Secretary's Advisory Committee on Animal Health
(SACAH)
Thursday, January 20, 2011
9:00 AM- 5:00 PM
Washington, DC

INTRODUCTION

Kim Ogle: Good morning everyone and welcome. Is everyone able to find a seat? Thank you. Okay we need to make room for Brian at the table please. Okay there's a seat next to Judith. Thank you all very much. Thank you very much.

I'd like to again welcome everyone this morning to the Secretary's Advisory Committee on Animal Health. We're going to be meeting the next two days on a very important committee that the Secretary has just newly formed.

The first order of business I would like for everyone to please turn off their cell phones as a courtesy for everyone but also it will interfere with the audio recording that's taking place. So please take a moment, check your cell phones and please turn them off. Thank you. We'll give everyone a second to do that.

We're very excited to have everyone here today. And I'd like to go over just couple brief housekeeping, logistic-type pieces of information for everyone. We have members here today of the committee that have been selected by the Secretary and we also have people from the public, the media and from USDA, so we have an assortment of guests here.

Some folks know their way around the building and some do not so it's very important I guess for everyone to have an idea of where to find the restrooms and where to go to lunch so let me try to explain those things to you.

Out the door here to the left is the men's room and to the right is the ladies room. And for lunch today the committee is invited to the Secretary's dining room with the APHIS employees. The media and the public, can you still hear me? Okay. I'm just checking.

The media and the public may leave the building and dine outside as long as they want to go through security when they return again, or they can go down to the basement level of this building and dine in the USDA café. If anyone needs further directions to find that café please visit one of the APHIS folks and we'll help you get down there for lunch, okay? All right.

I'd like to begin with introducing Undersecretary Ferrell. Would you like to say a few words this morning and welcome the committee? Okay. Thank you.

John Ferrell: There we go. Again good morning. I just wanted to on behalf of the Secretary and the Undersecretary, Ed Avalos, to thank you all for taking the time out of your busy schedules to come here today and to work on some issues that are quite frankly as you know very complicated.

The issue of animal health is an ongoing challenge to animal health officials and for producers all across the country on a daily basis and we just wanted to have a you know, a committee that can have a broad background of different perspectives and views and have a good grasp of the industries that you represent and work in each and every day.

And so I just, I don't want to take up any time, I just wanted to be here this morning and just thank you all for being here, so thank you.

Introductions

Kim Ogle: Thank you very much. I'm going to start off and I would like everyone at the table to please introduce themselves, I'm going to start off with Dr. John Clifford please.

John Clifford: I'm John Clifford, the Deputy Administrator for APHIS Veterinary Services.

Kim Ogle: I'd also like to add, after you announce your name please explain your affiliation.

Don Hoenig: Good morning. My name is Don Hoenig; I'm the State Veterinarian in Maine. I work for the Maine Department of Agriculture.

Kim Ogle: I probably need to tell you to press the on button for these microphones.

Kim Ogle: And wait a couple seconds for the green light to come on.

Charlie Rogers: Hello. Charlie Rogers, Clovis, New Mexico, owner and manager of Clovis Livestock Auctions in Clovis, New Mexico.

Genell Pridgin: Good morning. I'm Genell Pridgin from North Carolina and I'm a sustainable livestock farmer with beef, cattle and beef, sheep, pigs, and turkeys.

Brian Thomas: Good morning. My name is Brian Thomas and I'm a member of the Shoshone-Paiute Tribes of the Duck Valley Reservation in Idaho, Nevada and a local registered black angus commercial operator, cow/calf operator.

Judith McGeary: I'm Judith McGeary. I have a farm in Texas with grass fed land and pastured poultry and I also run a non-profit called the Farm and Ranch Freedom Alliance.

Phil Stayer: Hello I'm Phil Stayer; I'm Corporate Veterinarian for Sanderson Farms. We're the fourth largest poultry integrator in the United States.

Morris Johnson: My name is Morris Johnson and I'm from Arkansas. I'm a beef farmer and I'm also a member of the Small Farmer Leadership Institution. I'll be back here in March to graduate with 36 others.

Max Hernandez: My name is Max Hernandez. I'm from Washington State. I'm an open pastures sheepherder. I belong to the Rural Coalition on the Latino Farmers and Ranchers and the Washington Farm Bureau.

John Fischer: I'm John Fischer. I'm with the Southeastern Cooperative Wildlife Disease Study at the College of Veterinary Medicine, University of Georgia in Athens.

John Kalmey: I'm John Kalmey. I'm a dairy producer from Shelbyville, Kentucky.

Chuck Massengill: Chuck Massengill, I raise beef, cattle and meat goats. I am a Veterinary Epidemiologist. I'm also the Vice President of our State Cattlemen's Association.

Gilles Stockton: My name is Gilles Stockton. I raise cattle and sheep in Grass Range, Montana and I also work as a consultant on livestock economic development issues in Africa and the Middle East.

Howard Hill: I'm Howard Hill. Howard Hill, I'm a Veterinarian with Iowa Select Farms in Iowa Falls, Iowa. Also I have a farm where we raise black angus cattle and Brian I'll be glad to sell you a bull. We also have a rural crop farming operation and I'm on the Board of Directors of the Iowa Pork Producers and the Board of Directors of the National Pork Producer Council.

Liz Wagstrom: I'm Liz Wagstrom; I'm a Veterinary Public Health faculty member at the University of Minnesota.

Vicki Hebb: Good morning. I am Vicki Hebb. I work for the Inter-tribal Agriculture Council and am a co-founder of Native Woman & Youth in Ag. I am a member of the Cheyenne River Sioux Reservation in South Dakota and we have a cow/calf operation. We also raise bucking horses.

Boyd Parr: Good morning. I'm Boyd Parr from South Carolina and I work for Clemson University.

Cindy Wolf: Good morning. I'm Cindy Wolf, I teach Small Ruminant Veterinary Medicine at the University of Minnesota. I work closely with ASI on animal health industry, sorry that's the American Sheep Industry Association, and we raise beef, cows and sheep at home.

R.J. Cabrera: Good morning. I'm R.J. Cabrera and I work with the Writing, Editing, Regulatory Coordination Staff and I've also been the person primarily in charge of managing the committee and the meeting. I'm working with Michael Doerrer as his Deputy DFO. Thank you.

Kim Ogle: I'd like to recognize that there are two members that are not with us today. Dr. David Meeker who is in the rendering business from Virginia. He's the Senior VP of Scientific Services with the National Rendering Association, and Dr. Willie Reed who's a Poultry and Avian Diseases from Indiana. He's the Dean of the School for Veterinary Medicine at Purdue University.

I'm going to have Michael introduce himself as well.

Michael Doerrer: Good morning. I'm Michael Dorr. I'm the DFO, Designated Federal Official for this committee and in my day job I'm the Assistant Deputy Administrator

and Chief Operating Officer for APHIS Veterinary Services. My role is purely administrative to make sure that the committee has everything it needs to deliberate and to assist you in any way I can and R.J. joins me in doing that. So if you need anything throughout this meeting or in the next two years just let me know. Thank you.

Kim Ogle: And I guess I would be remiss in not introducing myself and my partner here today. We're going to be facilitating with you for the next two days. I am Kim Ogle and I work for APHIS. I work in an organization called Policy and Planning Development and my colleague here today Jan Grimes and I'd also like to introduce to you our administrator, our Associate Administrator, Dr. Gregory Parham. Welcome.

Greg Parham: Good morning. (Unintelligible).

Kim Ogle: I'm happy to welcome you, and if you too would like to say a few words.

Greg Parham: Again good morning and I really do appreciate everyone being here this morning. It's important work that this advisory committee is being assigned to do and as Deputy Undersecretary Ferrell has already mentioned, it's extremely important what you will contribute over the next 2 years as we grapple with some very complex issues.

So again, I'm not going to take much time, but again just want to welcome everyone and get ready to get busy. Thank you.

Kim Ogle: Great. I'm going to walk through the agenda a little bit later. I'm going to let Dr. Clifford have his welcome time and his opening remarks and talk about the expectations of the committee. Dr. Clifford.

Introductory Remarks

John Clifford: Thanks Kim. On behalf of APHIS, we want to thank everybody for their participation in this first public meeting in the Secretary's Advisory Committee on Animal Health. The committee will advise the Secretary of Agriculture on actions related to prevention, surveillance and the control of animal diseases of national importance and in doing so the committee will consider the implications of public health, conservation of natural resources and the stability of livestock economies.

In addition to animal disease traceability, the committee will discuss other animal health issues during this meeting to include the National Animal Health Laboratory Network, aquaculture, comprehensive surveillance, One Health, emergency response, and the Veterinary Services VS 2015 initiative.

I'm happy to be here today to explain the progress we're making towards strengthening our ability of responding to animal diseases and control them effectively with regard to animal disease traceability. The overall goal of animal disease traceability is having an adaptable approach that will help us find disease, quickly address it, and minimize harm to producers.

Advancing our animal disease traceability framework will support animal health, help reduce resources in the event of an outbreak and promote trade. Animal disease traceability will help move the country into the 21st century and is part of the VS 2015 initiative.

And today I will talk about why we need traceability and our plans to improve it over time. Thank you.

Review of Agenda

Kim Ogle: Thank you Dr. Clifford. I'd like to review the agenda with you and what we're going to be doing for the next couple of days. We're going to be talking about animal disease traceability, why it's important.

We're going to hear from Mr. Neil Hammerschmidt and he's going to tell us a little bit about the proposed rule and the new framework and then we're going to have a nice lunch in the Lincoln dining room, which is where the Secretary has his private lunches and his important meetings.

Then we're going to have a facilitated discussion about the disease traceability and we're going to talk about what the committee would like to do and how they would like to proceed and how they would like to work on this important issue.

Then we're going to hear from Dr. Barb Martin and Dr. Elizabeth Lautner on laboratory preparedness and about the National Animal Health Laboratory Network and the coordinating council. They're going to provide an update on those issues and you'll have an opportunity to have question and answer with them.

Then at the end of the day the public will have an opportunity to ask questions. Then we'll do a quick wrap up and then we'll end for the day and hopefully at 5:00.

Tomorrow we'll do a little recap of day one and then you're going to hear from Dr. Jill Rolland on Aquaculture. She's going to talk to you a little bit about the National Aquatic Animal Health Plan and the National Aquatic Animal Package and Testing Network. Then you'll have an opportunity to have a question and answer session with her.

Then you're going to hear a little bit about where we're headed in VS and what's going on. You're going to hear from Dr. Roxanne Mullaney on the VS 2015 and beyond. It's a description about what VS is doing strategically and what they're doing in their planning efforts for the future.

Then Dr. Thomas Gomez is going to talk about One Health and give an overview of APHIS' strategic activities and how the animal health world is intersecting with public health and the environment.

Then Dr. Aaron Scott is going to come and talk to you about the Comprehensive Integrated National Animal Health Surveillance System. Then you're going hear about emergency preparedness and response, a little overview from Dr. Jose Diez, and you'll have an opportunity to have a question and answer session with him.

Then we're also going to have a public comment opportunity in the afternoon where the public has a chance to ask some questions. Then we're going to wrap it up and hopefully end at 5:00 as well.

So we have an exciting two-day agenda for you and let's begin.

Kim Ogle: Thank you. Every little thing might help. All right. So once again Dr. Clifford is going to give us a presentation on the animal disease traceability, what it is and why it's important for us.

Animal Disease Traceability: Specifics of the proposed rule and new framework

John Clifford: Thanks Kim. Tracing capabilities is well developed in several animal sectors in the U.S. Rapid trace back capabilities already exist for a number of species such as poultry, sheep, goats and swine.

Under the former National Animal Health Identification System a high number of swine premises were enrolled into that system. Tracing capabilities for the poultry industry were achieved through the National Poultry Improvement Plan.

For the sheep and goat industry tracing capabilities are possible through participation in the Scrapie Eradication Program.

With the success of our brucellosis and tuberculosis programs for cattle fewer U.S. cattle have identification and trace backs in the cattle sector for the outbreaks we do have can take months, such as for TB it takes about 180 days on average to do a trace for tuberculosis.

We need improved traceability to respond to these cattle diseases as well as any foreign animal disease or emerging disease in the U.S. The former Animal Identification System was an initial attempt to fill the gap in the cattle sector but after hearing from our stakeholders we realized that a new approach was needed.

Almost one year ago the Secretary's February 5th announcement set a new course for the Department's approach for animal disease traceability. Through this new framework APHIS is implementing a flexible yet coordinated approach to animal disease traceability that embraces the strength and expertise of states, tribes and producers and empowers them to find and use the traceability approaches that work best for them.

Under the new framework we're establishing requirements for the interstate movement of farm raised livestock and poultry with some exceptions. The fundamentals include reestablishing the use of basic identification methods that have proven to be successful, widely accepted by producers and cost effective.

The cattle industry is our priority. Our goal is to get more cattle officially identified, the metal eartags we've used in brucellosis and tuberculosis programs provide this solution.

The flexibility of the new approach will allow the use of advanced technology; such as radio frequency identification if that is what the producers want. Likewise states and tribes using advanced technology may continue to do so.

States, tribes, industry groups and thousands of American producers invested heavily in the previous system and worked hard to make it succeed. As we transition to the new framework we'll continue to use and improve upon what has worked to support the new approach.

USDA will remain, maintain all current information systems and provide them to the states and tribes that wish to use them. Standards are important in traceability information systems. USDA will continue to coordinate the development of data standards and guidelines to support the traceability of livestock moving interstate. USDA's committed to advancing this framework through collaboration with states, tribes in the entire industry.

Finally and possibly most importantly USDA's committed to helping fund the implementation of this traceability framework. After the Secretary's announcement APHIS convened a State Tribal Federal Traceability

Regulation Working Group to recommend the content of the proposed rule that will support an outcome based approach to achieve improved traceability while focusing on interstate movement.

The new regulations will have the most impact on the cattle sector. For other species the existing regulation or proposed rules under development along with industry practices adequately support the needs for animal disease traceability.

In a few minutes Mr. Neil Hammerschmidt will give you much more detail in the draft proposed rule and at this time I would like, just like to point out that the proposed traceability rule fulfills the Secretary's and APHIS' objective to draft a rule incorporating the flexibility to let states and tribes manage their own programs with support and oversight from Veterinarian Services.

We're developing the rule to highlight regulatory goals rather than specifying the ways in which states and tribes are to achieve those goals. Traceability regulation will be outcome based, focusing on tracing capabilities.

It will also be based on extensive open communication with the public; a commitment APHIS takes seriously for animal disease traceability as well as our other animal health programs.

To inform the public about working group efforts and to obtain feedback we held eight public meetings to review the new framework and to share the current thinking on the proposed rule, including the traceability performance standards.

We also discussed this current thinking at the Joint Traceability Strategy Forum with the National Institute for Animal Agriculture and the United States Animal Health Association hosted in August.

We've held conference calls with industry sectors to update them on the progress of traceability framework and to hear their concerns. The working group reviewed and considered this feedback as it developed its recommendations on the content of the proposed rule.

And this first public meeting of the Secretary's Advisory Committee on Animal Health will continue this discussion. This committee will review multiple animal health issues including animal disease traceability.

Since the animal disease traceability is an underlying component of animal health programs and emergency response this is a crucial topic for this committee.

Through input from stakeholders including the public and this committee we expect the direction of our programs, such as traceability, tuberculosis and brucellosis to continue to evolve as we address the animal health challenges of the 21st century.

The demands and circumstances of national animal health landscape continue to change. Several forces including changes in the animal agriculture industry, technology advancements and emerging diseases are driving the need for adaptability.

A flexible approach is also needed to address threats beyond disease including food safety and international trade concerns as well as tightening budgets. VS 2015 is a strategic initiative that will help APHIS meet the changing needs of U.S. animal health.

As indicated, tomorrow Dr. Roxanne Mullaney will discuss that initiative that is underway now and will continue to pass the year 2015.

In summary, we have a successful traceability through the identification methods used in disease eradication programs and we are building on those successes and with additional resources in industry support we will build up on this basic approach over time.

And we appreciate the cooperation of state industry and federal officials and its integral to the safeguarding of animal health and traceability is needed to help safeguard animal health. It's a crucial component of disease programs and emergency response.

Thank you for your time and attention and Neil will discuss now the disease traceability framework in more detail. Thank you.

Kim Ogle: Okay. Thank you Dr. Clifford. Yes. I'm going to ask if anyone has questions for Dr. Clifford. Yes?

Committee: Sorry. I was just wondering if you could give us an update on the funding for animal disease traceability for the coming year. Some of us have cooperative agreements with USDA and can you give us an idea of where that stands?

John Clifford: We have some carry over dollars that we've carried over into this year, it's around four, four and a half million dollars for animal traceability and the President's request to Congress requested $14.2 million. I know that Congress is still working under a continuing resolution so we'll have to stay tuned unless Secretary Ferrell would like to say anything more?

John Ferrell: No

John Clifford: Okay.

Kim Ogle: Are there any other questions for Dr. Clifford? Okay. Something else I would like to have done earlier and I actually forgot, and I apologize. I'd like to introduce the Chair and Vice Chair of the committee. The Chair of the Secretary Advisory Committee on Animal Health is Dr. Donald Hoenig. Dr. Hoenig recognize yourself. Thank you very much.

And the Vice Chair is Ms. Judith McGeary, excuse me. Congratulations.

Michael Dorr: I also wanted to introduce one other person, this is Ms. Cindy Ragin. She's our Stakeholder Outreach Coordinator for Veterinary Services. She's going to be working a lot with the committee in the coming months and years so I just wanted to introduce her, let you see her face.

She's also working with us to make our committee proceedings as transparent and open to the public as possible and to get word about what the committee is doing out to as many of our stakeholders as possible, so I just wanted to recognize her as well.

Kim Ogle: Thank you Michael. We're a little early for break but I think we're going to go ahead and break early and give you a little bit of a longer break so you can walk down to the cafeteria and perhaps get a cup of coffee since we were unable to do that for you this morning, we were only able to give you water.

So why don't we take our break now and come back at 10:45, no let's see, what time is this? Let's see we'll come back at 10:15, that's a really long break, 10:15. Let's see where are we here, no let's see where are we here? That is a long time, let me see, 10:00, we're going to come back at...I know.

Committee: I'd rather be working than wandering around if that's possible.

Kim Ogle: You don't want to get a cup of coffee now, you want to wait?

Committee: I can use a cup of coffee but I don't think I need to have time for lunch.

Kim Ogle: All right. You want to go on ahead with Neil's presentation? Okay. It's your committee, you can make the decision. All right. Well Neil if you're prepared we'll going to go ahead on with you. So Mr. Neil Hammerschmidt is going to go proceed now with the animal disease traceability with the specifics of the proposed rule and the new framework.

