batts and Glen Morris from the University of Florida, we were thinking about it explicitly as an extension of the ERS work. So, it does that in a number of ways.

First of all, for the four pathogens that were in prior USDA Cost of Illness estimates, the big ones, salmonella, campylobacter, listeria

monocytogenes.

We took the ERS calculator and updated those numbers using CDC incidence estimates and updating for inflation and income growth, so they're essentially the existing ERS estimates updated for new information on incidents and new information on income growth and inflation.

In addition, and we expanded it by adding an additional 11 pathogens, we focused on these 15 pathogens because in the new CDC incidents estimates, as well as in the old meat estimates, they accounted for the vast majority of -- not just the majority, almost all of the illness, hospitalizations, and deaths that we see as being attributed to pathogens where we know the pathogen cause, so those 15 pathogens account for over 95 percent of the cases, hospitalizations and deaths that's the Scallan, et al estimates from CDC attribute to -- can attribute to a known pathogen.

And we focus on those because not only are they where we are getting the most public

health impact, but they're the ones we know we can do something about because we know how to target.

So, what we haven't dealt with are the unknown pathogens, which account for most of the disease, but since we don't know the pathogen, they're less susceptible to the kinds of regulatory programs that FSIS and other federal regulatory agencies are involved in.

In addition, there are a number of other changes. For those new pathogens, we tried to incorporate as many chronic sequelae to the initial infectious disease as we could deem quantitative -- as we could deem supportive by the scientific literature in a way that we could quantify.

And in addition -- and in that process, I will say, that we not only have gone through peer review in this process, but we had an expert advisory committee with senior representatives from CDC, from industry, from academia, from consumer groups involved in both advising us on the underlying methodology, initially, and the

choice of pathogens, decisions about chronic sequelae, but also reviewing our results and giving us advice at that level -- at that stage as to whether what we had done was justifiable or not, and I know there was one decision that we quite disagreed with and ended up -- we had included amputations as a chronic consequence of vibrio vulnificus infections and we got a lot of push-back from the Committee on that, and so withdrew that.

It's something we may come back to in our updates. Certainly the whole issue of chronic sequelae is something we're definitely coming back to in all updates.

So, the final change -- major methodological change and difference between prior ERS estimates and current -- and the current estimates, are the way we handle mortality and there's been some change in the economics literature and in senior advisory panels on how to handle mortality. The major change is that the old ERS estimates used an annualized value of

statistical life year, the value of a statistical life year is what are people willing to pay to reduce risk of mortality, and then express that in terms -- in population terms so that if we -- what would the whole population be willing to pay to reduce risk of death enough that we avoid -- we expect to avoid one mortality in a year.

So, in the past, ERS has annualized that and valued expected life years saved. The advisory panels and the literature -- the economics literature, has advised against taking that approach and so instead we follow practices approved by the EPA Scientific Advisory Board of using the same VSL regardless of age.

And I can talk about that more if you want in the question period.

Okay, so, with that then I'd like to turn this over to Brian who will talk you through what we have up on the website and if you can keep an eye on that, you may have already looked at it, but if you could also look at what we have in terms of how that communicates the information

that we have on cost of illness for you, for the public that you interact with.

MR. MACULLOCH: Okay. Good morning. And before I go into what's on the website, I'm just going to describe kind of how FSIS uses the cost of illness data and this slide describes the poultry slaughter rule and how we calculate public health benefits from averting illnesses, and this includes salmonella and campylobacter.

The cost of illness data was calculated both for 2009 and we used the new 2013 cost of illness data to calculate what those public health benefits would be from averted illnesses.

And now I'm going to just describe what's on the website. So, this is just the USDA website data product overview. And this is what you'll come to first and it just describes the types of costs that are displayed from inpatient to outpatient costs. It also talks about the users of the data.

And then if you scroll down on the overview page you'll have the Excel spreadsheets,

which you could click on the 15 pathogens, and when you click on them a spreadsheet opens up. And then this is just an example spreadsheet for cryptosporidium and this is the mean estimate. Each spreadsheet has four different worksheets, it has a mean, a low, and a high estimate and also a per case cost for different health outcomes.