Animal Disease Traceability: Specifics of the proposed rule and new framework

Neil Hammerschmidt: They said this computer was eight years old I think they're conservative. Okay. Can you hear me okay?

Certainly a pleasure for me to visit with this group this morning. The last 11-12 months have been really exciting for us as staff members on the traceability team, you know I think the opportunity to work with multiple working groups, public meetings.

I don't know how many iterations of this presentation we've prepared over the last 12 months and I was always good for me personally to go out, visit with the industry, come back make, work with the working group to make the appropriate modifications.

We feel pretty good that we've done the best we possibly could to bring this forward with consensus of the industry on some very serious issues or challenging issues and I feel confident that we've made good progress but certainly look forward to your feedback and responses as well.

I know many of you, a couple of you have been on the working group numerous individuals here have been at public meetings so hopefully this

won't be entirely new to you. We will provide a copy of the PowerPoint on the Web site that provides your materials. I elected not to copy all the slides but rather make a couple handouts of some of the information that might be more easily followed in charts today.

So one of the documents that I will cover quite a bit is on this document, one page might be multiple slides on the presentation so you'll have the opportunity to visualize those charts page by page.

But before I get started just some introductory remarks on the traceability rule making, we are adding a brand new section if you will in the CFR on animal disease traceability for livestock moving interstate. As Dr. Clifford indicated, outcome based focused on tracing capabilities, those capabilities are referenced or we're looking at measuring those if you will as traceability performance standards and of course applying to livestock moving interstate with some exemptions.

This might be more detail than you care to go through but I think it's very important that as we walk through some of the criteria we looked at it species by species and that's why we've presented the material in that handout accordingly.

But as we look at the regulation itself two primary points that I think really are emphasized in the regulation and they're on this slide with some exceptions, all livestock moved interstate must be officially identified and accompanying via an ICVI or other movement document. So again that's why those tables are set up in that handout on those two issues species by species.

Right up front I think it's important to acknowledge that there are circumstances where the regulation does not apply for all species or livestock.

Number one, if the movement occurs entirely within the tribal land that straddles the state line and the tribe has its own traceability plan that would not be considered an interstate movement. So if a tribe covers multiple states if they have their own traceability plan when they cross that state line it's not really interstate movement.

And the other across the board exemption from the regulation is when livestock move interstate to a custom slaughter facility. Certainly a local state regulations FSIS regulations obviously would still apply to those but not our animal disease traceability requirements.

Part of the intent here is to clarify up front that we know that those animals that move to a custom slaughter are traceable because the ownership obviously is the person that comes in and picks up the product at the end so clarifying that we don't need to add more traceability to those animals because the way they're processed obviously they are well covered.

So if we look at official identification first the regulations sets out more clarification on official identification and we look at probably more so in this approach by species and of course methods and the color markings at two brands for some species, devices, ear tag implants and so forth when we talk about a device that's attached to the animal it contains an official animal number that would be defined and we'll go through some of those.

So when we look at individual animal ID by far official ear tags is the most common practice, cattle, sheep, goats and so forth certainly there's group lot identification where ear tags is not necessary but I wanted to talk a little bit about ear tags because certainly when we look at individual animal ID it is by far the most common device used.

Probably over the last several years we've had multiple variations of official ear tags to the point where somebody would say is this an official tag and between the three of us on staff we really wouldn't know sometimes. So we've tried to help clarify what defines an official ear tag. First and foremost as we move into this the tag would have the U.S. shield imprinted on the tag.

It would also have a national, an official animal ID number. Those identification numbering systems as we formally refer to them is the National Uniform Ear Tagging System. Dr. Clifford made reference to metal tags, so that is the most historic, traditional method of identification in several species, cattle for example we often refer to it as the bright tag, it's a silver tag.

So some points of clarification in regards to this identification device, it has traditionally historically been a nine-character format that will continue for the cattle species, sheep and goats have an eight-character format.

But the point I want to make is to help address some of the needs of states locally there's been a request that we instead of using the numeric code, 60, I don't know what state that is off hand, it would be on the last page of your official ear tag, but the first two digits is the state numeric code, the states will be given the option to utilize the state postal abbreviation.

Part of that was driven by the option to distribute these tags direct to a producer if the state animal health official prefers to distribute those tags to that option. In the past these tags were all made available through animal health officials, normally accredited veterinarian would actually be the individual applying the tags.

So to make those tags more readily available, make them available for producers to tag their own animals those options are being put in place through policy.

The other numbering, another numbering system that you'll see on official tags is the animal identification number, AIN, the first three digits is 840, that is the numeric representation of USA via international standard. So we indicate that we're transitioning to 840 as we start the program we have recognized manufacture codes and USA is the first three digits.

The challenge, too often those tags and numbers are not traceable, the process that we've put in place for the 840 tags makes them highly traceable so we want to move towards the 840 version when we talk about the animal identification number eliminating the manufacture codes and USA.

The reason we have them in there to begin with a lot of cattle would be tagged with manufacturer coded tags. We don't want anybody to have to retag an animal to be eligible to move interstate.

And then based on a previous regulation, 840 is reserved for animals born in the United States. Again based on some of the feedback in Kansas City there was some thought to maybe move away from that previous regulation but the industry wants us to keep it so we're certainly glad to do that.

The third standard numbering system is a location or plot based numbering system most common in the Scrapie Eradication Program. So those three numbering systems with the U.S. shield basically will help us very easily look at a tag and know if it's official or not.

And I hope that'll make the determination easier to acknowledge down the road because we're going to be putting more expectation on people responsible for the administration of official ID to know, to indicate that those animals are officially identified.

If we have all kinds of identification devices and we can't look at the tag and know if it's official it's pretty hard for me to say the animal's officially identified. So we really want to help standardize that that really maintain the flexibility of different devices, different numbering systems and so forth.

So the other component that I mentioned was the Interstate Certificate of Veterinary Inspection. We talk a lot about certificate, movement certificate in our current regulations. The proposed rule will actually define Interstate Certificate of Veterinary Inspection. Today it is not specifically defined.

That actually makes it an official document giving us more authority to require accredited veterinarians to properly fill out that form because now it is an official document.

The regulations will also look at defining by species when the certificate is required. There's many times where other movement documentation will be adequate and we'll go through those species by species a little bit.

The other thing that we clarified is the administration requirements for the signing animal health officials. One of the reasons we talk even at this point so much about the animal ID tags and methods and the ICVI is we get further into the evaluation process of determining our tracing capability it relies tremendously on how we administer official identification devices and how we administer ICVIs.

And sometimes people think we're making this too complicated and as we look at maybe some other countries we're putting a lot of emphasis on the administration or tracking of a tag versus tracking an animal. Part of the justification for that is we want to make participation relatively easy for producers and most other countries have mandatory animal identification

where within X number of days a producer has to report the identity of a new calf.

The approach we're wanting to take is maintaining a good record of where those tags went so if that animal is involved in an investigation of trace back we know where that animal was most likely at when it was first tagged, really minimizing the amount of paperwork requirements that a producer would otherwise have to fulfill.

So that's why we talk a lot about the administration of these two issues because they provide the tools for animal health officials to achieve the traceability performance standards that we'll talk a little more about.

What I'd like to do now is go through these two issues, these two issues a little bit species by species. First aquaculture, they are considered livestock, their inclusion in the traceability regulation however will be considered as the National Aquatic Animal Health Plan is implemented. So there's really no section or reference to these two issues in regards to aquaculture.

Captive cervid traceability regulation will not have any effect on captive cervids. They are basically covered through 9 CFR 81.2.

So cattle, and we're going through these in this presentation in alphabetical order, so cattle and bison and some of the documents, excuse me, we do not have cattle and bison used consecutively but when we do talk about the regulation the reference to is cattle and bison together, not cattle, not bison separately but cattle and bison but I see some of our reports don't present it that way.

So when we look at official identification what methods are used for cattle? Official ear tag and group lot ID. So we've talked about the numbering

systems that are available to use on ear tags, the official identification requirement is to be phased in.

And we'll go through that a little bit because it's probably one of the more challenging issues we've dealt with over the last several months as far as discussion and probably will continue to be an area, I don't want to say of concern but certainly challenging that we properly address some of the issues as we move forward.

There's a, on the handout that I referenced on Page 7 there's this chart, so I know you can't read it on the screen so we'll walk through it.

So step one, when the regulation is published all livestock or cattle and bison would be officially identified unless they are specifically exempt. So we're looking at all sexually intact cattle and bison 18 months of age. Dairy cattle of any age are included. Cattle and bison of any age used for rodeo or recreation events. Cattle and bison used it shows in exhibition so these are the animals included in the official ID requirement early on.

So of course the class of cattle not included, beef cattle should be in bison under 18 months of age.

Other exemptions would include commuter herds where a rancher has pasture that maybe they've rented or whatever they're using for a season across the state line commuter heard agreements is at the state level. If for, in a specific case where I have to move my cattle to another part of my operation and in so doing I cross the state line and come back into that state we really don't think it's applicable there.

We're allowing for tagging sites. So if I load my animals up and need to move them but I don't have the facilities to tag my own animals a market or other

location could be used to tag those animals. I cross the state lines, I unload them at the tagging site, they're tagged so they're eligible or they're exempt from ID at the border but with the understanding they're tagged at unloading at the tagging site.

The other key point, maybe one of the most important is when animals are moved across a state line and state A and B elect to accept some other method of identification they have the prerogative to do so. And that really allows us to address issues of flexibility and what works best more locally or at regional levels.

A good example is brand. Brands obviously is not a national option because 37 or 33 plus or minus states don't have brand inspection authorities, 35, so it's impossible for those states to administer the option for brands. The approach we've taken if two brand states want to move livestock in or out to another brand state accepting brands is the method of identification they have the prerogative of doing so. So again that allows the flexibility for some of those decisions to be made at the local level.

This last bullet is basically if I'm loading my cattle up and they're destined for slaughter I cross the state line, I take them to the market, they're an approved for slaughter only market, those animals are designated for slaughter only. Those animals would not need to be officially identified with that ear tag. It's understood that they would be tagged or identified with a USDA approved tag in lieu of an official identification tag.

So those are the requirements if you will for step one. Now those exemptions are basically the last low in that chart are consistent. They basically don't change. What does change is that temporary exemption for the beef cattle under 18 months of age.

So through many, many rounds of discussion what we've ended up with is what we're referring to as step two, an assessment process where we're evaluating the workability of how all of this is working in step one with the understanding that if it's not working in step one we're probably not ready to take the next step to include more cattle.

So that's certainly the intent, you know we've wrestled, to be real honest, with what should we measure to indicates we're good to go. And at the end of the day we're proposing 70% of the animals that moved interstate that were in that top tier under step one that needed to be identified are identified.

Point of clarification, that is not to be interpreted but we expect a 70% compliance rate. Obviously we need higher much better than that, but I think what we looked at it's an indication that we've made good progress in the volume of cattle that are identified. Dave help me out here, based on (BSE) surveillance 35% of the adult cattle were officially identified and percent by beef and dairy, officially identified with an ear tag.

Very good. Thanks Dave. So at 70% overall we basically made significant increase in the volume, the percentage of cattle being ear tagged to us it's an indication that tagging practices are in place, tags are available and we're finding a way in the industry to get that job done.

Later in the presentation we'll make another reference to this additional bullet on the screen but it is in the preamble of the proposed rule to this effect that APHIS would ask an advisory group to review our data and evaluation for determining that the 70% rate of compliance has been obtained.

Additionally the advisory group may also offer recommendations on implementing the phase in process. So again that's what we want to establish is the ongoing collaborative approach that we've taken making sure the

industry is on board as we move that process forward and most likely there will be some points of discussion on how best to achieve some of this later this afternoon.

Then of course step three is at the point where all classes and ages of cattle and bison are involved in the rule except again for the bottom row where those types of situations, movements are exempt keeping in mind that the two first exemptions still apply where if I move direct to custom slaughter over a state line where the traceability plan is governed by the tribe those still would be additional exemptions, again point that they are not, those two are not species specific so they're not included in this chart here.

Are there any points that we need clarification on this? What I'm planning to do, and it won't take this long for every species, is to go into the ICVI criteria. So that would still be on the first page of the handout. But if there are points of clarification?

Committee: I had a quick question on the data. When you said that, I guess it was 39% of cattle are currently identified is that 39% of all cattle or 39% of the cattle over 24 months, I mean the cattle that are supposed to be identified under the current programs?

Neil Hammerschmidt: Yes. Those were the random adult cattle that were selected for (BSE) sampling, that's the population...

Committee: So that would include probably also some that had been moved as feeder cattle or.

Neil Hammerschmidt: Well could have but it was older (unintelligible).

Committee: It'd be older. Okay.

Neil Hammerschmidt : Yes. And it did represent approximately 156,000 animals in terms of that sample set.

Committee: Thank you.

Neil Hammerschmidt: And I didn't mention again that in, when we evaluate the 70% you know, this is an example of a population that I think gives us a good, pretty good indication of where we're at. We'll be looking for other populations that we can readily make those calculations on to document if you will the percentage of animal ID.

Committee: Neil in one of the exemptions I think it's the third one where you say they can go direct to slaughter but they can go one approved livestock facility on their way, is it safe to assume the back tag ties them back to where they have originated from?

Neil Hammerschmidt: That would certainly be the connection from the consigner, you know if the slaughter tag comes back to the market based on the collection of the back tag at the slaughter plant gets us back into the market the market should have records indicating the consigner.

Committee: Because the rule wouldn't say the market had to have separate portion of their facility dedicated for that animal use, right. We're assuming you're going to use the same loading chutes and the same pens?

Neil Hammerschmidt: Oh definitely, the nothing would change there because we're already have cattle going through markets designated for slaughter only.

Committee: Okay.

Committee: Yes Neil, the 70% if that's merely a measure of the number of tags applied and we don't have the traceability associated with that that wouldn't have, wouldn't seem to have much value if we apply tags and then consider that accomplishment.

Neil Hammerschmidt: And that's certainly a good point. I think what, and you'll see probably at the very back of the presentation is some of the timelines that will address that because you know, we put this regulation into effect we're going to have to grow into it over a period of time because the traceability won't happen the next day following the publication of the rule.

So all of these issues have to be achieved over a period of time, the measurement of official ID is what we're really looking at is, maybe somebody will argue but certainly ID I believe has a positive correlation to traceability. So the more animals we get identified we feel comfortable that there's increase down the road associated with traceability.

It's more of, not maybe so much with how well the system's working from a traceability standpoint but the assessment really is to help us look at when we're ready to move to that next class of cattle. And so that's really the focus of that but I appreciate your point.

Committee: And Neil following up just a little bit on the exemption, which I support for the back tags, cows going directly to slaughter, but in the harvest of that, which is a separate issue, is they're related to traceability the harvesting of all ID's if there happens to be an official ID on the animal that also has a back tag what steps are being taken to assure working with FSIS that the permanent ID, the official ID will be harvested in addition to the back tag.

Neil Hammerschmidt: Great point and I'm glad you're bringing that up because that might be one point that I don't have in the slide presentation but we've talked

about it previously within the regulation APHIS is also including a requirement that all man-made ID be collected at federally inspected plans.

Certainly the enforcement of that has some responsibility but we've relied on that through an FSIS rule, we will also be complimenting that with an APHIS regulation and actually you know it's going to take a lot of effort but actually out team met with FSIS and FDA yesterday talking about these types of issues to really start development of a process or a plan to address some of those issues down the road.

So if we look at the, please.

Committee: On the, when you find that interstate travel for adult cattle do you have an estimated number for adult cattle that we might start this program with and then what, an estimated number of what cattle under 18 months we'll add to the program?

Neil Hammerschmidt: I'm going to call on our numbers guy, you might not have those right off the top of your head but we can certainly get those, we've done some of those estimates a little bit, Dave if you're prepared please go ahead.

David Meeker: Excellent question. We have been attempting to get those numbers as solid as we can. It is a bit of a challenge. We do know from National Agricultural Statistic Service data that in 2009 approximately 19.2 million head of cattle did cross state lines, those however are not divided up into classes of cattle and we also recognize that several of those may move interstate more than once.

So we're attempting to work with our state partners and solidify some of that data, great question but that's the limited amount of data that I currently have on hand.

Committee: I guess where I was going on that is the, is when we bring feeder cattle into the system or cattle under 18 months of age we're going to increase the numbers probably, you're probably going to double the numbers. And we need a system that's functional before we do that.

Neil Hammerschmidt: Understood and I appreciate the point and you know I'm sure we'll have some time for open discussion after this and those are probably some of the points that we, you might want to pick back up on by all means.

Good questions on animal. At this point in time unless there's specific questions on some of the animal ID things that I covered on cattle I'll move over a little bit on still on cattle on ICVIs.

And I want to say it now because I think I overlooked it a little bit, and my point previously we're going to use animal identification ear tags, those animals that are ear tagged the process of administering those tags, recording the distribution of those tags to help us correlate to the producer that most likely first tagged that animal.

Committee: What about when you take cattle to Canada (unintelligible).

Neil Hammerschmidt: Right. My understanding Dr. Clifford current international regulations, requirements would not change.

John Clifford: That's correct. All requirements now for international movement would remain the same. So they have to be permanently identified to leave the country, cattle coming into the country have to be permanently identified to enter.

Committee: They will come back with the same number (unintelligible)?

John Clifford: They should.

Committee: But (unintelligible) first thing they do they cut the tag and (unintelligible).

John Clifford: Well I mean if Canada is removing tags then that's something we would need to discuss with Canada because if it, if it's got a tag removed then it's probably going to come back as a Canadian animal not as an animal that was born in the U.S. because all cattle from Canada that are native to Canada have to come back with a brand or a tattoo plus an ear tag.

Neil Hammerschmidt: When we look at ICVI's, Interstate Certificate of Veterinary Inspection as a solution or option practice to help up increase traceability we know we need to do a couple things. We need to make sure that we have some level of standardization of the ICVI across all states.

We need compliance in how they're completed so they're providing the information that's called for, and most importantly that we move these paper-based records into electronic searchable data. And yes we have a couple solutions to help the process where accredited veterinarians can complete those certificates electronically. We want to grow that utility, those utilities but I don't think we're going to get a high, high level of electronic ICVI's or (unintelligible).

So we know early on that a high majority of our certificates are going to be paper based and as we go back through some of the performance standards we recognize that this certificate is not a movement document or a confirmation of the animal mood but rather that it is a document that reflects the animal is eligible to be moved but there's probably a high correlation to that.