So, in this example you could see that the health outcomes increase in severity as you move from left to right in the columns. It also includes productivity losses and the value of statistical life as far as mortality costs are included here as well. And then this is the per case assumptions and this is the cost per case for different health outcomes from inpatient costs to mortality to death.

And then the website also contains information. If you'd like to update the cost of illness data for like -- for 2014, there's a consumer price indices that we use to update the 2010 numbers to 2013. And it also describes how we've updated the VSL and everything is available

there if you'd like to even go back in time.

And then I'm going to hand it back to Sandy for the updates.

DR. HOFFMAN: Thank you, and what I forgot to do, which was very important, is to thank FSIS for their contributions to us getting this up on the web. So, once we had the journal publications out, FSIS was very eager to get -- that we get this out, which we had been planning on doing anyway, but to get this up on the web, so they were very generous in giving us Brian's time to help me get that put together in a way that we could present it on the web, and that additional staffing was just really invaluable. It's the sort of task where you need multiple eyes on things and really careful checking and developing spreadsheets and I very, very much appreciate that.

So, going forward, the updating that -- Brian and I did some updating. We took the 2000 -- the numbers from the journal articles, which were expressed in 2010 dollars, but used the

Scallan, et al, recent CDC incidents estimates, but we took that from 2010 and updated it for inflation and income growth to 2013 dollars. That's one type of updating. It's a type of updating that we provide the information -- we provide information on the website that would allow any of you or any of the public to go ahead and do that updating themselves. So, there's always updating for inflation.

The kind of updating we're talking about on a five-year basis is much more fundamental. Over time, both incidents will change, the types of treatment and hospitalization costs, medical treatment costs, will change over time, the information we have about the consequences of infection will change over time, and we expect that new hazards will also emerge over time, and hopefully some pathogens may become of less importance over time as we have seen with trichinosis over a longer period of time.

But on a five-year period, then, what we'll be needing to do is to look at changes in

hospitalization costs and the biggest task, really, is to review the underlying scientific research to see what kind of changes there have been that would support different kind of disease modeling. So, do we know more about chronic consequences of disease, can we now actually quantify that outcome that we knew was out there but there wasn't enough evidence for us to actually be able to quantify how many cases we were getting a year. So, it's that type of fundamental research we'll have to be doing on an ongoing basis each five years.

So, we have a number of questions that we're going to have to tackle and if you have -- can help us with input, we'd very much appreciate it.

The first one is, are there other hazards, whether it's pathogen or non-pathogen hazards, that we should be including? How helpful is it to -- would you or those you interact with find to have us do the full set of pathogens that are included in the CDC estimates, both the

identified and the non-identified? And recognize that all of that effort takes additional resources, so there is an opportunity cost to us doing that.

For hazards for which -- that CDC doesn't have disease estimates, you may or may not be able to help us with this, but we need to think about how would one develop estimates for that incidence? To the extent that you have information on -- that would be useful in thinking about that, that would be very helpful.

Then for any of the pathogens that we have current estimates in, we're very interested in looking at chronic sequelae and making sure we're not missing significant chronic sequelae, so if you have any information or you're seeing things that are happening with chronic sequelae to infections, we're very interested in knowing that.

The other thing we have to keep our eye open for are emerging hazards, so that may emerge because of changes in biology, it may also emerge because of changes in industry practices, import

-- what we're importing and conditions in importing situations.

(Recess)

DR. HOFFMANN: I think the last one may be a little bit too technical for this committee but we are also having to consider whether there's any evidence that will help us estimate the likelihood of those different outcomes, again, in particular changes in the likelihood of chronic sequelae or the likelihood that hospitalizations now are shifting to non-hospitalized cases as treatment or recognition improves, or vice versa.

Finally, what I don't have on here and realized after we had sent the charges out that we probably should have had on here is as people who are either using this or interact with people that use these data products -- can you give us any advice on how we can present this better to the public.

One of the big changes we have made is a shift from having an on line web based calculator to spreadsheets. The truth of the matter is we

did that primarily because we couldn't afford to maintain the calculator, and that was getting in the way of us getting timely updates out.

Secondarily, my feeling was that most people are using Excel spreadsheets, and we felt that might give you more flexibility and it's a more custom way of interacting with data and models. So, some feedback on that could be useful as well.

I think we can shift over to the questions, both now, and if you have feedback, we will look forward to your feedback as a committee, and also please feel free to contact me directly if you have other feedback.