But again we're relying on that document as our best source of information to help give us some information on where animals from and to across the state line, okay, it's not maybe the best solid solution but it's probably the most practical solution we have at this point in time again because we don't want to add tremendous burden on people receiving cattle saying when you can bring cattle into your location you have to report their movement.

So we're not requiring the movement, the reporting of movements by the producer, we're relying on this certificate and other movement documents to help increase the record retrieval on these animals that moved.

So what we've already developed to make available to our states realizing that much of this information is on paper an option for the state is the use of cooperative agreement dollars is the key existing paper based animal health certificates into a database so that as we go down the road we're hoping that a high percentage of those records, that even though they were completed on paper can be searchable.

Without doing that our ability to enhance our traceability according to our objective is minimized so we're also putting that in place. So bottom line is ICVI's are very important, yet at the same time we realize that their use probably isn't practical.

And so we've established some exemptions by species, the first one's very similar to identification basically if they're moving direct to slaughter, some other type of movement documentation is appropriate, I believe here it says an order shipper statement that the producer fills out themselves are complete versus having an accredited veterinarian coming out and preparing the certificate.

In and out of, or out of one state, back into it as we've talked about ID commuter herds, this one's important to understand cattle and bison under 18 months of age may be moved between any two states without documentation other than ICVI as agreed to between those two states.

Animals over 18 months of age, the adult breeding animals for example would be required to move on an ICVI.

Some of these again are very similar to the ID issues directly to a livestock facility, so if I moved my animals to a market, they across a state line, I don't have to have a ICVI, they can move on a shipper, owner/shipper statement with the understanding that that market most likely has a veterinarian on that location to examine the health of those animals.

But if those animals are moved from that market interstate then one is required but if they would be maintained within that state then an ICVI is not necessary.

Then of course two and back from a veterinarian clinic is the next bullet. A lot of this text is very, is identical to the way the regulation was drafted so we're using some of that for clarity or consistency and you'll get a copy of this but I'm trying to explain maybe a more easy interpretation of what's written.

Another concern that has been discussed as we talk about traceability in the cattle sector is the recording of the official numbers on the certificate. Bottom line is the feeder cattle, more specifically define those as the cattle under 18 months of age or even if they're feeder cattle over 18 months of age basically they're steers or state heifers in that population.

The recording of those individual numbers on certificates would not be required unless they are dairy cattle or animals used for rodeo, exhibition

recreation purposes because I think all the animal health officials across the country and even support from that industry wants the rodeo animals included.

So that covers the cattle sector as far as official ID and ICVI. Any points of clarification and we'll start with some of the other species real quick?

Committee: I guess I don't understand that last exemption, so feeder cattle I mean how does that fit into traceability if you're not requiring ICVIs for cattle under 18 months how do you trace those animals?

Neil Hammerschmidt: Again, where an ICVI is required to recording of each individual number on the ICVI and would not be required. A lot of issues I think went into play there, discussions with industry representatives in those sectors. The burden slow down of cattle movement and speed of commerce to record the tag of all the feeder cattle moving pretty significant; and also in consideration that those populations don't live as long.

So they're, granted we still want them identified to work from but giving the difficulty of recording all of those numbers, recognition that that population has a shorter life span, this is the recommendation of the working group into the proposed rule at this point in time with those types of considerations.

Committee: So I guess the answer is they're not traced.

Neil Hammerschmidt: They wouldn't be by individual number, we would know where the animal was most likely first tagged at but from what location the animal is shipped from you're correct.

Committee: Now a quick question on that again because the phrasing I'm trying to make sure I'm clear on this. It looked like if the cattle have to have an official ID then the ID has to be recorded on ICVI but because it looks like the exemption

under 18 months that's also the exemption for at least phasing in not having to ID.

Neil Hammerschmidt: What's your question?

Committee: Okay. Is it, am I reading this correctly that if the cow has to have an official ID then the official ID has to be recorded on the ICVI because it looks like the ones that don't have to be recorded...

Neil Hammerschmidt: Okay.

Committee: ...match up to the ones that at least in phase one don't have to have an ID.

Neil Hammerschmidt: In that period where less than 18 months of age are exempt from ID there's no options to record the ID.

Neil Hammerschmidt: In step three when we are officially identifying feeder cattle...

Committee: It will still be that they...

Neil Hammerschmidt: Those numbers still would not be...

Committee: Okay.

Neil Hammerschmidt: …necessary to record on the certificate.

Committee: Okay. Thank you.

Neil Hammerschmidt: Very good. Thanks. Horses equine, this species really didn't have as much to work from in the current CFR as other species what we were proposing in the regulation in regards to the official identification method or

options for horses and other equine basically covering the entire gamut, what's currently used practice today.

So you'll see a pretty wide variation in what defines an official ID method for horses. You see if written on your charts that basically a description's sufficient to identify the individual horse as determined by the state or tribe animal health official of the destination or APHIS representative, this can include name, age, breed, color, gender, distinctive markings and so forth.

Again working with the industry on what is typically practiced on Coggins test and other forms today. In addition to those electronic ID if they're using implants, ISO compliant with (11) 784 and 85 to ensure compatibility with that technology or digital photographs and then acknowledging that there is referenced to the identification of slaughter horses in 9 CFR for Part 88.

So again the horse would be officially identified by any of those methods, so it's very broad, certainly allowing the animal health officials to work with other methods that they determine acceptable and again reference to the slaughter horse movement in Part 88.

When we look at ICVIs we're saying that the horse must be accompanied by an ICVI or other interstate movement document or as agreed to by the state tribe involved in the movement.

So again, giving the states local authority to accept what they feel is appropriate for that type of horse movement. And then again reference to the existing parts in 88 and also EIA in Part 79 where they defined a horse that's a reactor for that test.

So again for equine, while there's clarification definition on official identification it's very broad, all encompassing intentionally to allow for

current practices as we defined official ID because there was nothing, if you will, to hang our hat on in the existing regulations for horses.

Poultry identification methods, again as indicated before, sealed a number of leg bands relying a lot on the National Poultry Improvement Plan, 9 CFR Part 145 to 147 group lot is an official identification method. Again the option for ID devices and methods as agreed upon by those animal health officials that are moving and receiving the animals.

So again some definition on official ID for poultry and the regulation basically says official ID is a requirement for the interstate movement of poultry. From the ICVI some of the exemptions are very similar to the cattle, so I won't go through them in great detail, they're in your handout but they're moving from plots participating in NPIP accompanying with that documentation defined in that program.

Again move direct to slaughter, they are moved somewhat similar to the cattle exemption to a veterinarian or a diagnostic location basically that's an exemption. And again if there's a case where they pass through one state but go back into the state where they were moved from.

There's also exemptions that if they are moved between any two states or tribes with VS 493 or documentation other than an ISBI as agreed upon with the animal health officials in the two states then that's taking from existing regulations, taking advantage of what already exists and then movement under permit in accordance with part 82.

So for the most part capitalizing on what's in current regulations in the CFR and making them clearly written in the traceability section. Sheep and goats bottom line is nothing changes. The traceability regulation merely references those existing regulations in Part 79.

Swine has the same issue or the same approach referencing 7119 regulations that currently exist that the industry has full support of and taking advantage of the tracing outcomes from existing regulations.

So that is kind of a quick walk through in regards to official ID and ICVI requirements by species. There's a lot of information there, hopefully the charts that we provided helps you with a reference document, there's a lot of information there that the bottom line is that's basically what we're looking at as the content of the proposed rules for official ID ICVI species by species.

If we're good to keep going I'll go into a little bit the discussion on the performance standings. Are there any questions or comments you want to make on ICVIs, official ID of any of the species please?

Committee: Yes you said you weren't going to spend much time on swine and you were true to your word there. And the swine industry of course has done a good job on this traceability ID and everything using group ID on slaughter pigs and I go back to what Dr. Clifford said that I think you, if I quoted you right you said cattle was priority.

I'm not sure if that's code for we're going to spend all our money on cattle, but we do have one issue where we, I think we have an ID problem and that's where sows, (cole) sows get commingled. Those animals for the most part are either ID'd by ear tag or by tattoo but once they're commingled none of those records are maintained.

So if for example if we have a load of sows that would go eventually get split and go to five different packers then there's a needle and one of those animals we get notified that some of our animals are in that but we don't, they don't know if it's our animals or not.

So what producers have done, some producers have done is gone to the electronic ID but they're paying for all that themselves so I'm just pointing that out that even though we think we're ahead of the game I think we still have a place there where things do fall apart on the sow and boar ID.

Committee: Very good. I appreciate those comments.

Neil Hammerschmidt: I would just echo what he says from the State Animal Health Officials, they do an excellent job but that small segment is where all our traces are and we have the same problem within this disease thing that we make it commingled so some initiatives that have been put forth by the industry look promising for a premises location, a location identifier for those sows where they originated, so hopefully that might, could be incorporated in somehow.

I'm just going to say I think we recognize that as well and you know while our primary focus might be to improve traceability in the cap sector we recognize these gaps and we want to close those gaps as well across all sectors where they exist so.

Committee: Hey quick question, this is maybe should have been after John's presentation, when you talked about maintaining the existing infrastructure here that you have for ID already does that mean you will be maintaining like the premises ID allocator and those tools that the states could use?

Neil Hammerschmidt: Yes. Those will be available to the states that want to use them.

Committee: Excellent. Thanks.

Committee: This question probably should've been asked earlier also but when you were talking about ID devices, ear tags and the option or either using the numerical state code or the postal code, that's going to cause some problems.

In our industry we try to use these numbers for management purposes, a lot of different, there's a lot of different programs that these numbers have to fit into and just a simple thing is changing from a numerical state code to a postal code is going to cause ripple affects all through, there's a lot of reprogramming that's going to have to be done in management programs, DHIA, all that sort of thing. Is that really a necessary change that needs to be made? Aren't most people familiar with numerical state codes?

Neil Hammerschmidt: Certainly a good topic to discuss further actually earlier this week that came up on a conference call with state animal health officials acknowledgement that certain industry programs will hiccup a little bit, have conflict with different numbering formats.

So from our perspective this numbering format change has been requested by several states, it's their option whether they make that numbering system available in their state for those specific tags.

So you know, if we continue along that path we certainly need to do a good job working with everybody including the states and industry on acknowledgement that even though that tag's available if you're a DHIA producer you might not, or dairy producer in DHIA maybe you don't find those tags acceptable for yourself.

But that state will continue to make the other series available so we're not deleting that so in your state just because that tag, even if it's available you're not forced to use it, you'd certainly be able to use the series that you always have.

Committee: And I haven't been involved in the discussions on the ear tag especially with the cattle thing but why can't we have an ID by premise on that tag and then have a, you know you got two sides to the tag so why can't you for the production records use a production ID?

Neil Hammerschmidt: Yes. Now you make a good point and actually if you look at the first page of this handout when you look at the options for official ear tags a location based ID number is an option granted that is pretty much specifically used to the sheep and goat industry but that is the designated official numbering format that individual producers could elect to use.

You know I think the challenge that we need to make sure we potential conflict that we avoid is the duplication of those numbering systems or those numbers. They need to be not just nationally unique but unique for a long period of time so they don't replicate.

In the Scrapie program there's a process that to ensure the uniqueness of that number I think the swine industry, Dr. (Wemer's) already has a process in place to help not (unintelligible).

So bottom line is that is an option that is defined as an official numbering system, I'm just pointing out that we would certainly want to work with organizations that follow that numbering system to make sure there's a practice in place to make sure the producer doesn't use 9999 and then start over with the same series again. Okay?

Committee: That sounds like a great idea.

Neil Hammerschmidt: Mr. Chairman's good for that? No I'm just glad somebody raised their hand. There's a request for a break.

Kim Ogle: Why don't we take a 15-minute break and come back at quarter till, okay? Thank you all.

Break

Kim Ogle: Okay. We're going to gather back together now. Would everyone please take their seats? Are we dialed back up here?

And just so you know we got a little information about these microphones, it's not necessary for you to be very close to it. The microphones are more for the audio pickup, they can hear us fine, we've done a check in with them, the recording is fine, they hear us fine so the closer that we speak to them that's creating some of the backlash that we're hearing so they told us to leave them alone and the audio pick up is fine.

Okay. We're going to begin now with Neil and he's going to pick up on the traceability performance standard.

Neil Hammerschmidt: Kim how do you put this back on?

RJ Cabrera: I had a discussion with Michael and Kim during the break and just so you know we're going to have a little bit more clarification on the role of this committee with respect to the traceability rule and so forth after Neil gets through, so a couple people have already asked me well where do we stand with this and how does this work? So Michael's going to go through that a little bit I believe after Neil goes through his presentation, so just to let you know what's coming.

Michael Doerrer: I might just give you a little bit of, if I may, give you a little bit of history.

Those pictures behind you all over there on that wall that's in Williamsburg, Virginia, this table was actually built specifically for that meeting where there was, I think there was eight countries it was during the Reagan Administration, Margaret Thatcher, I think the Prime Minister from Japan and a number of other countries were there, this table then was donated to USDA, this is the Williamsburg Room.

And also the Secretary's office made a special...

Dr. Clifford: Dispensation.

Michael Doerrer: ...yes dispensation for you all because normally you are not allowed any food or drink in here and that's in order to protect this table, so just wanted you all to have that bit of history there's a little plaque there that tells about it so that you know.

Neil Hammerschmidt: Okay. Let's go through the traceability performance standards a little bit. The whole idea of the performance standards is to support the direction of establishing an outcome-based regulation while we have standards and processes identified it's still not an approach where you have to do X, Y, Z, we're looking at achieving traceability.

It's a way that we can standardize measure tracing capability across the entire country, again measures of a desired outcome, not the method of achieving it and probably this is one of the bullets that differentiate previous attempts maybe more so than anything else is keeping in that flexibility looking at what do we want to accomplish and how do we measure that.

I think it makes the process more complicated and more challenging but certainly a good approach to look at when we're really wanting to measure

tracing capability, maybe not precisely how we got there but what is our capability.

This approach is not focused on a specific disease in that the intent was not to design a tracing system for every different disease but a tracing capability that could fulfill the needs of the majority of the diseases that we anticipate in the various species.

This is also in your handout and I know the print isn't, it's not my intent to have you read the screen but you have that information in your handout. To simplify these let me just go over the top. So we've got an activity that is associating with the trace back investigation and they're specific to those that could be applied to interstate movement of animals.

I think when the working group first identified processes that would help evaluate tracing capabilities the list guys, how long, 12, 16 items? As we looked at it from where we're looking at it from an interstate movement perspective this is kind of how they shook out that it's really applicable to this regulation and it certainly is a tremendous step forward.

The middle column basically says for clarity who's doing what and then the preliminary standards, and I think part of the discussion later today or later this morning, I want to point out that these are called preliminary very specifically and intentionally because we want to learn more about what our current capability is.

As we put some of these practices in place and if you, when we go through the timeline you can see that we're not actually looking at officially, formally measuring tracing capabilities for the states until well into the program good possibility nearly three years after the final rule is published, so those are out

there and I think we do more harm trying to put those in concrete today than we'd achieve.

We have to continue to evaluate these, fine tune the concepts and move forward so I want to clarify that.

The other point of clarification is as we're preparing to bring the regulation forward intentionally there's some specifics that will be held outside of the CFR. This is one of them because we anticipate more information, more fine tuning on these measurements and percentages and timelines.

And we think we would burden the process to have to go through a rule making process but we'll work with the industry and publish through notice of availability the information of these change, obviously they're not going to change on a whim but as we get more information we want the ability to adjust those when deemed necessary.

So standard one is pretty basic. I have a reference animal and a reference animal is basically specific to an animal that was officially identified or issued a number after the regulation and that moved after the regulation final rule is published.

A lot of concern early on that we were going to put this regulation in place today and require these traceability performance standards on animals that were moved three years ago where we probably wouldn't have that type of information.

So clarification on what animals would be considered in the evaluation process. But basically whether it's an actual disease event or a randomly selected animal to test their tracing capability we have an animal.

And I think in the example that we used in one of the handouts that we made available to you if you printed off that information that was online we talk about an animal, a dairy animal that moved, that was first tagged in Wisconsin birth premises in Wisconsin someplace, went to Texas and then it went to California.

So in this, in that scenario standard one California has this reference animal. It should be officially identified they have to advise the state where that animal is officially tagged and you see proposed timeline for achieving that in what say one business day, 95% of the time, a pretty basic process, if we do a good job administering official identification tags we should be able to do this nearly (unintelligible) the time in very limited amount of time.

Certainly the noose tag numbers has the state on it so that's pretty much a give me, but 840 tags, and that's one of the reasons why we're insistent upon maintaining a good distribution record of some of these other tags where by looking at the tag you don't know what state it might have been applied in.

So in that scenario California says hey Wisconsin we got this reference animal, it has this number from what we've found it was first identified or officially identified in your state.

So Wisconsin, standard number two they need to look at their records to determine who tagged the animal, get in contact with the producer, have some method of saying this is where that animal, based on our information was likely tagged, we're saying a record of where that tag was issued, high correlation that that would be where the animal was first tagged officially.

It might not be at the birth premises if that animal had moved a second or third time within the state of Wisconsin that is dependent on local requirements.

The third, so going back to California I again have the animal, I advised Wisconsin that it looks like this animal was tagged in their state, where did the animal come from when it entered my state, in this example California.

California needs to advise Texas that they have this reference animal that was shipped from Texas to, came into California. How was that likely to happen? What's the source of information? What's the best source of information we intend to have? Health certificate, Interstate Certificate of Veterinary Inspection.

We did one, John test exercise is that fair to say? And this… I think we all realize that getting this information electronically is very keen but the way states store ISVI records are in archive storage units because this number over time might go back a few years and some states actually put in a request to get information out of the archives and the request might not even be processed for a few days.

So bottom line is we need to move this type of information to searchable queriable data and that was one of the reasons why I talked about how we plan to use some of our funding to key this paperwork into a database.

So I could key that number in at the state level and at least give me the certificate number that maybe points me specifically to where that paper is stored or have more the needed information on electronic record itself. So that's number three and you see the percentages and the timelines required there.

We anticipate as we put some of these policies or practices capabilities in place we'll be able to improve our retrieval time, we'll be able to do it more quickly as we progress with how we basically administer some of these

records, and that's why you see the performance standards getting more stringent over time is the intent.

Then number four Texas shipped this animal to California, they need to determine what location that animal was shipped from, and again the best source that we know of for determining that information is on the ICVI so they also need to pull that information because according to our standards on defining an ICVI we're asking for the consignee or the consigner who's moving the animal and what location the animal's being move from, specifically an address that would most closely fit the location of where the animal was shipped from.

In a nutshell those are the four performance standards but it certainly helps us connect a lot of the critical dots that we know today we don't have the capability of doing as timely as we'd like.