MR. PAYNE: We have a question from Mr. Waldrop.

MR. WALDROP: Hi, Sandy. Chris Waldrop, Consumer Federation of America. I have two questions to start with. One, does chronic sequelae include long term health outcomes?

DR. HOFFMANN: Yes, it does.

MR. WALDROP: All that is captured?

DR. HOFFMANN: That's right. I'm considering that all as chronic sequelae.

MR. WALDROP: Okay; great. The other question is just sort of off the top of your head what would it take to be able to capture those unknown pathogens and do some sort of cost estimate for that large number that we don't -- I understand your rationale about focusing on the pathogens we can do something about, but just in terms of looking at the entire costs if we are doing all this in the U.S., what would it take to try to grapple with that?

DR. HOFFMANN: Well, what it takes is basically making some fundamental modeling assumptions. Now, Bob Scharf has done a set of estimates where he has done that, and he's assumed that the severity of those diseases are the same as the average of all the other diseases.

FDA has also done some estimates for the pathogens, for the illnesses where we don't know the pathogen cause. They have made a modeling assumption that they are not as severe, which

seems to me is a reasonable assumption because those are the diseases where we are not seeing presentation for treatment and testing.

It does seem to me reasonable to assume they are not as severe, but it is going to be that type of modeling decisions, and there is going to be even more uncertainty about those estimates obviously, so it is really an issue of making modeling decisions and sensitivity analysis.

MR. PAYNE: Next, Dr. Lorenzen.

DR. LORENZEN: Carol Lorenzen, University of Missouri. You just hit on my next question, since I have not had economics in almost 30 years. I was wondering if you are going to be in our subcommittee meeting so we can get at what these modeling assumptions are that you develop these models with, because when I read the background material, I didn't have time to read those papers, not that I would have understood them.

DR. HOFFMANN: I would be happy to do that.

DR. LORENZEN: Okay. How did you get to the people that weren't hospitalized and didn't contact their physician, how did you estimate those numbers?

DR. HOFFMANN: I'm going to have to go back and I'll look at that over lunch. We are constrained -- the whole model is driven by the CDC estimates. We have cases and we have hospitalizations. The assumption is that those cases that aren't hospitalized did not get to that severity, and then I have to go back and look.

My recollection is that is based on individual research studies that are looking at kind of the relative rate of people that are presenting for treatment and those that aren't, but I have to go back and look at it. It may be FoodNet data that's driving that.

MR. PAYNE: Dr. Phebus?

DR. PHEBUS: Randy Phebus, Kansas State University. Along the same lines, probably on your last response, for non-0157 versus E.coli 0157, some of the background information indicated

that your model is treating those two groups as being the same. I think there is more and more data that the disease outcomes of the non-0157s are less severe, probably more of them in that not presenting to the hospital category actually.

DR. HOFFMANN: Right.

DR. PHEBUS: So, the question I have is, are you pretty confident that you need to stay with that, the characterization of them being similar in your model, or should that be something that we might want to tinker with?

DR. HOFFMANN: It's certainly not something that we are wed to staying with. Even in the current model, the model is having different severity because the non-0157 doesn't present as many cases of HUS. The outcomes of those hospitalizations, already there is evidence they are less severe than the outcome of the hospitalizations caused by 0157.

All of those assumptions are up for grabs. They have to be based on what the current science is.

MR. PAYNE: Next, Dr. Booren.

DR. BOOREN: Hi. Betsy Booren, Meat Institute. Two questions. First, has there been any consideration with this type of analysis -- I'm sort of thinking a lot of my questions have been harmonization -- about is there any alignment to do this with Healthy People 2020 outcomes?

It seems there are many food safety type outcomes within the Healthy People. This would be a logical analysis that may track on the same time line and resources. That is the first question.

The second question is on these models, from an industry standpoint, the information on these models are incredibly important. I'm curious, how does it track with potential policy models that are being developed, both within FSIS as well as OMB, to track very similar analysis as they are developing regulatory policy? Are there similar models? Is there any context you can provide within that?

DR. HOFFMANN: On the first question, on the first issue of Healthy People 2020, great

idea, and I want to talk to you more about that. The second one, I think I need a bit more clarification. I'm not certain I'm understanding what you are referring to.