So I think a good comment, good suggestion and if you didn't hear fund a state or two to develop more thoroughly their traceability system. I think what we've done to some degree we know some states are out there already and we've looked at some of those states capabilities, Dr. (Granger's) smiling over there because he spent time in Michigan and he knows that some of those states out there, and I know Washington has been...

Neil Hammerschmidt: And I think the very sincere point that we know there's some states out there that have followed, have responded to their local needs and have some pretty good traceability systems in place, yet at the same time not everybody might not want to do the Washington model, maybe not. We know it demonstrates that it works. Exactly.

Yes.

Neil Hammerschmidt: Right. And so that's certainly the approach exactly that we're wanting to take is you know, Washington is content with the solutions they've brought forward, build upon those versus having to remodel them for this type of program.

So I think we've built in that type of flexibility to the best of our capability. Please.

Committee: Yes when you're evaluating the performance standard, if I'm a veterinary medical officer someplace in that chain and I want to find out where that animal is ASAP if we have, if that person has a health paper with that information on it, the consignee and consignor have copies of that. It doesn't even need to be recorded by the state. We could cut that time down just going directly to that, to the consignee or consignor to get that information.

So if you did that would that be, would you consider that part of the performance standard to shorten that time up going from your seven days to your three days or?

Neil Hammerschmidt: Yes. Let me see if I understand your comment correctly because I think we had some of this discussion and some of the feedback we got caused us to take a different turn, because eventually we were looking at having those records maintained by the producers so they could also be more readily available and there was some concern about making that responsibility that of the producer.

Right or wrong I think the issue is on an individual animal, I have an animal ID number, I don't know who moved the animal. I don't know how to, I don't know who to contact to get your copy of the ICVI.

And I might have a reference animal in California for example, I'm looking at the number, well I know it probably spent some time in Wisconsin because it's got a Wisconsin tag on it, but if that animal's at the plant I can certainly trace it back to one of those locations hopefully, but I still might not be able to find the person who received the animal as timely as some might think.

Committee: Just a comment about that. In the (unintelligible) rabies eradication days we had literally stacks of health papers in the office in Des Moines that were not recorded, they just couldn't get to all of them, but we successfully handled the program through producers that maintained those records.

And I'm not so sure that today, and you know if we get to electronic that's a different situation but we're probably a long ways away from electronic, I'm not so sure that you're not going to go to state veterinary offices and find stacks of health papers that have not been recorded yet. I don't know, maybe some state veterinarians in here might prove me wrong, maybe they get recorded ASAP but...

Neil Hammerschmidt: Yes. We know they don't and I think that's, you know what you're proposing is another alternative to actually keying those records in. And if we can go there it is to have federal funding to support those activities.

Committee: And to follow-up on that, you know, we're - as a state animal health official in 2011, we're still doing things the way we did in the '50s; exactly the way we did it in the '50s. I wasn't around then - well I was around then but I wasn't (unintelligible) then.

But, you know, nothing has changed and yes, we have stacks and ICVIs in our office because we don't have the resources in a state like mine and in other states to keep them or even file them.

And so the key to all of this in meeting these performance standards and some byline or some sort of an electronic system that's consistent across state lines across the country.

And right now it's chaotic because you see different states with resources going at it in different ways; buying their own systems. There are three or four of them out there; some states have started their own.

And I know USDA is heading towards identifying an off the shelf product that many of us will then be able to use that will help a lot, but that's what needs to happen if we're going to meet these standards, in my mind.

Committee: Exactly. And I think that's certainly the perspective that we're taking is that we've got to move from paper-based systems to searchable data. And acknowledgement that we're not going to have a high percentage of ICVIs initially completed electronically, it appears an investment in keying that information is one alternative. And certainly as we have discussions there might be others.

Committee: If we had an electronic health paper -- most veterinarians have computers -- I think they'd much rather have their staff fill that out electronically and they sign it than to fill it out by hand.

If we had it I think you'd find that veterinarians would adopt it very, very quickly. I know in the swine industry we would.

Neil Hammerschmidt: Yes, very good, I appreciate those comments because we have a couple of options available today. We need to address some of the issues; one is of cost and one is from a user-friendly perspective, making it more easy for practitioners to use.

Let me back up. That is one of our highest priorities is to make solutions like that more readily available. We realize the adoption of that technology will still come over time.

Committee: And I just wanted to point, you know, I think it also depends what part of the country and what kind of operation you're running.

I can tell you the livestock vets - large livestock vets in our area, you know, many of them aren't set up electronically. They were also working out in range conditions where, you know, trying to figure out how to bring out a laptop or try to deal with electronics is incredibly difficult.

I think depending on the type of operation, there could be a lot more trouble for a lot of our large livestock vets.

Neil Hammerschmidt: Some brief comments on what we have termed traceability tier designation, so we evaluate the states and tribes on their tracing capability. This would be a way of categorizing the results of those evaluations.

The idea is to having three tiers. And again in your document there's a more full description acknowledging that there is still opportunity detail these out. It certainly acknowledged that that's necessary, so this is a very abbreviated perspective.

Tier 1 would be an indication that the state or tribe met or exceeded the traceability requirement.

Tier 2 - they didn't achieve them entirely but they didn't miss them by a high degree. And the intention there is as we looked at the opportunity, is to acknowledge that Level 3 is where there's significant shortfalls.

The tracing capabilities are not just missed they are missed by a significant degree. There is no gray area.

So there was a sense that we wanted to give an option in the middle where they're not that far off the mark. And so corrective action, working with the industry could probably get them back up to Tier 1 with the idea of avoiding the need to put in what we're referring to -- and we'll talk a little bit about additional requirements.

That's pretty broad and I know there are concerns who inherits those requirements, and we can have those discussions. Is it the state or is it eventually the producers.

And we really didn't get far enough to specify specific additional requirements. This is certainly a topic that we would value others input and feedback on because if we're taking this approach, we know that for it to work, it you're at Level 3 and there's no ramifications, what's the incentive to be at Level 1 or 2.

So some very broad concepts as far as how we look at displaying the results of one's evaluations.

Before we open the discussion up on this, there's some issues that I want to make sure we're clear on, and that's a little bit in regards to the timelines.

And I apologize for not having this chart as a handout because it's going to be difficult to read. But if you looked at any of the materials that was online, it was in the first document referred to as the Comprehensive Implementation Plan, but we'll make this chart as a one-pager available.

Some questions during the break as to what's our timeline for the publication of the rule, and my timeline on the top shows on my screen but not on yours. Do you know if we can fix that? The first bar on my chart is the years, so it's going to be really difficult to read.

But anyway, if we put out there -- yes, I appreciate that Michael. What I'm trying to illustrate is so that first row is the rule-making process.

So if you look at the third rectangle, that's when we would publish the final rule which is targeted for 2012 -- April 2012 -- or the mid October or mid 2012, the middle (unintelligible) reflects the proposed rule target which is April 2011.

So the first column is 2010, 2011, 2012, 2013, 2014; 2015. So the cattle implementation really shows where we are at as we move forward with Step 1; let's ballpark it at the middle of 2012.

And then you see the assessment phase with a broad range anywhere from mid 2013 to 2014; plus or minus. And then full implementation where we want to make sure we're clear that there is no precise date being established in the regulation for when the requirement for the identification of that class of animals would be enacted.

That is dependent on the assessment phase. Working through the evaluation that's been designated as the assessment phase, so no specific implementation date and that's why you see the broad line there on cattle implementation on your far right.

Compliance factors I think are very important, just acknowledgement that as we start the process we must have a high level of compliance with the

regulations because if we don't, we're not going to achieve our tracing capability performance standard.

Cattle have to be identified and other species have to be identified. We've got to have compliance with the ICVIs, and we also want to make sure that we are properly collecting ID -- official ID -- at the slaughter plants.

So all of these points are going to be evaluated from level of compliance because I don't think we can expect a high improvement in traceability if we don't achieve a high level of compliance.

And I don't think we need to talk heavy handed compliance but, we certainly recognized that if we have a regulation out there and we forget about it early on, we're probably not going to achieve anything is the point.

And then probably the key point we want to make here in regards to the traceability performance standards, an indication that even in 2011, the first rectangle, we're still working at establishing traceability benchmarks. What is our current capability?

And we're trying to put some evaluations in process that we don't have to evaluate every state but as a nation, where are we at with some of those measures so that here is where we're at today. The whole idea is to make progress.

To measure our progress we've got to know where we are at today, so that's the idea.

Then the next rectangle is, establish national traceability baselines. As this regulation is put in place, what are the results that we're seeing as a result of the regulations? Are we making progress?

And after the regulation is in place for a certain period of time, we should be more comfortable in updating that other chart where the performance standards are defined.

Should it be 80% or 95%? Should it be a half a day or two days or four days? We don't know. So I want to make it clear that those are, as a result of discussion given kind of what we thought was the best estimate at this point in time, through that baseline review establishing those, those will help us set those more specifically.

And then the last rectangle at the bottom is way out in 2015 where we would actually formally anticipate we'd be evaluating states and tribes on their traceability capability in comparison to the performance standards.

So even if we're looking at a final rule in '12, these traceability performance standards really don't come in to play formally for a few more years. And I think that's the point I was trying to make earlier, we've got to grow in to this over time so that the animals we're tracing were moved and tagged according to the regulations at that point in time. We can't go retroactive on these regulations.

But the point is, these traceability tiers are out there. We've intentionally not put those types of measurements in stone because I think we do more harm that justice in trying to predict that. So we can be criticized for not having a complete description, but at the same time that was an intentional approach by the working group saying, well we just really need to keep evaluating this and take into account what we learn as we go forward.

Key points - yes, please.

Committee: ...sharing the timeline with us, knowing how things can move and the whole process of having to get it in the Federal Register, have your comment period; address the comments, before you can get to the final rule.

I think we really strongly urge that the agency has the ability to handle the expected number of comments, turn around that final rule, get the proposed real publish done, you know, as quickly as you can so that we can really get to the final rule by spring of 2012. It's so essential to have that final rule so we can really make progress.

So I know that - I'm sure you're expecting thousands of comments. And so whatever agency resources you need to handle that and keep that process moving, we would be very strongly supportive of making that happen.

Neil Hammerschmidt: Excellent point. And we do expect a significant number of comments.

In closing just a point about continued collaboration; again I feel really good about the process we've followed over the last 10/12 months. I think it's reflective on how we've responded to some of the concerns.

As I've indicated, there are still unknowns as far as detail on the phase-in for example and it's identified here. Within the preamble of the proposed rule, there will be reference to an advisory group. APHIS intends to consult an advisory group with representation from APHIS states and tribes in industry.

The advisory group could offer recommendation on various issues relating to traceability such as the phase-in identification requirement for cattle and bison, what additional traceability requirements should be applied, the states and tribes that do not meet, our proposed performance standards, and

feedback on the effectiveness of the very elements of the traceability program during the implementation process.

So it's really the next phase of this as the regulation is - the final rule is published; what other issues do we need to cooperatively address. And these are just a couple of examples.

(Kim), Michael, it's my understanding that maybe that's part of the discussion to follow.

So we've asked a lot of the questions along the way. I appreciate the questions, any that you feel the urge to present at this time before I conclude my part? And I'll be here.

Michael Doerrer: So the time is about 11:30 now. As you see on your agenda we have basically until three o'clock today to discuss traceability. So that is a block of time that you, the committee, can use to begin your deliberations about traceability.

I think it's important to clarify as Dr. Hoenig said, exactly what the expectations are for the committee as it relates to traceability.

Obviously traceability is one of the USDA's most pressing topics; one of our highest priorities. Certainly one of the highest priorities for the Secretary.

As Neil said, the proposed rule is slated for publication in April, so approximately three months - three and a half months from now.

So what is it you're expected to do as a committee? First and foremost it's important to clarify that you are a committee of representatives. You represent various segments of the wider agricultural community. The Secretary selected

you based on your diversity and your ability to represent the view of your constituents.

So first it's expected that in your capacity as representatives, you would be able, in rather short order, that is over the next six to eight weeks -- over the next couple of months -- to determine whether there are any urgent, pressing issues related to the proposed rule that you feel it's imperative that the agency be aware of, so we're talking show-stoppers.

Are there issues related to the proposed rule and the text of the proposed rule, that you believe the Secretary should be aware of now, before the publication of the proposed rule.

Barring that, in the longer term, we would expect that the committee would be able to also comment on the proposed rule after it's published, before it becomes a final rule. So, you know, as you know, we have the ability -- obviously that's what it's for -- to adjust the rule after it's published as a proposed rule before it becomes a final rule.

We take the comments we receive into account and adjust the regulatory text as needed. So that's another opportunity for the committee to have input into the regulation.

And then as (Anil) was talking about, there would also be opportunities for the committee to comment as provide recommendations on specific issues related to the implementation and evaluation of the new framework. So that's in the longer term.

So we can talk more specifically -- and I would ask Neil and Dr. T. J. Myers who is the Associate Deputy Administrator for National Animal Health Policy

and Programs. We can talk more specifically about, you know, are there specific questions that we would see the committee addressing.

The intention now, today, is for you to be able to basically come away with the information that you need to begin your deliberations, to begin thinking about how you'd like to go about forming your recommendations.

We would expect today that you would begin thinking about how you'd like to organize yourselves to evaluate the information you have and begin forming recommendations.

We would expect today that you could ask questions of the man experts we have in the room, to clarify your understanding of the framework.

We would expect that we could talk about what additional information and data you need in order to evaluate the framework as it's been presented.

So these are the sorts of issues that and the kind of discussion that we would expect you to have today.

Is that clear - are there questions about that? All right, so I would ask Neil and T.J. may, as a good way to start us off, if you want to talk for just a minute or two, more specifically about the kinds of issues that you would really appreciate the input and the guidance recommendations from the committee.

And then I would ask the committee Chair and Vice Chair to maybe lead us in the discussion for the next, you know, 45 minutes or so, and then we can continue our discussion after lunch.

Is that agreeable to the committee? Very good. And T.J. actually if you want to -- John had to leave for a while, so if you want to join us at the table.

Speaker You know, and I think we could identify some of these by species, but certainly as we've indicated, you know, the cattle is probably the species that's going under the most change through the regulation.

And we know that there are a couple of issues of concern. I think we identified some of those that came to our mind on the slide. A big one I think is the whole concept of additional movement requirements, if a state or tribe does not meet the traceability performance standards.

And you know that's again, far down the road, but yet dialogue early on I think might help us - direct us in the right direction, what is a possibility from your perspectives without question phase-in of the (unintelligible) feeder cattle or the young cattle under 18 months of age.

You know, we've left it intentionally not very prescriptive because again, I think that could do us more harm than good. But the intent there is through a collaborative dialogue and how we structure that to make sure the stakeholders most directly involved with those issues are heard and understand. So we appreciate those issues before we attempt to move forward.

What was the other issue? It's still up on the thing; it should be.

Don Hoenig: Just another issue about the process but I talked to - that Judith and I talked with Michael about during the break, this committee has the ability to meet outside of this in-person setting.

We can meet via conference call I understand, to discuss administrative issues?

Michael Doerrer: Yes, that's the other issue I wanted to clarify. This obviously is - the committee - we had planned for the committee to meet in person face-to-face at once, hopefully twice, over the course of the year, but we have the ability to meet any time you want by phone.

We can - yes, we can do conference calls. We have a standing line. Those calls, if the committee is engaged in deliberations, those calls will be accessible to the public just like face-to-face meetings, so it will be virtually the same.

We can also, if there are administrative - particular administrative issues that you want to address, those sorts of things; we can hold calls any time basically.

So this not the only venue for you to begin your deliberations - to have your deliberations. This is a venue for you to at least begin to figure out how to have your deliberations and we can at least agree on that.

Committee: Michael, from just an organizing standpoint and coordinating standpoint is it any more difficult to have the calls open to the public than to hold a closed administrative call?

Michael Dorr: No.

Committee: I mean what would...

Michael Doerrer: No, no.

Committee: Okay, thank you.

Michael Doerrer: Well it's obvious to me that traceability is a (unintelligible) right now with the USDA which is one of the reasons that they gathered us here so quickly in the middle of January when we could have had a snow storm and all be snowed in, but we all got here fortunately.

John Ferrell: Yes, and I think we will get more of the positions as we go on in this discussion. I think I wanted to do was make sure that any issues of clarification on what was just presented to us be ironed out right.

Right now we have the people here who can answer those questions; T.J. and, you know, John Wiemers.

So I'd like to give the opportunity to everybody at the table to at least in the USDA on any issues of clarification, and then move on from there. As far as what, you know - as Michael said, I think more importantly after a study, are there any showstoppers.

And so what we've heard is the train is rolling down the tracks with the proposed rule. The language has moved beyond your level, right. And T.J. could comment a little bit more on that, but if there is anything that, as Michael said, that is a showstopper, then we ought to get that out in front first, and we have time to do that.

We don't have to do that within the next hour or within the next two days. We can do it within the next six to eight weeks, so there some urgency there but not extreme urgency.

T.J. Myers: This is T.J., you know, just to expand on what John was saying and what Michael said, for those of you who may not be familiar with the regulatory process, once the agency and the folks that are here representing the services

have developed and drafted a proposed rule, that there are a certain number of clearances that it needs to go through before it actually hits the Federal Register as a published document.

And that's where this rule currently is. It's working its way through that clearance process, so that includes (unintelligible) office of General Counsel to make sure that it's legally sufficient.

Going through the Budget Office to make sure that budgetary considerations have been looked at; going through departmental clearance for policies.

And then if you've ever read a proposed rule you'd see there is always, you know, an environmental assessment; a paperwork assessment; a number of different assessments that are done on any particular rule.

So Michael mentioned six to eight weeks. If we are trying to get this published in April, I would encourage you to identify any red flags, showstoppers; anything that you think we've forgotten to consider. As you've heard Neil discuss, we've focused a lot on cattle because that's where the greatest need has been. That's where the greatest number of issues has been.

There may be things that we've overlooked in our focus on cattle that we need to hear about before it gets published. But the closer we get to April, the harder it is to go in and change language and still meet that April publication date.

So the earliest that you can identify issues that you think need to be addressed before something gets published as a proposed rule, the better. So I would just encourage you to keep that in mind.

And then as Michael said, once it is published there is multiple opportunities for this committee to assist us in looking at comments from the proposed rule and making a final rule as good as it can be; helping us through that implementation process until we have that final rule.

Committee: I'll throw something out on the table. Maybe it's a showstopper; maybe not.

I had not seen anything in what you have sent us to read that explains why this traceability program is necessary. Do you want me to expand?

T.J. Myers: Sure.

Committee: Yes, to begin with there's no list of what disease you're tracing. I think producers out there are perfectly willing to go to the time and expense of participating in a trace if they see that there's an economic return for that if you are dealing with a disease that, you know, we as an industry have determined that we want to do something about.

But your documentation that you sent us here, the 60 pages it doesn't explain why it's necessary. I understand why it's desirable from the point of view of USDA and veterinary epidemiologists, but desirable and necessary are two different.

T.J. Myers: We have not focused on specific diseases to trace because what we have been thinking is that the need for traceability is the need to be able to respond to any particular disease that might come on.

It might be (unintelligible), it might be tuberculosis; it might be (unintelligible) or even influenza. You can't predict what that disease outbreak might be that would require us to be able to trace and identify

animals that have been exposed to a particular disease quickly so that we can (unintelligible) the health community respond to that disease.

So we have not focused on a specific disease, but the need and the purpose is the ability to be able to respond quickly to these events.

So Neil, I think in our earlier public meetings -- and it will be put on the Web site -- we talked a lot about what the need is and what the purpose is. So if you have those documents that haven't been included in what the Committee has seen already, we can certainly provide to Committee members.

I will give you an opportunity to chime in as well Neil if you like.

Neil Hammerschmidt: Well yes, I think it's certainly a good point that we need maybe to back up a little bit and share the documentation on the justification of the need for traceability I think Dr. (Clifford) mentioned specifically for cattle.

TB traces today can take on the average of 180 days. That's specifically I think, in the eyes of animal officials, and there are those around the table that can also talk to it from an animal health perspective as well as a producer.

Is that acceptable, the amount of time that it takes to respond to what we already know. And we can certainly specifically pull out case examples of our capability today that we feel very specifically justified that we need to put something in place that we no longer have.

Why is it an issue today and not 10, 15, 20 years ago? And I think if we look at it, regardless of the species, why are sheep and goats okay as is? What did you put in place; a program to advocate Scrapie using identification.

If we still had prevalence of brucellosis like we did years ago, we probably would not be having this discussion on cattle because a high percentage majority of the breeding cattle moved on a certificate and were officially identified.

Today we have official ID that used to be probably in the 90% down in the 35%; untraceable. So I think what we're really trying to be is proactive to make sure we rebuild the level of traceability that we had in the United States quite a few years ago.

We recognized that our tracing capability has a greater void today in the cattle sector than in did 10/15 years ago. And, you know, it's kind of a positive in a way that because of our success with the eradication of some of the diseases, we have inherited a void in traceability. When in the sheep industry let's say, you eradicate Scrapie, will you let your traceability program die away or do you want to maintain something that achieves that.

So I think in the cattle industry part of our success in eradicating some of the major national diseases has caused that void.

At the same time we see reoccurrences of some of the diseases. TB I think is a good example where case studies show that we really, if time is the issue in responding adequately and appropriately to a diseases, we have significant failures.

Committee: We have at least three.

Committee: Yes.

Committee: We talk about one health; we need to think about one global population. Today, unlike 20 years ago or 50 years ago, people are moving all over this world.

And if you - we just had an exercise where some of our Board members went to the Port of Entry in Florida and they were astounded at the pile of meat that was collected in one day down there that was contraband. This is meat that's coming in from countries that have foot-and-mouth - all kinds of diseases.

In our industry over 20% of our product is exported today. So it's critical that we would identify a disease quickly and contain it if we're going to maintain foreign markets.

And we're not just concerned about diseases in the swine industry because we've got these inter-species diseases, and so we're as concerned about what happens in the cattle industry and the sheep industry as we are in our own industry.

So as far as the justification for traceability it's the viability of the livestock industry in this country. I mean I don't know how else to explain it.

Max Hernandez: Excuse me; you know what I think happened; people don't know what it is. When I was 9-years-old in Chile we lost all our cattle to the foot-and-mouth disease and I was a witness.

When the Army came and after my father (unintelligible) cut their (unintelligible) and [dug] a pit for days and days. I remember my mother, my brother, myself - everybody crying. You know, we lost everything.

And after you go through that you really are a true believer. You know, then they burn it and they cover the pit and then we start all over again.

I was about 9-years-old; I think it was in ’49. But that really makes you believe, you know, that this is completely necessary. We are not exempt. Someday, you know, we’re going to get a big check-up here with these diseases.

Committee: I have to echo that. A life change or career change for me was when I went to England in 2001 and saw foot-and-mouth disease and that changed my whole outlook on things.

But I won’t go in to that now, but first Judith and then Charlie.

Judith: I think, you know, I’ve been involved in these discussions a lot and I’ve heard a lot of, you know, what T.J. said and what Neil said and I still keep coming back with the question that - and I know my folks are going to come back with the question of, can we pin this down a bit more?

You know the concept that traceability is important for disease control yes, of course it is. It has a role to play in disease control.

But, you know, to me there are a lot of questions and I’d love to see whatever data USDA has on things like why are the traces taking so long. You know, where are things going wrong? Is it clear that this program will address that?

It’s somewhat specific to me, it also expands on this idea, you know, of (Joel)’s question of what disease are we tracing, I look at the performance standards.

And I heard this comment made during the listening sessions and I go one business day or seven business days or whatever it is. Well whether or how

quickly something gets traced partly depends on the sense of urgency and the budget of the state agency.

So for instance, you know, I'm quite sure that if there were a foot-and-mouth disease outbreak, the state agencies would throw a lot more resources into that trace back very quickly than they do when it's, you know, low path avian influenza.

So does one business day mean one business day with all of the agencies resources thrown at it or does it mean one business day when they're dealing with something like low path influenza?

You know there's a lot of ambiguity when you're not talking in terms of specific diseases. It creates a lot of ambiguity over what do these performance standards even mean. What should they be; why are we setting certain ones.

I understand the USDA's reasoning, but trying to take that out of a context of explaining what diseases there are. What's the data on the timing of the current traces, what's the data on why these traces fail; it makes the conversation very difficult to, you know, to move forward with.

Committee: Charlie, go ahead.

Charlie Rogers: Is it legal for this committee as an extension of the federal authority, to comment on a formal rule making process?

Michael Doerrer: What do you mean by comment on a formal rule making process?

Charlie Rogers: Well, we're an extension of a federal authority. Is it legal for us to comment on a rule making process?

Michael Doerrer: Yes.

Charlie Rogers: It is?

Michael Doerrer: Yes.

Committee: Okay, so that's a new one.

Charlie Rogers: If we comment on it, is it going to do that as a consensus; the whole group will agree on that comment?

Michael Doerrer: Well first, it is - when you say, again comment on a formal rule-making process, it is legal for you to comment on regulatory test; regulatory proposals that USDA has. And in fact that's what the Secretary has convened you to do.

The second part of your question; does the Committee work by consensus, right?

The Committee presents recommendations as a whole. So you all will work together to develop your Committee's recommendations and then those recommendations will be presented to the Secretary to the Department.

And Dr. Hoenig and Ms. McGeary will take the lead in working with you and figuring out, you know, how to develop your recommendations and how to present them.

Does that answer your question?

Committee: That's where my question comes in is maybe just for further clarification, but there's a working group that has met and done many conference calls and has visited this issue thoroughly.

There is a letter from the CIDG that has the three largest cattleman's group all signing off on their suggestions.

Is it our task to work in tandem with some of those groups, especially with cattle being the primary species that we're - you know, that is being devised for or is it our task to bring forth different issues?

It's my opinion that I don't want to go reinvent the wheel and this has already been done by this working group.

But from everything - I'm not part of it but, our organization has been. And it sounds like a lot of progress has been made.

[So] I don't our Committee to step backwards and two, if we end up going different directions. We're not getting any closer to a published rule.

Michael Doerrer: In tandem; no. I think it's important to clarify that this Committee is a discreet, standalone committee. It is not related to the Traceability Working Group.

And I think it's important to clarify the composition of that group and this group. The Traceability Working Group -- and T.J. and Neil can clarify further -- that working group is made up of state and tribal official representatives, and federal - state, federal, tribal.

So that is a government working group. It is a working group of government representatives.

This Committee is not, right. You are representatives of particular segments of the agricultural community, specific groups within the agricultural community. You are not here as official government representatives.

Now some of you represent state animal health officials. Obviously those are the government entity - state animal health officials. That's the government officials.

But, you know, Dr. Hoenig for example, is here in part to represent the views of state animal health officials as a constituency.

So I know it's a fine line, but you are not here to work with the Traceability Working Group. Your recommendations are separate and apart from that.

So the Secretary is seeking the guidance and recommendations of this group as a discreet group representing various segments of animal agriculture.

The Traceability Working Group is something completely different and apart.

So I don't know if that - does that sort of clarify.

And this group is governed by the Federal Advisory Committee Act as well. That's another important distinction...

Committee: Right, right. And just, just...

Michael Doerrer: ...whereas the Traceability Working Group is not.

RJ Cabrera: And just to tack on to what Michael said, a word or two about the Federal Advisory Committee Act. We call it the FACA in government; everything has an acronym in government.

The spirit of the FACA is about public participation. And what you're asked to do as a member of this committee is to outreach. You're expected to reach out to the stakeholders in your community, to network with the organizations that you are associated with.

To talk to them; to find out what they're thinking. You know, we're interested in finding out what the stakeholders are thinking about these issues.

Number one, traceability, (unintelligible) Secretary is most interested in right now. It's the number one topic. You know, the Secretary wants to know, what the stakeholders are thinking. And you've been selected to work with the community of your peers to find out and bring that information back. Is that helpful?

Michael Doerrer: I think this group should not ignore what's been done prior by the other group. I mean they've been working that for a long time. They've made tremendous strides. So we need to remember that and possibly more input should come from those groups.

Michael Doerrer: And, you know, present it was a product of that work. So that's what you're deliberating on, you're deliberating on the work that they've done heretofore.

Man: Maybe just to expand a little bit on what Michael said, that initial working group as he said, it was made up of federal, state and tribal members because the Federal Advisory Committee Act requires that if we are going to gain the kind of input that we need to develop these goals, there are a couple of ways that we can do it.

One is to have an Advisory Committee like this and another is to have an inter-governmental conversation. So we're essentially taking both approaches. But because of the makeup of the two groups, they bring different perspectives.

So you're correct in that governmental conversation that we've had with the federal, state, and tribal folks to develop the framework to date has been very key in bringing it to where we are and hammering out a lot of issues.

We've done a lot of outreach to industry during that process through phone conferences and other meetings and other mechanisms, but I think this committee has the ability to really be those representatives of a broad industry producer consumer type of constituency.

And so we do encourage you to go and do that outreach to those folks that you represent to bring back other ideas that maybe we haven't heard yet.

Committee: Okay. So I'm trying to completely understand the purpose of this in reference to cattle. And I'm thinking about a couple of different scenarios.

Mostly what we're talking about is interstate movement and cattle going to slaughter through traditional type channels and not every farm works that way.

In my particular situation , you know, my cattle are born on my farm and stay there until they go to slaughter, but I might bring in a bull or some heifers or cows from out of state.

Now what we're talking about is tagging if that animal was coming interstate movement. And (unintelligible) given a slower, you know, disease it's not - it

doesn't have as rapid or as big an impact as say something like foot-and-mouth.

I guess then I am asking is whether the goal is to quickly ID and control a foreign animal disease like foot-and-mouth disease. And how will tagging interstate movement accomplish this because for a foot-and-mouth disease this seems to not offer an effective monitoring and trace back in that particular situation.

Dr. Clifford: If I may, our authority as a U.S. government is for interstate movement and interstate commerce.

Now we've narrowed this to interstate movement specifically and we've said that it's up to the states to determine how they want to regulate traceability and animal identification within their state. So this basically makes that distinction. So it's really a state issue beyond the interstate boundaries.

By that I mean having said that, all of us recognize I think the importance of having good traceability, if there's an introduction of a highly contagious infectious agent that's rapidly spread throughout the U.S.

But I think, you know, also we recognize that I think the original NAIS tried to get at a lot of that, but it was also a program that was very expensive and wasn't well received from sectors of the industry.

Brian Thomas: Also, we have been doing outreach with this program. And the question that was brought forth to me was on this: cattle or bison moved interstate must be officially identified prior to the interstate movement unless they are moved.

And in the community - one of the tribal leaders said the commuter herd agreement can be used, but it's up to the tribes. The question is, is it up to the

tribe to use part of this policy to put into their grazing ordinances to say, well you can't use that commuter. You have to have your ICVI prior to them moving on to our reservation.

So it would actually be up to the tribes to develop their own traceability standards as per going off of this regulation.

Speaker: So Brian, I guess can you help me a little bit. You're talking about animal movements within the tribe itself; totally within the tribe or you're talking about from other locations, back?

Brian Thomas: Like for example we have reservations in Idaho and Nevada, we also have buffalo on the reservation. But an individual, when they've seen that part of the comment, the tribal leader responds, "Well, we can't let you just bring your buffalo or your cattle here because you had bison intermingled with your cattle. It might have brucellosis. You know, we don't know how clean they are."

And so I guess and this is the part we need to put in our ordinance or grazing ordinance or tribal ordinance is that, before you move your livestock to our reservation, they have to have their own - you know, they have to have ICVI because the tribes do that.

Speaker: So the commuter herd is an agreement between two locations?

Brian Thomas: Yes.

Speaker: It could be between two states, two tribes, or a tribe and a state. So if you don't agree to the commuter herd agreement then they shouldn't be allowed to move their animals, just because that's an exception.

We built that in though, where there's agreement between states or between tribes. So it's up to the tribe.

Committee: So it's up to the tribes to develop their own policy...?

Speaker: Correct....using this as an example to go back on.

Committee: John, another way to say that is that you have federal standards for interstate movement, but states and tribes can act more stringent movements right, as long as they don't have less movement - less restrictions.

I mean within a state for example, you can make...

Speaker: Within a state yes. The reason I'm hesitant with that comment is because I can't - we can't just [make a blanket] statement that says that a state and tribe can have more restrictive movements than what the requirements are for interstate movement because there will be some examples of, or statement of preemption: federal preemptive authority.

And the reason for that is to bring consistency of movement. So for example - - and I think [this is] the best example we can give is that all states - all states and tribes - according to the regulation for movement in interstate, would have to accept official ID.

Now there's a whole host of official ID as you've seen today, but they have to accept all forms of official ID.

They can't say we'll only accept this type, and it has to be RFID. Because if we allow them to do that then suddenly the state with the highest standard for [this requirement] affects the entire country.

So in general, yes, but there are exceptions.

Speaker: Talking about the commuter herds brought up to me on the Document Summary of Official ID and ICVI, Page 1, the second bullet from the bottom, there has been an exemption for the ID where states could work out a deal, you know, an arrangement for something in lieu of an ICVI.

This particular version of it has that only applying to [cattle] under 18 months, and I had never seen that exclusion have an age in it. I'm wondering if that's something new or is it just something that got inserted by mistake?

Speaker: It wasn't in an [earlier] version. I didn't catch it then.

Speaker: I'm sorry, one of the questions we did have is when is an ICVI required, and we addressed it specifically for cattle with approach intentionally so that the older adult animals would actually be moving across the entire country on an ICVI.

You know, unless specifically exempt—[for example] going direct to slaughter--but the younger cattle, again that's specific from the option of the state, although that was, you know, a point that came through further discussion with the working group.

Speaker: Well I had missed that. My comment would be on that particular one, I think is the flexibility of allowing states to do something besides [using] an ICVI for unique circumstances. My experience with swine health plans waiving ICVIs and doing other things like spreadsheets is dramatically improved, reduced burdens on industry, and helped us.

And I think it would be good for states when they can do it within the context of their guidelines if they work out an alternative. I don't see the reason for

the under 18 months. I would like that taken out to preserve that flexibility we may find a better way for two states to work together.

Committee: I think the showstopper is where we've gone with this program. Well first of all, the compliment I can give it is that it's gotten more simplified and that the average producer is going to be able to understand what's expected of them. And that was not the case when we started with sheep back in '91.

But to me the showstopper is the fact that it's paper-based and I think that's where the program is going to fail us should we have some fast-moving disease.

And I don't think it's realistic, maybe we're just behind it as veterinary practitioners in Minnesota, but most of us don't travel with tough notebooks. Most of us don't travel with a printer, and we're expected to leave that Health Certificate at the farm when we're finished our work.

So whether we can come up with a . . . well then, the other part of it too with the paper-based is, it's highly inaccurate. I mean people don't always make their zeros not look like 6s, etcetera.

And a lot of people, I can't read their writing anymore, just even names. So can we come up with a way that would take our existing, for instance, metal tags and have a sticker. And as you get ready to put that official metal tag in as the veterinarian, you can pull that sticker off; stick it on something that then can be transmitted.

So we have a resource issue and we have a technology gap, but out in the business world we don't have that technology gap. And I'm just urging us to stick to something like Excel that we know how to use.

I have done electronic Health Certificates and maybe I'm just a slow learner, but 2 years ago when I gave up on them, it was because I go do the paper-based ones faster.

So those are my comments.

Max Hernandez: Excuse me, the metal tags sound pretty nice, but in reality - in real life, most of the time, you know, they are lost and then you don't have anything.

And the other problem with that in the (unintelligible) is not (unintelligible). You know, it's just a big problem, you know, if you want to get - to be inspected it takes days.

Probably sometimes, you know, self brand inspectors, you know, it's a common thing because it simply is not the people. You know, it just - you know, it's a terrible problem. You know it don't sound like a big problem here but when you really ready to move, you ready to move, you know.

Committee: This may be getting down in the weeds a little bit but, you know, I hear some comments about - well first of all, Neil has made the point that the - now I'm old fashioned, I call them Health Certificates okay -- ICVIs -- are key to the traceability program.

And when we talk about electronic implementation of the ICVIs, I hear some comments that are negative towards that.

My comment would be if part of the industry is ready to move that way, let's not let the people that are not ready to move that way hold us back. Because -- I'll just use the example of North Carolina -- we have millions of pigs that move from North Carolina to the Midwest, and those are done with like you said, electronic plans. And it's very functional; it works very, very well.

So I understand that somebody that has just a few animals and the veterinarian goes out there and may not be able to use an electronic. But where we can, let's take advantage of that technology.

I mean it would be ridiculous not to try to move forward into the 20th century here with computerized records.

And again, we're going to have stacks and stacks of papers that are not going to get recorded. And like the gentleman said, one of these days we're going to have a problem.

And if it takes us two weeks to find it with the millions of pigs that we're moving and cattle that we're moving and everything, this - if it's foot-and-mouth it will be over the whole United States before we get a chance to get our arms around it.