DR. BOOREN: My understanding is as regulatory policy is being developed, there is a series of models and outcomes that are looked across all policies, whether it is economic, health outcomes, and so forth. The illness component, what that means. For instance, modernization of the poultry rule. I would assume there was some discussion on how that would impact illnesses and those outcomes.

Are the models being used within policy at our regulatory agencies or perhaps someone like OMB similar to this model? Can you provide any context to try to better understand how reflective that may be from an industry standpoint to what we are seeing coming out in policy?

DR. HOFFMANN: So, I was just looking around to see if Todd Furey or someone from the Policy Office was here. Essentially, I have to

say ERS is not a regulatory agency. We are a research agency. Unless there is someone from FSIS here that wants to address this, I'll attempt to address this.

The numbers that we produce, it's a resource that FSIS has that they can use in their analysis of any regulatory analysis. That is true of any other agency. It's public information that's out there and can be used.

There are many other components say to a regulatory impact assessment of a regulation. Health is a piece of it. These numbers can be used and are used in doing the regulatory impact analysis. I expect it's an input to other regulatory analyses.

MR. PAYNE: Dr. Crupain?

DR. CRUPAIN: Thank you. Michael Crupain, Consumer Reports. I have two quick questions. It was a very interesting analysis you guys did. I'm curious why you haven't included Staph Aureus as one of the organisms you look at because the paper estimates almost a quarter of a

million illnesses from that a year.

DR. HOFFMANN: Primarily because at the time we were initially doing this analysis, we were actually working off meat numbers, so we were looking at what was leading in meat. Staph Aureus is something we can reconsider and include.

We are fairly satisfied with the sets we had developed because it did cover 95 percent of the illnesses and cases. We felt like we were still getting very good coverage. Again, that is open for reconsideration and that is good input.

DR. CRUPAIN: Following up on that line, have you considered using some of the newer estimates they have about which pathogens are attributed to which commodity and looking at that? It would add a level of complexity, but it would be very interesting.

DR. HOFFMANN: We actually have done that type of analysis, not based on -- for those who may not be familiar with this, a group of CDC scientists recently came out with a set of -- not recently, a couple of years ago -- came out with a

set of estimates of attributing foodborne illnesses to foods based on outbreak data.

Prior to that, we had also done an analysis that used both -- Caroline Smith DeWaal has been doing this for many years, doing attribution based on outbreak data. We did one that combined an expert elicitation to try to get a feel for where in particular outbreak data is not representing the non-outbreak cases well.

We did a similar analysis in one of our general food protection papers where we looked at both an outbreak based attribution and outbreak plus expert elicitation for those pathogens where it looked like there was probably a misrepresentation of the non-outbreak cases.

We don't have that up on the website. We could potentially. It's in the journal literature.

MR. PAYNE: Next, Mr. Waldrop.

MR. WALDROP: Chris Waldrop, Consumer Federation. One more question. You talked about wanting to make these updates every five years.

Do you know if CDC, because they are dealing with the incidence numbers, are planning on having a similar sort of every five year update or are you going to be dealing with the CDC not updating for 10 or 15 years, so it's harder for you guys to do that?

DR. HOFFMANN: I don't know what CDC's schedule on this is. As you know, it's a very complex and extensive modeling process that goes into the incidence estimates. I don't know what their expectations are.

We are kind of thinking okay, they came out, it was about a 10 year period. I don't know if that is what it will be in the future or if it will be more frequent.

Our decision thinking is kind of informed by what has happened in the past with incidence estimates, but more importantly what we expect will happen with hospitalization costs. We know we are seeing changes in hospitalization costs. The incidence estimates are representative of a typical year during the period over which the

incidence estimates are being done. There is variability year to year in hospitalization costs.

We didn't feel like it was appropriate or frankly that we had the resources to do updates that reflected hospitalization cost changes annually. That's a significant task and we just don't have the resources, on top of which, the variability year to year probably is a misrepresentation of long run trends.

What we plan on doing is a five year window with an average hospitalization cost over a five year period. That is our thinking currently, but we are going into a planning period and hoping to get advice on whether that approach seems appropriate.

MR. WALDROP: You may be doing updates based on new hospitalization numbers but you wouldn't have new incidence numbers, so you may not be able to do anything with that?