So I'm just advocating, because your segment of the industry isn't ready, don't hold the rest of the industry back.

Committee: I fully agree with that because also as USDA as a whole is moving to its recordkeeping, I would rather be able to have one set of records and track those records, you know. If I'm a producer that can do it electronically in a spreadsheet or, you know, choose to do it electronically and then track the gains on my cattle and do all of that at the same time and then at the point of sale be able to certify those records, there's something like that.

Because I'm one that he's talking about. I live two and a half, you know, hours from anywhere and have never seen a vet on our place ever. A brand inspector, you know, but that's because of our bucking horses.

And so on our cattle I just think [it would] be really proactive for us to be able to do one set. I'd rather not have a folder this thick for APHIS and then one for NRCS and yet another one for FSA because I'm already fighting the LIP Program and it's a great program, but the documentation is very extensive. I'd rather be giving it all at once for a good purpose.

Charlie Rogers: I think there would be some remote areas that you're going to have trouble getting a veterinarian available.

In New Mexico we got the New Mexico Livestock Board and they are available in all areas. The work under the State Veterinarian and they also do everything electronically; everything is done electronic.

They will have a premise - they'll have a GPS on every inspection they write. So there are other options out there for when a veterinarian is not available if we'll look at those.

Committee: I know we're predominantly talking about cattle at this point, but you were referring to feeder pigs going out West.

Okay, you know, there was talk at one time about a batch lot type of identification under [as] with chickens. But, you know, say you're a farmer and you're sending feeder pigs out to the Midwest, you know, are you going to - are we going to allow them to do a batch type identification system, and who's going to end up paying for that tag.

And let's talk about on a per animal basis. So instead you've got a smaller farmer who may be, you know, maybe raises 250 pigs a year and they don't raise them, you know, in a hog house or whatever and they're not doing - it's not an all-in, all-out type, you know system - not a batch lot system, it's a continual harvest system.

Is that placing more burden - financial burden - individually - per animal, on that farmer than what the farmer who has, you know, 2000 hogs in a hog house and can just do one ID for the whole batch because it's going at one time to one place.

So that's kind of a concern for me—the financial burden on those farmers who maybe don't harvest in what's considered a modern manner or traditional type manner.

Max Hernandez: Well, I think, you know, that the consumer will have to pay more for meat or produce or chicken or whatever.

Committee: But if the whole batch is going out at one time then - and they can only do - and they can do one batch ID per head, the cost is not the same as it is for the person who's harvesting, you know, six or ten or whatever at a time continuously out of their group.

To me I'm wondering what...

Speaker: Can I respond to that?

Committee: Yes.

Speaker: The group - it's not all about all-in, all-out. It may be a certain number of pigs out of a barn, but whatever is on that truck is the group ID, okay.

And so, you know, it would be no different. Now quite honestly your example, I don't think there would be very many of your producers that would have ten pigs that would probably ship them to the Midwest unless they were show pigs or something like that.

So it's the same - the process would be the same. The group is whatever is in that group. It's not, you know, the barn that's in North Carolina, it's whatever that shipment group is, that gets that group ID.

Dr. Parr is that right? Is that how you understand it.

Dr. Parr: Yes, the concept there is, if it's one animal or 1000, it becomes an issue if they've mixed with animals from another group. And if they move even if it's one and they move as one and are harvested as one, the groups still apply, as I understand it.

Committee: Okay.

Speaker: I think we're going to try to stick with our agenda and here and break for lunch now. And as you heard the Lincoln Room is on the third floor.

Facilitator: Yes. In case some folks arrived after we began, I'll go over those pieces of information.

The Committee members and APHIS employees are invited to have lunch in the Lincoln Room which is part of the Secretary's Dining Room. It's on the third floor in the Whitten Building here.

Members of the public may have lunch in the Café here in the building; it's in the basement. Take the elevator down to Level B or you can exit the building and eat where you'd like. You just have to go through Security to come back in, okay.

Committee: (Unintelligible).

Facilitator: Yes, you're not required to eat with us but you're invited to come.

Committee: (Unintelligible).

Facilitator: That is true, yes. That's true. So when we return we're going to do a little bit of work. We're going to identify areas where we possibly need more information and come to some kind of agreement on how we're going to proceed next, okay.

Please do me a favor and take your trash with you and clean up the room.

Yes, Dr. Morris?

Committee: (Unintelligible).

Woman: Yes, you can leave your things here. For folks that have coats, there is a coat rack right outside the room if you'd like to hang it up it will be perfectly safe. Thank you.

LUNCH BREAK

Return to Animal Disease Traceability Discussion

John Clifford: First of all I'd just like to philosophy. It's not even philosophy, it's just comment on a date.

Probably a lot of you have heard that this is the 50th anniversary of when John F. Kennedy gave his first inauguration speech. And to me in my life, that was a really significant event. Even though I was only 10-years-old those words resonated down throughout my life and I think affected the direction I headed in.

And I think everyone here, if you're of that age you remember that. You remember those words and maybe it affected you the same way.

But you're all here doing that work. You're working for your country. You're working for the agriculture industry. And I think (unintelligible) for doing that.

And to me that moment 50 years ago today on the steps of the Capitol were an extremely event in my life, even though, you know, I didn't hear the speech but I remember the words as I grew.

And so I just would like to start out the meeting saying thank you for being here and thank you for your input. This is an important work we're doing and I'll leave it at that.

I did get clarification - somebody asked me can this - again, once again, can this Committee comment on a proposed rule. The answer is yes, if this Committee chose to we could comment on a proposed rule after it's published in April. Anybody could comment on the proposed rule, so we can consider that at the time.

I think what I'd like to do now is continue our discussions from this morning leading towards are there any red flag issues; are there any showstoppers. And we might not be able to rally identify them until some of us have had a chance to go and talk to some of the groups that we represent.

So I don't think there's an extreme sense of urgency but there is urgency to it because I think we need to get that ironed out within several weeks. And we could potentially [set up] a conference call again in a couple of weeks to get back to that. So I would like to continue that discussion.

Does anybody else have any other thoughts on that before we get started. Chuck...

Chuck Massengill: John, I would repeat the concern I spoke earlier is that at the implementation phase that we look at the application of the entire process, not just the application of identification devices as a measure of success before we move in to Stage 3.

And the other thing, I spent the last 30 years of my life managing and evaluating animal health regulatory programs and I know that Health Certificates in many states are stored in some sort of a device or box or file - something, typically based on the state of origin of the certificate.

And when we found an Arkansas ear tag in Missouri, we went to the Arkansas origin Health Certificate to look for that documentation. And it may have come to Missouri from Oklahoma or Kansas or Texas or Iowa.

So I would hope that the people that look at this, being able to gather that information on the state of origin - immediate state of origin of the animal. In the example, I believe the animal came to somewhere from Texas, we probably would have difficulty finding that and I hope it wouldn't put that high on our list because that information is going to be awfully hard, I think, to find.

So I guess I would hope that - the idea of getting where we can have a query-able data source, that's going to make a big difference. But golly that's expensive.

John Clifford: The other thing I want to say that I forgot to say was that we are commenting right now on a framework which is somewhat specific. But what Neil presented to us this morning was not the text of the proposed rule.

And the way Michael explains it to me is that they really don't want to share the text of the proposed rule although they could, until it's published because it might change between now and when it['s published and then some people would have some heartburn over the fact that it changed.

So they've been as specific as they can about what's contained in the rule by presenting that framework to us.

So I think we - just to get that clear, we're commenting on - we're discussing that framework today.

Charlie Rogers: And John, I think if you're talking about showstoppers, something you can consider -- and I'm just going to use numbers that are example.

If we start with a dull cap and we're identifying ten million cattle a year that are crossing the state lines, if we implement feeder cattle too soon -- and I would be thinking you're talking about adding 20 million cattle. So now you're at 30 million cattle.

If you add feeder cattle too soon you could collapse through the system. So we need a system that is successful and functioning before we add feeder cattle.

And also when we're talking about feeder cattle we should also remember that the average movement of feeder cattle is one time. They start at the ranch; they're sold one time; they're in the feeder. That's the average move.

Now there are more. Some never change ownership. Some ranchers retain ownership through the feeder. So those cattle with the bookend system - feeder cattle or cattle under 18 months of age - are going to work well with a bookend system.

We don't need to be thinking about reading movement and once again adding to the system. And I think that if we kind of bear that in mind, we do not want to overload the system.

John Clifford: Everybody understand what the bookend approach is?

Charlie Rogers: The bookend approach would be the rancher, farmer, whoever, puts the metal - let's keep it as simple as possible - it's a metal clip in there. Now that movement - okay, that calf goes to Clovis Livestock Auction and it's sold. But I don't have to record that movement because that animal is going straight to the feed yard.

Okay, so now you have a problem at the feed yard - a disease there. You've got this tag number; you've got the original, all you have to do is fill in the blank. And that's a bookend system where you're not reading movement.

Because if you're reading movement of feeder cattle or cattle under 18 months of age, you're not only adding 20 million cattle to the system, you're adding - recording that movement also. So you're maybe doubling that.

So you are [over] loading the system. We need to always keep in mind the load on the system [and] speed of commerce. When it comes to feeder cattle, speed of commerce is a big thing.

We do not want to slow speed of commerce down. And reading individual numbers on feeder cattle is definitely going to slow down speed of commerce.

And I don't see the need for that because it will work as a bookend system and accomplish our goals.

Committee: I wanted to build on what you were saying. I was talking a little bit with Neil at lunch and saying that, you know, his presentation this morning helped me to appreciate that the reason the ICVI stuff is being incorporated as an attempt to continue the concept of getting some movement reporting, but not place the burden on the producer.

And I appreciate that intent but I worry about it swamping the system, as what Charles was talking about here.

And I question the need for the intermediate movement reporting. I realize that we're now trying to shift some of the burden of it, but the question still goes back to why are we worried about the intermediate movement reporting.

And again, one of the specific pieces of data that I think would be useful for us would be to look at the success of the Scrapie Program and look at - because there isn't any intermediate movement reporting.

The Scrapie Program is the true bookend approach and what are the numbers on the success and fail rate on trace backs within the Scrapie Program. Because if that approach is the bookend approach that works across the board, you know, the question becomes do we need any intermediate movement reporting, whether it's feeder or breeder even.

I mean why would we be introducing this extra stress on the system.

Boyd Parr: Just to comment, you have to be a little careful. You know, we chatted at lunch too. For Scrapie it's a disease that's transmitted at birth. And so if we design the whole system based on one disease we're going to have potential

problems if that happened to be foot-and-mouth and those intermediate [movements] become very interesting.

But it's not even foot-and-mouth and it's a point getting back to one of the things that (Gilles) said, to me as a State Animal Health official, the thing that scares me the most is a disease I don't know about yet that we need to respond to quickly.

So I think that's also - we definitely need to keep in mind those that we do know about, we know we have those to deal with. But this system needs to function for the disease that we have not discovered yet that the public and the industry will need us to respond to.

And I think this framework does, but you have to be careful about the bookend [which] works well in some diseases and management. As I understand Charles, he was talking about it more in the feeder cattle that don't make many movements, whereas the breeding cattle over a long period of time they move a lot of places. And depending on the disease, that may end up mattering.

Committee: And I hear what you're saying (Boyd), but I think my point was a little bit different than how you took it.

I wasn't looking to the question of how successful the Scrapie Program had been at eradicating Scrapie, you know, because that would be a disease specific issue.

The question is when there's a need for a trace back in the sheep or goat population, how quickly can that trace back happen and how successful. What's the success versus failure rate?

Because regardless of the disease, if that tagging bookend system has achieved a high quick rate of traceability, then the concept is would it matter which disease we're talking about.

Boyd Parr: Yes, but I think they define their success as tracing birth herd and not everywhere they've been in-between. I'm not sure.

Dr. Clifford: I think it's worth it to note that, you know, while there is a perfect system that all of us recognize the burden and that's recording all movements, doing the maximum of everything, that's extremely expensive and burdensome.

There is the bookend system which is probably the least amount that you can do and yes, you can often trace the bookend approach back to the point of origin.

The problem is though is some disease are long incubation diseases; some are short. Some are transmitted in different ways versus others.

If you're only concerned about getting back to the herd of origin it's fine. But in diseases that are highly transmissible, you have to get ahead of the disease. And the only way you can get ahead of the disease is by not just looking at the animal itself and/or of an index herd, but also those animals that they have been in contact with. And that takes into account part of the movement issues.

So when you all think of this, don't think of it as exactly just what you see in front you from a standpoint of tracing. There's data out there that we collect every day. It's not like the Web site where we know everything about everybody.

But, you know, if your animal is vaccinated for brucellosis (Gilles), it's in the system. If you animal is tested for TB, it's in the system. And there is other

contact information about other animals that may have been tested there that day.

So when we go look for an animal with a tag, we're looking at the whole breadth of information we have, including ICVIs. It doesn't matter whether it's an ICVI or just a movement certificate that's in the system because hopefully with time we'll have these in a data system that's electronically accessible.

And what this will do for highly contagious infectious agents is give us the ability to identify contact animals and quarantine or stop movement of contact animals to prevent further spread of highly contagious agents.

Boyd Parr: And Dr. (Clifford), and we are talking now I think about tracking movement of adult cattle in the beginning.

So I'm not advocating that we don't track adult cattle - their movement. I'm not advocating that, I'm just advocating that feeder cattle, you know, be careful of that. If you overload the system with feeder commerce and animal handling, a lot of...

((Crosstalk))

...choose to come in to (unintelligible).

Dr. Clifford: Okay. We understand that and we support it.

Committee: Right. I just think we also need to understand this disease crisis could impact the feeder commerce also. And you've got to balance that against - I mean I know it's going to slow you down a little bit, but think what it's going to slow

down is if you have a foot-and-mouth outbreak; it's going to put you out of business, so there's a balancing act here.

And this thing we're talking about it's certainly not a perfect system, but it's probably better than what we've got now. And what we're talking about now is how we've reached that balance of what's possible and what we really need to get the job done.

Boyd Parr: I'm not sure that this system would handle a foot-and-mouth disease outbreak at it's very best.

Committee: No, it wouldn't.

(Boyd): So...

Committee: No.

Committee: I'm not even sure how much it would help.

Committee: Dr. Clifford was talking about highly infectious diseases.

Committee: I'm not convinced that any system that we had is even much better than what we have now which is assumed to be very poor, would be the least bit helpful if there was a foot-and-mouth outbreak. And so I'm not sure that's a standard that we need to be needing.

And also to build on what Charles was talking about in feeder cattle, I don't know if it's been demonstrated that we need to do anything in feeder cattle yet.

And it looks to me like there's really two different issues on the table. Number one is improving the movement of paper. Move it as an administrative procedure of what is already going on in terms of interstate veterinary certification and adding more animals to be traced, you know, the part that would come back to the producers with putting more tags in and stuff like that.

There's two very different issues there and I think the most important one is to get the administrative procedures working better if what I'm hearing is that everybody here thinks that it's a mess; if that's true.

I probably brought on too many issues at once there.

Committee: Myself -- I truly believe that we should tackle any disease - any emergency with the same force. And then after the problem is solved, [then] we do something different.

But I don't think we should differentiate the diseases, because if they are not taken care of properly they can create bigger problems.

John Clifford: To me one of the biggest issues is (unintelligible) in cows what (unintelligible).

Like Neil said, if you looked at - I'll step back; sorry. If you looked at 20 years ago; 25 years ago when we had the last infected brucellosis herd in New England in 1982 I think; so almost 30 years ago, I would venture to guess that there were twice as many cows in the United States identified officially, as there are now.

And that enabled us to eliminate brucellosis. It enabled us to get TB down to an extremely low level. And we can argue why we're still dealing with TB

and where the origin of it is, but when it takes us 180 days to trace out a TB cow, that's just not acceptable. And a lot of that is ID. A lot of that is ID, a lot of that is recordkeeping.

So to me this idea that we not only need a better system of identification, we need a better system of recordkeeping and we need to head towards an electronic system is just - it's where we need to go.

And I believe that so strongly that I can't stress it enough. So you don't need to worry about where I stand on ID or traceability; that's where I stand.

And I'm not afraid to say it in a public setting because I've seen what can [happen]. And I'm sure that if we got 100% of the cows in this country ID'd, I'm not sure that it would help us in a foot-and-mouth disease outbreak. I don't know whether it would, but it's not going to hurt. It's not going to hurt.

And that's the worst case scenario. And I've seen it and (Max) has seen it in Chile as he so, you know, dramatically told us. And that's my worst nightmare.

And if anything can contribute to helping us shorten the amount of time that we can - that we have to under the restrictions of a foot-and-mouth disease outbreak then bring it on. Let's -- don't bring foot-and-mouth on -- bring on the system. You know, let's do it.

Committee: When you say it, it's not going to hurt, you know, but there are a million something producers of livestock out there in the U.S. And if all million plus have to do this every year; go through this process of putting in ear tags, you know, incrementally, that amounts to a lot of time and money so it does hurt.

And if those producers are feeling that they're wasting their time, you know, they're willingness to, you know, listen to the government (unintelligible).

John Clifford: I think part of it is that we just haven't seen the worst case. And one thing they told me that was when I went to Argentina five and a half years ago as part of a Risk Assessment Team that looked at their ability to eradicate foot-and-mouth disease and vaccinate all the cattle in the country for foot-and-mouth disease.

And what it told me was that that those producers in that country were committed to eliminating foot-and-mouth disease and keeping it out; and that they 99% supported a foot-and-mouth disease vaccination program.

Every cow in that country was identified and they vaccinated 58 million cows twice a year and the farmers paid for it. And we went through an auction in Buenos Aires and saw 10,000 cows go through in two hours.

The ones that were going to the EU were all identified with pink tags -- individual identification tags. The ones that weren't with another tag.

So they did it - the producers supported it. Was there a cost; yes. Was there a benefit; I think absolutely.

So no doubt there's a cost to it but is the long-term benefit of it going to make things more profitable; hopefully.

Committee: Well then - excuse me. Talking about FMD again, Argentina is dependent on exports and we like to have exports of our beef but -- this might be a little heretical -- but we don't depend on exporting beef.

And if we had FMD in this country and we lost our exports, you know, as an industry we would survive.

Now I've worked a lot in Africa where FMD is endemic and nobody notices it, you know. So simply to have FMD in this country as endemic disease is not a catastrophe from a personal production point of view.

Dr. Clifford: I would just recommend that you think about that as yourself because FMD affects not just cattle, but bison, cervids, swine, sheep, and goats. It affects a lot of different species.

And some of the species, for example, I think the swine industry has 30% of their market is in the export business.

Committee: Twenty percent.

Dr. Clifford: Twenty percent, sorry.

Committee: We're trying to get to 30 though.

Dr. Clifford: You're trying to get to 30; well I've heard the 30 (unintelligible), but it's still a large portion.

The dairy industry is involved in exports as far as milk and milk products - cheese and things like that. So I know the beef industry only sells about 10% of their product in exports, but it's still going to have a major impact on the economics of this country. Let's not kid ourselves, it will.

Committee: The other thing I'd add to that, if we think about a disease that's not intra-species and we only have to think back a short period of time when all of a

sudden the Russians weren't taking leg quarters -- chicken leg quarters -- what happened to the price of pork? What happened to the price of beef?

You know we're in a global market and what happens is that if you have an oversupply of any one of these proteins you affect the price of the other proteins.

And, you know, if we had a foot-and-mouth disease outbreak in the United States, I think the next day hogs would be worth 50% of what they're worth today, if we're lucky.

Because we can't eat 20% more of our pork; if we could we'd be doing it.

Committee: That's where my question comes in, it's for Neil or John or (T.J.). From the perspective of USDA, are there expectations internationally for what this program will be, for trade agreements coming up, for exports.

Is there pressure on USDA from the countries that we're exporting to get this established and is it affecting those?

(Unintelligible), you know, we've mentioned other countries where they're doing every single animal and every, you know, single number and, you know, it sounds like their standards are quite a bit higher than what we're looking at.

And so I guess I would just like some kind of overview of what that's going to look like for us.

Dr. Clifford: I think that's a good question, but let me just for a second go back. Why are we doing this; are we doing this for trade; no. We're really doing this for animal health in the U.S.

But [from] the standpoint of doing it for animal health in the U.S., does it have other things that's gained from that, [during] the trade negotiations? Absolutely.

And it's probably not as much from a negotiation phase of saying our animals are traceable, it's the fact that our trading partners are using it against us today by saying they're not traceable. And our product is traceable.

So it's being used against the U.S. today and I think people around this table besides me can speak to that much more effectively than I can.

But I want it understood, we're doing it and our purpose and our mission as Veterinary Services is to protect -- and APHIS -- is to protect animal health in the U.S.

That's our primary component. That's why we're doing it. We're not doing it just to benefit 10% of trade here or 5% there.

Committee: And then I mean to add to that as a responsible country, we set the standard by the quality of our beef for the world. And so we're kind of setting a precedent for the world to assess as well, correct?

Speaker: Correct. And we're lagging far, far behind.

Committee: Sort of back up a little bit to the FMD, you know, the opinion has been expressed that we probably can't get ahead of an outbreak or at least there's a discussion to be held on that issue.

And, you know, you're perfectly right, you know. Cattle can survive a blockage or a stop in exports better than the pork industry could, which really brings it back down to preventing FMD in the first place.

Because once it's in this country and once it spreads into the wildlife, you know, and there's a network of white-tailed deer from here to Seattle and wild hogs from here to Texas.

And once it's in the wildlife we're going to be a long, long time getting rid of FMD.

And so really it may not be within the purview of this Committee but the issue is preventing import of FMD in the first place.

John Clifford: And we agree the best way to approach it is to prevent its introduction. That's why [we're here today]. We're here to try to prevent its introduction. We mitigate risk.

The thing I would so like to bring back; this isn't just about FMD guys, it really isn't. I mean that's the worst case scenario. It's about animal disease issues. It's about - and as Boyd said, it's about the disease we don't know about tomorrow.

So you look around you and see the diseases that have been merged worldwide, those same things could happen at any time in any location. Viruses change; they adapt.

(Unintelligible) emerged in this country in 1980. Under the new approach we're talking about is being able to look at merging disease issues through better surveillance and comprehensive surveillance and being able to then

make good decisions relative to whether it's in the best interest of the industry to eradicate it and hit it hard.

Whether it's best to look from a control standpoint and develop better vaccines and diagnostics for this new emerging disease; whether it's an educational component for the private sector that we provide. . . .

But those are the things that, really, we need to be addressing tomorrow. The industry is also faced with many, many issues today that you're faced with every day on food safety and other issues that are causing concerns out there.

What we're really trying to do is develop a comprehensive surveillance system to help the industry find new emerging diseases to address problem diseases of the day, both on an ongoing basis of management, principles, control principles and eradication principles, not just for FMD. Not just for TB.

We want to help you all thrive -- and you may not want our help...

((Crosstalk))

...well in some cases.

Committee: John, we haven't even talked about zoonotic diseases.

John Clifford: Absolutely. I mean, you know, okay we get NEPA. You know, we've already had our go with influenza. I mean we all went to the public to be able to monitor our livestock when it comes to the zoonotic diseases. That's going to be expected of us.

And that's not going to be, "do you want to?", they're going to demand it and rightfully so, because people die.

Committee: This is somewhat of a procedural question actually for Michael or R.J. -- there you are.

In terms of highlighting, you know, major issues for the Secretary, you know, my understanding from what you guys were saying earlier, as the rule is basically written, you know, and it's going through the process, I suspect from what I'm hearing around this table that we may not have, you know, issues that a majority of the Committee are saying are, you know, red hot, you know, it's going to be a bombshell.

On the other hand for certain individuals there are going to be issues that we're going to come back and say, our constituency considers this a bombshell.

Is this something when we're - are we going to present to the Secretary a majority vote of the Committee of here are the bombshells, or would it be appropriate as we develop this over this following, you know, next several weeks to have a list of this isn't a Committee consensus; this isn't a Committee majority, but members of the Committee want to give you a heads up that these may be bombshells when the proposed rule is published.

Michael Doerrer: I think the latter is more the case. There is no requirement that, you know, you have...

Committee: It's not recommendation?

Michael Doerrer: ...50% plus one in order to submit.

Committee: Okay.

Michael Doerrer: So, you know, the Secretary and the Agency were looking for guidance and your input. So whatever form you think that ought to take is what we'll take.

Committee: Thanks you.

Committee: And Michael, if I might add, what I'm hearing as I've listened to the -- can you hear me better -- okay.

What I'm hearing as a result of this latest discussion, it could be broken down into several components.

I'm hearing you say you may need some additional information in some areas. I'm hearing you say there is still some areas that are unresolved for you. I'm hearing you say that you're having some issue with some of the areas that you may need to go out and talk to your constituents.

So I'm seeing perhaps a white paper or some type of report with different components.

You may want to do some research with your stakeholders. You may want to break into some groups; let's call them subcommittees. No - okay.

((Crosstalk))

Facilitator: Michael said no. Those of you that have common areas of interest and work on those areas together outside of this main meeting group and you would work with Michael and R.J. and do some more research and outreach with your groups, and then you have more data to put in that report for the Secretary.

I haven't heard you talk any about the implementation plan or how you might enforce that. I think that was something Neil mentioned he'd like some feedback on. Is that right Neil?

Neil Hammerschmidt: Any of the issues that they see in regards to implementation.

Facilitator: Mm-hmm. So I wanted to remind you that was a piece of data Neil would like to hear some feedback on; some discussion.

Michael Doerrer: Let me clarify that. Whatever way the Committee decides to proceed with considering traceability or any of the topics that they want to consider, in order for it to be an official product that the Department can consider, it still has to come back.

So even if a group of you were to meet and discuss traceability; great. It would still have to come back to the full committee for discussion -- public discussion -- before it could be considered by the Secretary.

Committee: And the Chair would coordinate these [small group meetings]?

Michael Doerrer: Yes, the Chair and Vice Chair would coordinate it with R.J. and I. And actually that's probably a full topic of discussion: how you all want to proceed, administratively. When you want to have a call, you know, how you want - the nuts and bolts of how you want to proceed with your deliberations.

RJ Cabrera: I'd like to propose our first administrative call for next Thursday where we actually get together and lay out the plan for how we're going to proceed.

You'll have your calendars with you. We can come up with dates for the public deliberation meeting and then also set up perhaps one or two more purely administrative meetings of the Committee.

And I will also propose that those calls take place between eleven and two; so we'll cover all the time zones, kind of midday. So stay tuned for that.

Michael Doerrer: If that scenario is agreeable?

RJ Cabrera: Is that all right?

Michael Doerrer: And we can then follow-up with you by email to work out the details specifically.

Facilitator: Go ahead.

(Max Hernandez): (Unintelligible) concern. The ID of the animal traceability, many of them they are very -- excuse me -- many of them are real afraid, you know, that you are intruding in their personal business; in their personal life.

They're afraid that you might be calling the Internal Revenue Service and tell them how many head they have. And then the other thing I'm really concerned is about response in case of emergency.

A lot of times we can have the best plans and if it's not the proper response, you know, to take action, you know, the problems they get multiplied so quickly and they get completely offhand.

And that is the thing, you know, most of the time people is afraid to respond even if they are false alarms. You know, they should be a response that way, you know, the problem is covered.

But I think that part is as important as the plan that will help.

Michael Doerrer: You know I've actually been really pleased. I've heard you all mention almost all of the topics that we planned to cover during this meeting - emergency response and preparedness, laboratory preparedness which you're about to hear this afternoon; comprehensive surveillance.

So we did make an effort with your input to try to put together an agenda that addresses a lot of these related issues, so I'm glad to hear you want to talk about that.

Committee: I do too.

Committee: Okay, (unintelligible). Let's take for example (unintelligible). Okay, so even though we're not necessarily talking about specific disease, but say we're tracking we find that there (unintelligible) parking trailers in a certain area. At which point and under whose discretion will it be to start implementing some kind of eradication of that. I mean, like, you know, the chief industry decide they're going to partially eradicate (unintelligible) so all this information is for gathering, what are you going to do with it, at what point are you going to say that is something that needs to be tackled? I mean, obviously, if it's foot-in-mouth, yes, (unintelligible).

Speaker: So I read our regulatory authority lies on the issue of animal health, under the Animal Health Protection Act and that's the only purpose we would be utilizing it for within APHIS. So, the other things that I've mentioned are maybe additional benefit, but we have no intentions of taking our data and information to provide it just to a public health agency to do what they want to with it.

Committee: Well, part of our call was to - or part of my understanding of our purpose was to talk about issues that link between animal health and human health.

Speaker: Well, those things that affect both animal health and human health do come into play. Yes.

Speaker: And we actually have one health on the (unintelligible).

Dr. Clifford: So, for example, let's talk about just real quickly, H1N1, the human pandemic that was referred to as the swine flu. Swine do get flu, and we've played an active role in downplaying the swine flu and the fact that it's H1N1 human flu. Could it have originated in recombination and other things in a swine population? Possibly, yes. But the fact is, what we did with that from a non-regulatory standpoint is work with the industry to develop a surveillance system to be able to look at new novel viruses as they were emerging and improve diagnostics and vaccine development for animals, at the same time sharing that data and information with the public health to do the same thing on the public health side.

So, it wasn't a regulatory action against swine producers, because it's not a regulated disease in swine. So we would not be taking action on behalf of a public health agency on issues that don't have direct impact or effect on animals that we do not feel should be regulated from an animal standpoint. H5N1, which is a highly pathogenic avian influenza, yes, if we found that in our country today, we would take action because we already considered high path AI an actionable program.

So, if you had IBR case, we would assist you, but are we going to take immediate action on IBR? No, we would assist if it became an issue. We might take additional actions if the industry -- and it became economically important enough to be able to address that issue, but then it would be an issue

like that. If there is a disease that is specific to public health, primarily more than animal health, and it's passed through the human food supply, we would have to look at that.

So, for example, BSE. So, what actions did we take to BSE to protect human health, and animal health? So, those types of things if something like that came up, we would have an obligation to address that. But, MRSA? No.

Committee: Is there going to be a penalty for not participating in ADT?

Dr. Clifford: In this program? The penalty would be -- this would be a requirement for interstate movement. So if you're within your state and the state has no requirement, there's no penalty. If you move an animal, unless that animal is exempt, across [state lines, then . . . .]

Committee: Right.

Dr. Clifford: State or tribal lands where it would be required federally, then there could be a penalty applied to you.

Committee: I think earlier we were asked about the traceability tier and what we might come up with for additional requirements. One thing we need to consider as we go home, the traceability tier three is brought on by the state or tribes inability to be one or two. And that could be financial, that could be personnel, but ultimately, more requirements goes back on the producer. The end result here is we may be penalizing the producer, not the state or tribe, for not being able to meet trace tier one or tier two. I don't know, that's when it bothers me a little bit because we're going back -- the producer's the one who's going to get penalized.

Dr. Hoenig: One comment there, and then Judith that I'll make, but that's what drove us all to Scrapie - Scrapie consistent status and we were the 49th state to be Scrapie consistent, Vermont was the only one who was behind us. The reason that we did it, and that we all realized we had to do it, was because our producers, had we not been Scrapie consistent, would have suffered from an economic disadvantage from not doing it. So we did it and that actually had more, what I would consider to be - that it's stricter requirements than this program has because it requires identification on change of ownership. And that's an intrastate requirement.

Right now, you know, almost every animal that comes into my state, unless it's going directly to slaughter, is identified - officially identified and it comes in on a CBI mostly, unless it's going directly to slaughter. So a lot of these requirements already exist. What doesn't exist is that it's not codified in the CFR that the USDA is going to require these animals to be ID'd for interstate movement as well as the cattle issue, which is why the cattle issue was focused on so extensively this morning. We had mandatory ID for sheep and goats, and have had for how many years?

((Crosstalk))

Committee: There we go. Yes, 2001. I didn't think it was that long, but anyway.

Man: So just to answer that, yes. That lack of consistency would have made every producer, every sheep producer in Maine, who wanted to take animals out of state, they would have all had to be Scrapie - part of the Scrapie program, which would have added a burden of cost to them. So, we fell in line with everyone else.

Dr. Wolfe: Can I just speak to that for a moment? That was always in the regulation of the Scrapie program, but there weren't the resources and the pressure to

execute it, and then the industry decided after the program was probably in place about 5 years; that it wasn't fair to producers that some states kind of operated like this and some operated like that, and they put [on] pressure.

And the challenge here is going to be that we have multi-species under one program and how will we decide we're ready to put pressure for maybe the next level, because without that pressure there aren't going to be the resources for this program to be consistently applied. Am I wrong John? It's going to be hard to do the real traceability. The easiest part, to be honest, has got to be tagging the animal. To do the real traceability is going to need a lot of resources.

Committee: That's also in response to what Charles said, I think it does drive home the point -- how critical it is for there to be a state-industry partnership within the state, because, obviously, the state can do a wonderful job and the producers aren't interested and you're going to be tier three. The producers can do a wonderful job and the state asleep at the wheel and you're going to be tier three. And so, those hopefully are the exceptions, but the only way both of us succeed for the benefit is to work together in partnership, which hopefully we can achieve.

Committee: I can see that where the penalization now pulls the two groups together, but I guess one of my concerns is budgeting right now. I mean the money available to make these things work in each state is probably going to be different. And some states may have trouble with just the budget part. And the producers could get penalized for that, which is something they wouldn't have any control over.

Committee: Well, we've been assured on multiple occasions, from John there, that this will not be an [unfunded] mandate for states, and my legislature just convened and I'm relying on you (John) because I'm not getting from [the state].

Dr. Clifford: The Secretary has indicated in the beginning of this process, this would not be an unfunded mandate, so if there are inadequate resources to carry out the program, we're not going to carry it out. None of us will.

Committee: Okay, I will somewhat switch topics slightly to a procedural question, which I just wanted to put on, sort of, the agenda for people to think about as we go into the next set of discussions. Our next round on this, which is do we have any comments on the procedure for the proposed rule? And the sort of thing I'm thinking about that I've already heard from some of my stakeholders is, you know, how long should the comment period be? What mechanisms will there be for people to submit comments other than the online federal register? How will outreach be done during the comment period?

Like I said, I've already been hearing a bit of this from my folks as I talked to them before this meeting and I just wanted to toss it out there as something for folks to take back when you're talking with your stakeholders. For us to deal with in, you know, as part of our future agenda, is do we have input to USDA on the process of the proposed rule making. And if the USDA guys answers, "we have absolutely no ability to affect that," let me know now.

John Clifford: Well, I think, you know, you can - you all as individuals in those groups can always request an extension for the comment period. You can provide us input on how you think we should best reach out with regards to getting that input. That's not a problem. We take input in written form, we take input by electronic form. So, I don't know what other forms there would be. So, we'll take it either way.

Committee: I think there was some rule in the last couple of years where it wasn't clear that there was a written option, it was just through the federal register online, and maybe I'm wrong, I just know...

((Crosstalk))

John Clifford: Well, we take written comment.

Committee: Okay.

John Clifford: We accept written comments.

Committee: I think it hadn't been clear in the publication, I can't remember which one it is.

John Clifford: We would normally do a 60 day comment period, that's pretty typical of our rules, so.

Committee: We just went through a proposed rule on the GIPSA and I think there was something like 67,000 responses. Am I right?

John Clifford: There was a lot. In fact we had to assist GIPSA in the review of the comments because they needed help because they didn't have -- a lot of people in the department helped GIPSA with that. That's an enormous number of comments -- huge.

Committee: Right.

John Clifford: I hope we don't have that many. No offense, but I hope there's more agreement than that.

Committee: The more public comments, the better John.

((Crosstalk))

Committee: I'd like to point out the difference between the, you know, the 60 day rule or the 60 day comment period to me is adequate because the industry knows this is coming. The difference between this and GIPSA was all of a sudden, boom, here's the rule. We had no idea what was coming down the pike on that deal. So, you know, it took the industry a while to get up to speed on what GIPSA was all about. This, I think the industry has had a lot of time and a lot of input into it, whereas we didn't have any input into the GIPSA rule.

Committee: John do we have a rule - do you have a rule ready to write? Is that correct? It's already written?

John Clifford: There's a rule that's written that's being reviewed, it doesn't mean that it can't be changed.

Committee: But we - there are some things that we're not being really include in the rule. Is that correct? Like the phase in process and how we would determine when to phase in, is that in the rule or no?

John Clifford: I think it's discussed in the rule itself on how we would intend to do that, but it's not - it doesn't have a lot - high level of specificity around that. It talks about working with a group, I believe.

Committee: Well, the rule would say what Neil presented this morning, which is that we would look for that 70% accomplishment rate for adult cattle as one measure, and then we would also look to a group for, an advisory for additional input on workability of the rule before we would move to that third phase. So, it does discuss that in the preamble.

John Clifford: So we've heard loud and clear - especially from the cattle sector and the marketing sector - that they want input on that, then that's a component of that.

Committee: Well, I think we just want - we want a successful program.