DR. HOFFMANN: We would use the new incidence estimates as they arise, but we can move ahead with five year updates based on the

hospitalization.

MR. PAYNE: Dr. Phebus?

DR. PHEBUS: Randy Phebus, Kansas State. Could you give just a little bit more explanation of this VSL value? It seems like that is a magnifier or amplifier in your formula, and I'm not tracking on that very well.

DR. HOFFMANN: Well, frankly, it's been a difficult concept across agencies actually to try to explain this. It is used by most Federal agencies.

Let me back up a moment. My brain just flittered off into a couple of other different directions.

What we are trying to do in economics is measure changes of welfare to the public. Through a very long history and lots of mathematical work and philosophical work, we think as economists that we can measure welfare in the sense of where do people want to put their resources, that where people put their resources is a reflection of what they think is important and what they think

affects their own well-being.

If markets are working well, we think that their expression of what they are willing to pay for an outcome is a reflection of what it's worth to them.

In regulatory analysis what we are always doing is looking forward. We are making decisions and we expect to get changes in the future. Even as an individual, I'm making a decision on how I can protect my health. We do make decisions daily about expenditures either in terms of money or time that we are willing to expend on protecting our health from illness and from death.

When you think about when you make an automobile purchase, you are making decisions about the safety of the vehicle relative to the expenditure that will affect the expected outcomes in accidents.

What the VSL is an estimate of what people are willing to pay for small changes in risk of death. The studies that underlie most of

the Federal regulatory analysis are based on workplace studies of the relationship between mortality risk and wages in the workplace. That is saying when I go to choose a job -- there are issues with this literature as there are with most empirical literature -- that literature is saying when people go to choose a job, they are informed at some level about what the risk of death is in that industry, and they are making choices between wages and being in jobs with different risks of death. That's one way it is measured.

Another way it is measured that I've been involved in in my own research is we go out and survey a population, and there is a lot of work that goes into how do you communicate small changes in risk of death and how do you describe mechanisms that people can use to reduce that risk of death.

It might be that in a survey you might say we are developing a new product, and if you use this product, it will change the risk of certain types of deaths by a certain level. Out

of that, we get individual estimates of what you are willing to pay for small changes in risk of death.

That term, "value of statistical life," which is a horrible term, comes from the fact that you take that and you have a risk of death. I can extrapolate that to a population to get an expected change of one death in a year, and then I can scale up the willingness to pay concomitantly to get the implied value that people are putting on that reduction in a risk of death at a population level that is enough to reduce our expected death rate by one.

That is where it comes from. You are right, it is a driver of estimates, and that is true across regulatory programs. We actually see across regulatory impact analyses that death accounts for well over 70 percent of the impact. I think it's driven by two things.

One is that for death, we actually have an estimate of willingness to pay, whereas for mortality, we only have the cost of treatment and

estimates of the amount of time and the value of time that's lost to being ill, which we use as an estimate, as an approximation of willingness to pay, but we know people should be willing to pay at least as much as they are losing from being sick. We know that is very conservative and an under estimate of what they are actually willing to pay.

For morbidity, we have a very conservative estimate. For death, we have an estimate that should more closely approximate what people are actually willing to pay. It does skew estimates towards mortality.

MR. PAYNE: Okay. According to the agenda, we have time for one more question before we break for lunch. We have a question from Dr. Singh.

DR. SINGH: Manpreet Singh from Purdue University. Following up on Randy's comment about the VSL, I'm trying to also wrap my mind around this. Is that more related to perception or actuality? The comment you made was the cost

associated with something but the cost should not really affect the safety of a food in this case.

DR. HOFFMANN: Right. Where I thought you were going with this is on the perception, certainly on the labor market studies that is driven off perceived -- the worker, who takes a job, is basing their decision on perceptions of risk. The risk that is actually measured is the true risk.

So, the complaint about that whole line of literature is that the willingness to pay is not well informed.

The survey literature, you can control the communications much better. There the issue is do people actually believe they will get that benefit or face that kind of risk, and there is a great deal of work on risk communication in those surveys that goes into having a convincing survey to convince people that yes, this is actually something that you could get and you would have to pay to get.

MR. PAYNE: Thank you, Dr. Hoffmann and

Mr. Maculloch for your presentation and for the discussion.

We have come to our lunch break. On the agenda, we have an hour. If we can reconvene here promptly at 1:15, we will go over the challenges. According to the agenda, we have some questions and comments. If you have any questions that come up during the break, we can address them then before we break into the two subcommittee deliberations at 1:30.

We will see you again at 1:15.

(Recess)

MR. PAYNE: If we may take our seats so that we can start this afternoon's deliberations.

While everyone is trying to get back to their seats, I'd like to remind everybody about the resources that we have just available on the other side of the wall there on the outside, in front of our little table top exhibit. We have a wealth of resources, a vast array of free resources. These brochures are out there. You can order from these. Anything is free of charge.

Please take these with you and distribute to the contacts that you have.

Hopefully, everyone was able to get a good lunch. Now that we have had the overview of the two issues or charges given to the full committee, it is time to break into the two subcommittees for the afternoon deliberations. What I'd like to do just for the record is go through the list of each of the subcommittee members.

For the first subcommittee which will focus on the issue of the evaluation and management of chemical hazards within the National Residue Program, we have Dr. Michael Crupain, Mr. George Wilson, Dr. Krzysztof Mazurczak, Dr. Manpreet Singh, Mr. Brian Sapp, Dr. Michael Rybolt, Dr. Betsy Booren, Dr. John Marcy, Dr. Patricia Curtis, and Mr. Michael Link, Jr.

You all are part of Subcommittee 1, and what you will do is you will meet, reconvene in Room 6. When you go to Room 6, I want you to make sure you take your tent cards with you, so that

our moderator, Mr. Dan Puzo, who is going to be guiding you in the meeting to keep everything on track, will be able to know whom to call upon as we get to know each other.

That is Subcommittee 1. You will be relocating in Room 6. You are just going to make a right and look for Room 6. Again, you will be with Mr. Dan Puzo back here in the corner, who will be your subcommittee meeting moderator.

For Subcommittee 2, you will focus on the FSIS and ERS Cost Calculation Model. We have Dr. Carol Lorenzen, Dr. Alice Johnson, Mr. Christopher Waldrop, Dr. Randall Phebus, Mr. Kurt Brandt, Dr. Dustin Oedekoven, Ms. Sherri Jenkins.

Unfortunately, we had two members who were not able to make it to this meeting, Dr. Tanya Roberts with the Center for Foodborne Illness Research and Prevention, and Ms. Sherika Harvey with the Mississippi Department of Agriculture and Commerce as part of that subcommittee.

That is Subcommittee 2. You will remain

here in this auditorium. The subcommittee moderator is Commander Jeff Tarrant, over to my left, raising his hand. He will be guiding you, keeping things on track, so that we are able to reconvene the two subcommittees as the full committee at the end of the day at 4:30.

I do want to emphasize that the public is able to participate and sit in on each of the meetings, go back and forth. They are open to the public. You are welcome as the public to make comments or ask questions during the process. The moderators will keep things moving along.

For each of the subcommittees, you will have our presenters on hand if you have clarifying questions you need to ask.

Are there any final questions before we break into our deliberations?

Okay. I don't see any questions. We will go ahead and break into our two subcommittees. Subcommittee 1 in Room 6.

(Recess)

(Recess)

MR. PAYNE: Welcome back, everyone. We will reconvene as a whole committee before we adjourn today. For Subcommittee 1 -- I drifted in and out of both of the subcommittee meetings. There seemed to be very productive dialogue.

We thank our respective subcommittee chairs. For Subcommittee 1, it was Dr. Michael Rybolt. For Subcommittee 2, Mr. Chris Waldrop. Thanks to our moderators, Mr. Dan Puzo for Subcommittee 1, and Commander Jeff Tarrant for Subcommittee 2.

Just to touch base with our subcommittee chairs, do we have any final issues? Do we have our subcommittee reports saved?

MR. WALDROP: Yes, ours is saved on that computer.

MR. PAYNE: Mr. Waldrop has reported his subcommittee report is on this computer. For Dr. Rybolt, your subcommittee?

DR. BOOREN: I'm the chair. He was the assistant. He did a fabulous job. We have a general outline, depending on what is needed for

tomorrow morning and fine tuning, I guess that's a direction we will need from you.

MR. PAYNE: We will begin the meeting tomorrow morning promptly at 9:00. If you need extra time as your own subcommittee, come in earlier, if you need to do some fine tuning on your report, and then during the meeting itself, after we start, each of the subcommittee chairs will report out.

DR. BOOREN: Here is what I propose and you can tell me if I'm off base. The file that we have that's saved on a computer, if the subcommittee trusts a few of us to wordsmith overnight, we can meet at 8:30 or 8:00 tomorrow morning to go through it. We have the general consensus, but if there is anything that sort of jumps out -- let's say 8:15, 45 minutes, to sort of go through it, and then we will be ready at 9:00.

Is that amenable to you, Mr. Payne?

MR. PAYNE: That works.

DR. BOOREN: Okay, then I need a copy of

that.

MR. PAYNE: We will get you a copy of that. Just for the record, that is Dr. Betsy Booren as the Subcommittee chair. For tonight, you are welcome to leave your binders in here. I would recommend obviously taking all your personal belongings with you. Binders will be fine in here. It's locked up.

Any other final questions or comments regarding the subcommittees? Commander Tarrant?

COMMANDER TARRANT: I think the thought process was Natasha Williams was going to go upstairs with flash drives and make copies of the drafts that have already been created, hand them to you so you can have a physical hard copy and you can work on them, so tomorrow morning you have something already. If you choose to meet again tonight and make more changes, that is certainly up to you.

DR. BOOREN: We will take the flash drive and we will do some wordsmithing and meet at 8:15.

MR. PAYNE: Okay. Any further questions or issues?

[No response.]

MR. PAYNE: I do not see anyone who has signed up for comments on the registration sheet outside, so we have moved to the period of public comment. If anyone would like to make a comment, you are welcome to do so. I see an indication from Mr. Tony Corbo.

MR. CORBO: Thank you. Tony Corbo from Food & Water Watch. First, I sat in on Subcommittee 1, and I found the discussion to be very fascinating. It was a thorough discussion. I commend the subcommittee's work on the questions, because they were pretty comprehensive.

I wanted to make some comments, and I keep coming back to this at these meetings, about the international program, and the fact that Ms. Doherty spent a lot of time explaining the changes in the FSIS international program.

FSIS' international program has been the envy of the world. I've never been a fan of

equivalency because I find the concept to be very squishy, but the surveillance system that FSIS has with the audit process and the port of entry inspection is excellent.

There has been a weakening of the process. The one issue that has always been a concern of mine is that even countries that have achieved equivalency, and we send auditors to those countries to evaluate their food safety systems, if they are recurring problems from year to year, that country never gets tossed out of the club. Once you are in the club, you don't get out.

I'm glad to hear there is going to be some rationale applied to the audit process because what was implemented in 2011 in secret did not make any sense, so we look forward to the Federal Register Notice that is going to come out next month that is going to respond to comments that were filed two years ago.

We are concerned at Food & Water Watch about trade pressures being applied that are

weakening our standards. The Animal and Plant Health Inspection Service is changing animal health standards. For example, for foot and mouth disease and BSE, that are going to put pressures on the FSIS food safety program.

Unless the agency gets additional resources to deal with the additional imports because of those changes in policy, I think the agency is going to run into problems.

We are increasing our meat imports. We are increasing -- we are seeing an increase in food imports in general. We think the agency needs to start thinking ahead in terms of dealing with these additional import pressures.

FSIS has also been recognizing alternate inspection systems that have not been fully vetted in these foreign countries. We have two major trade negotiations going on simultaneously right now, and we urge that the agency resist any attempt to weaken its import food safety program. International trade should not trump food safety.

Thank you.

MR. PAYNE: Thank you, Mr. Corbo. Any other comments?

From the committee itself? I have been informed that we have drafts of each of the subcommittee reports, and one final call for comments. Mr. Derfler?

MR. DERFLER: I don't have any. We are adjourned.

(Whereupon, at 4:42 p.m., the PROCEEDINGS were adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

DISTRICT OF COLUMBIA

I, Mark Mahoney, notary public in and for the District of Columbia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

(Signature and Seal on File)

Notary Public, in and for the District of Columbia
My Commission Expires: March 14, 2018