John Clifford: Absolutely, so do all of us. We - this is our last shot, I think. We want you all on board. As I said to Judith, I was saying that in jest, I mean, obviously we want everybody to comment and we especially want you to comment on things that you have concerns about. But you know, we're trying to meet - we're trying to make a rule that is simple, is possible that can meet, you know, the cross-section of agriculture across the entire US, and place of a lot of that flexibility back to the state level and tribal level on implementation.

Committee: John, is it going? We want this to work. And I think Dr. Wolfe brought up a very, very good point. Maybe the easiest part is to require all the livestock producers to put ear-tags. And then once we are doing that, and putting in ear-tags now and forever, we'll see administrative procedures in the state and [would] USDA be able to handle that information, relay reform. This is...

John Clifford: When you say administrative procedures, can you explain what you're really referring to?

Committee: Well, I guess I'm talking about how you handle those piles - boxes of interstate movement certificates.

John Clifford: That are hand written and not entered. Well, part of this is to move toward electronic based information. So, getting those systems electronically compatible and entered in to systems. So at the state level, that's one of the things we want to do, is move toward that. We recognize for success, we can't be a total paper-based system. That doesn't mean though that every producer

has to have an electronic-based system; they could still be done by paper, but we need to support, if it's done by paper, we need to support getting it electronically entered. But most of it, we would like to see done electronically.

We're all in an age now where, you know, electronic (ICBIs) or an electronic movement certificate of any type can be done and encourage their use. And that's really the way we're going to have success. And that's our intent.

Committee: John, this is sort of a different topic, but before we get off traceability, I wanted to mention one of the questions this morning. My concern about the either/or of (unintelligible). My industry, I think he would say this (unintelligible) pretty readily, since the idea of animal ID's and traceability. That's the reason you're able to stay in phase one and all dairy cattle are involved. And I think because of that involvement, you'll have a higher percentage of identification sooner, but due to the real issue with the people in our industry, that's going to cause a lot of problems.

We're still trying, in my old home herd, we're still trying integrate an A40 number into the DHIA and other records that we use. It's been 3years since we've been using A40 tags. It's not a simple matter and I would certainly encourage you to relook at that, if there's some other way you could put that numeric code on that tag on the other side of the tag or some way rather than to mess up the number - the ID number by using a letter code for the state.

John Clifford: John, it's my understanding, and Neil I'm looking at you, and I don't know if you need (Dave) or (John Weimers). It's my understanding it's because the DHIA records don't allow the postal - or is it the postal or numeric code?

Committee: Well, traditionally it's stored in the program for the numeric code.

((Crosstalk))

Committee: The numeric code. So, my question is John, I don't see any reason why -- just because you have the postal code available in the state, why would it - if you - if both are available, why would the dairy industry have to use anything other than what they've been using because you wouldn't. You wouldn't have to, but if you've imported an animal in form another state, and it already has tags on it...

John Clifford: Oh, I see what you're saying.

Committee: It has to have the numbers on it, and there's (unintelligible) manager system, you either have to change your system or you're going to want to put a new tag in them. Either one of those things you're going want to do.

John Clifford: A suggestion to the dairy industry is unite together on that and develop a unified diary approach that all states would adopt for dairy animals. And that takes care of your issues. I think...

((Crosstalk))

Committee: Unified diary industry?

Committee: I think you've got some players here that can help though.

Committee: I think it might be as easy for you to change your recommendation as for us to unify the dairy industry, but anyway, I wanted that in.

John Clifford: You know what? I think there's ways to working this out. I do. We'll work with everybody on this. This is why we're here and it's to try to work through this, we'll help and see if we can't work this issue out. One of the worst things

I want is that kind of, you know, having to retool and, you know, that's not what we're looking for, so okay? Well, said John. So, we'll help.

Man: (Unintelligible). [Request for information on Administrative Meetings.]

RJ Cabrera : Well, very briefly, whenever the committee convenes as a committee, it must be publicly noticed and that's an entire process within USDA that takes about 30 or more days. And so, in this first meeting besides talking about ethics and other guidelines we have to honor, we'll put together a schedule. We can notice more than one meeting at a time. We can set, you know layout, simple landscape out in the next six months even. And also take care of housekeeping, and any other things. It's strictly committee management.

Michael Doerrer: Not deliberation.

RJ Cabrera: No deliberation.

Don Hoenig: So everybody understands that the conference call in two weeks - well next week.

RJ Cabrera: Next week.

Michael Doerrer: Will be to discuss those issues and that we would then lay out a calendar for carrying on this discussion further.

RJ Cabrera: Sure.

Michael Doerrer: And then perhaps the calendar for other - future meetings or a future conference call.

RJ Cabrera: And I would also offer that the chairs could task members with assignments and other things that when we do come together to deliberate, that, you know, there will be some work done over that space of six months. So, we can have as many calls as we want. We can, you know, it's a dedicated line. Groups can also get together if you wanted to discuss a topic or what have you, but you have to bring it back to publicly...

Michael Doerrer: Right.

RJ Cabrera: Did you understand that, very clear?

Don Hoenig: I'm not afraid to delegate things and I'm not afraid of subcommittees, although I don't see a subcommittee here right now, myself.

RJ Cabrera: No.

Don Hoenig: That's just - I'm not clairvoyant, but it's not hitting me in the head right now that we need a subcommittee. But I think is what we do need is a break. And we'll take a ten-minute, fifteen minute, five after? Three o'clock? Three o'clock. Come back.

Committee: Let me ask you this one question. When you come back at three o'clock, are you ready to move on to the next presentation?

Don Hoenig: Yes. We've beat traceability to death right now.

John Clifford: Okay. So let me leave you with one final thought on traceability. You know, how do you see yourself seeing, as a group, most efficiently and effectively able to tackle these unresolved issues. I want you to be thinking about this, okay? All right. Be back at three o'clock.

((Crosstalk))

Michael Doerrer: Before we get started, I just wanted to draw your attention to the fact that we have delivered to you your letters of appointment and certificates of appointment. You'll forgive us; we tried to save the taxpayers a few dollars by delivering them in person rather than shipping them. But they are both suitable for framing and I encourage you to do that at your own expense.

Facilitator: Okay.

Don Hoenig: Now we can...

Kim Ogle: Now we're going to resume. Everybody back? Okay. I would like to introduce to you Dr. Elizabeth Lautner and Dr. Barbara Martin. They're going to speak to you about the laboratory preparedness and the National Animal Health Laboratory Network Coordinating Council. Dr. Lautner?

Dr. Lautner: Thank you and good afternoon. We appreciate the opportunity to present to this committee today. To help put a little bit of context of what you're going to hear today and what you'll hear tomorrow, tomorrow Dr. Jose Diaz who is the Associate Deputy Administrator for overall lead on emergency management will be providing a broader overview with some more details about our emergency preparedness and response.

Today we're giving you just a little part of that emergency preparedness and response on the laboratory side. So today what I'm going to do is give a brief overview and update on the National Veterinary Services Laboratories and within the National Veterinary Services Laboratories we coordinate the National Animal Health Laboratory Network and (Barb) Martin, the NAHLN coordinator is going to provide and update on NAHLN. So, again we appreciate the opportunity to be here today and please stop and ask us

questions any place along the way if we're not clear if you want to ask some additional clarifying questions.

For any of you that maybe are not as familiar with the National Veterinary Services Laboratories, or NVSL, our job is diagnostics. We're the reference and the confirmatory laboratory for USDA and as such are responsible for the diagnosis of domestic diseases of interest that we have program areas for as well as foreign animal diseases.

In general just in FY10, we had about 62,000 commissions and 500,000 tests. And just to be clear, we're not the diagnostic lab, we don't do the diagnostics that your university diagnostic lab or some state diagnostic labs may do, we're more of a referral laboratory to help with the confirmation or provide additional assistance that may be needed.

I'll go through this pretty quickly and highlight some aspects of this as we go, but really job one for us is diagnostics. We have the capability to do 24/7 diagnostics, so if there's a high-profile case where there's concerns such as for FMD, or high path avian influenza, we make sure that we have staff available at all times to be able to conduct the testing throughout the day and into the night. We also have the ability to have samples brought to us very quickly, with an express service through FedEx, in those types of high profile types of cases.

So job one is diagnostics, but we also have many other backup types of activities, or activities that may not be as transparent to everyone. One of those is providing reagents. Many of the tests that are done do not have a commercial market for some of the diseases that we're interested in. There is not a commercial market for the tests, so we help provide and produce reagents that may be needed for tests in other labs.

Training is an important part of our mission for states, state laboratories, university laboratories, international laboratories, both training that we go out and do and training that's done in house by people coming to visit us. We also give out proficiency testing, so in some cases, laboratories are performing a screening test and we all want to be sure that we have a very strong national diagnostic system so we help provide proficiency tests that laboratories conduct on a regular basis. The National Animal Health Laboratory Network you'll hear quite a bit about here very shortly.

One of the aspects as well, is while we may have certain diagnostic tests in place, we need to be sure that we're continuing to look at how to improve our diagnostics, so diagnostic development is an important aspect to improve our techniques or capabilities.

We also participate in internationally with other diagnostic laboratories. That's a benefit for many reasons. One is, we'd like to know what's going on in other countries. It's important for us to know what diseases they have and also what serotype strains, if there's any variance that there are, because perhaps there's a change that would result in our diagnostic test or maybe vaccine we would plan to use not being effective because there's a change globally in what's happening with that disease.

So, we also have an opportunity to have a repository and that of islets (sic) and that helps us if there is something we would detect in the United States. We may have an idea about what pathway did it come into the United States by identifying where was this last seen or where is this particular strain been more frequently seen.

We also, by knowing what other countries have, we can help provide for safe trade with those countries, as well. We also, as part of those international responsibilities, we work with the World Organization for Animal Health, or

OIE, and that is similar to the World Health Organization for Humans, and this is where the reporting is done of specific diseases to the international community. We collaborate in many ways there, both in a collaborating center with a center for veterinary biologics, in Iowa State, but also as a reference lab for 11 different diseases. This means samples can be sent to it from around the world to help that country with the identification of that disease.

We also participate with the United Nations Food and Agriculture Organization out at our Plum Island facility saddle for diseases such as Foot-in-Mouth disease, classical swine fever and African swine fever. This organization, and I won't go through much of this because I don't think the organizational structure matters, it's what is it we're supposed to be doing for emergency preparedness response.

We have three laboratories at Ames, diagnostic bacteriology, pathobiology, and diagnostic viralology. Our fourth laboratory that might be of more special interest to this committee as well is our foreign animal disease diagnostic lab, and that's located out at Plum Island, New York, in an island off of the eastern end of Long Island.

Just a real quick, these are not by any means exhaustive of the types of diseases that we work to help with confirmations of, but just to give you an example of the diseases we may work with. One of the questions has been how do we respond when there is an outbreak of a disease in this country, or an increase of incidents of a disease?

An example would be piroplasmosis, where we needed to have additional testing capabilities for equine, and in that we very quickly approved nine new laboratories to test, in proficiency tests, in very short order to help with the additional testing that needed to be done.

Another example would be contagious equine metritis, when we have some increased testing and increased concern related to that disease. The seminal (unintelligible), we've worked to develop new diagnostics to give a faster rule out. Many of you are familiar with SE with an egg situation, and continue to look at what's going on and what can we do to help contribute to the diagnostic mission there.

We also provide support for different activities, such as (TP) programs, wildlife surveys, and as I said, we continue to look at new tests that can be developed since there are new issues that are identified that we want to be sure we have the diagnostic capability for.

Our diagnostic viralology laboratory is a very busy laboratory, you can see many of the diseases there and this was the laboratory that actually first identified the West Nile Virus. We were looking when that was first introduced into this country and we were working through the issues with the humans and the birds in New York.

The pandemic H1N1, a little more recent situation, we worked very quickly, and (Barb) will talk about this a little bit with the NAHLN, but in that situation we needed to have a diagnostic very quickly developed and available for our diagnostic laboratories for swine influenza surveillance, and were able to work jointly with the Agriculture Research service, which is the USDA intramural research arm, and took the diagnostic test they developed, validated it, testing it against all the strains of influenza that we had to be sure it would detect influenza's broadly and then worked to validate a differential PCR. So very quickly, we could make a determination if it was pandemic H1 or N1.

And actually this was an example where there was great international cooperation as we all were very quickly scrambling to make sure we had the diagnostic test available. And the diagnostic protocol that was developed

through the National Veterinary Services Laboratories and the NAHLN ended up being adopted internationally as the algorithm for testing.

One area, a new area that we're getting more involved in as the aquaculture and just recently added aquaculture facilities to our new facility. PSC's are an important area that we continue to work in, BSE's, Scrapie, chronic wasting disease, and we have the laboratory component, we're the confirmatory laboratory for those types of diseases and specifically, especially, the BSE.

As I said, proficiency tests, we put a lot of proficiency tests out to work with laboratories that are doing a screening test to ensure that we're having a good standard nationwide diagnostic system. I'll take a couple minutes just on the foreign animal disease diagnostic (unintelligible); this is the one that's located on Plum Island. Some of you may know that in June of 2003, the actual landlord functions or the administration and operating the Island was transferred from USDA to the Department of Homeland Security.

Currently, out at Plum Island, the Agriculture Research Service has a research group there, we have our foreign animal disease diagnostic laboratory, and Department of Homeland Security has a research program that looks at vaccines. So, specifically at Plum Island, what we have the capability there is to look at the foreign animal diseases of livestock. The foreign animal disease of poultry and equine are actually handled in Ames, Iowa at the Ames facility. The foreign animal diseases of livestock are conducted out at Plum Island.

There's many different activities that we do diagnostics, obviously is our main mission there. We also though maintain the foot-in-mouth disease vaccine bank for North America, and that's jointly administered between Canada, Mexico, and the United States. We also operate a training school there to train veterinarians and we have a group of over 450 trained veterinarians that are

dispersed around the country and either state officials or federal officials that are trained and go out if there's a suspect foreign animal disease case.

We also work with other countries to assist them as well as for us it's very important to work with other laboratories since there are a limited number of laboratories that are working on these foreign animals diseases. There's a whole list of diseases that fortunately, for us there's many of these we're probably not all familiar with because we haven't had to worry about them or we haven't had them specifically in this country, but we maintain the capability to test a broad range of diseases.

I won't go through all of this chart, but just an example if a veterinarian out in the field suspects a foreign animal disease, they contact their state or federal animal health official, and one of these specially trained foreign animal disease diagnosticians is dispatched to go out to the farm and collect the appropriate samples to send in. And those samples then, if they're livestock, it's a concern about a livestock foreign animal disease; they'll come to Plum Island.

We also have the capability and (Barb) will talk about that, is we've got a number of laboratories around the country that can do the preliminary screening tests for diseases such as foot-in-mouth disease and classical swine fever. So we can have all the samples on their way to Plum Island, we can have a laboratory already doing a very rapid screening test as well.

We also, if you think about zoo animals and others that might come into this country, there's a very strong system of quarantine and testing of those animals, so we have the ability to do those types of tests when needed. And again, on an international side, we - I'll provide a little bit more information of what we do there.

This is just examples of what we've done with other countries to provide assistance to other countries, and obtain more knowledge about what's circulating around the world, and again to be sure that our vaccines and diagnostics are up to date for what's going around the world. One of the areas, obviously, especially concerned about it, is the Caribbean, where, you know, we have near neighbors there and have worked with Haiti and the Dominican Republic on their CSF's there, as well as identify (unintelligible) virus down in Haiti and are working with them to help with that.

We continue - we've helped countries such as Guatemala and Nicaragua and their diagnostics, we've worked with Iraq, they actually were having a vaccine failure and we helped to identify the vaccine that would be most appropriate for them to use.

We've worked closely with Mongolia, interesting now we're working with Mongolia on a validation of pen-site diagnostics. So, as the diagnostics are changing and there's the ability to have pen-site, we're working with other countries that are actually having the actual outbreak. We can put the virus in animals and test the pen-site, but we really need to know what they do in the field situation, how well do they actually perform in the hands of many different individuals and different samples.

Dr. Lautner: Yes, the pen-site that we're working on right now is with (unintelligible). A couple -- I just wanted to highlight a couple examples and just a - show that the diagnostic development work that we do. There's a lot of interest in what's called DIVA, being able to have a vaccine, that when you vaccinate the animal, you know whether they become infected or they're just vaccinated when you're doing a serology test. So, we're working to enhance FMD diagnostics in that manner.

Classical swine fever, there's still some issues with cross-reactions with other diseases and we're working to try to improve those diagnostics. I mentioned the pen-site; we actually have at least three countries right now that we're working with on the pen-site diagnostics to look at those in-house. We also know in a recovery phase from a disease we have to do a lot of testing to show that we're disease free, so we're working to enhance high (unintelligible) capabilities for the NAHLN laboratories in serology testing.

We also know that we can - that there's much to learn about what viruses are out there in different species and we've developed microarrays that allow us to test for genetic material of all known human and animal viruses in samples that would come to us. (Barb) will talk about the validation of the assays.

One thing we are also interested in is what does FMD look like in species - animals such as the feral swine, prong-horned mule deer, elk, and their capabilities to transmit to our domestic livestock population. We also are conducting work looking at FMD detection in oral fluids. For swine, one of the ways that you're looking for PRRS now is in ropes that are hung in pens, that you can do diagnostic work from the rope. So, we've done some preliminary work to look and see is can FMD detection be done where you would not have to have the individual samples taken and those types of things.

Just I won't go a long into this, but this is an example where we used our microarray, we were working with the Philippines with the PRRS that they had, Porcine Reproductive and Respiratory Syndrome, and actually we're trying to help them with their diagnostic work that they were having with very clinical - high clinical mortality and morbidity. We ended up through that using our microarray and actually identifying for the first time anywhere in the world, Ebola Reston in swine.

And this was unique - this virus is uniquely seen in the Philippines in their primates in very limited areas with primates and actually in this case it had spilled over into the swine farms. And we were able through our diagnostic work to help the Philippines work through that and worked with CBC on both the human aspects of that and the animal aspects of that.

Just to conclude, one of the areas that we're working on is to be sure that our diagnostics are harmonized with Mexico and Canada. So because of the live animal trade that we have between our countries, we want to be sure we're all having diagnostics that gives us the same results and we have harmonized our diagnostics with regard to foot-in-mouth disease, we're continuing to do swine vesicular disease and vesicular stomatitis. And we actually have harmonized our tests as well for avian influenza and bovine TB.

Another aspect that we work on an international basis is with other laboratories to help improve their capacity so that they actually can become a reference laboratory and can help their part of the world continue to enhance what they can do for disease detection.

I'll just close with - wanted to be sure to just give a quick update on where we are with the National Centers for Animal Health. I know many people around the room had for years have heard about the master plan and the construction project at Ames and wanted to just give a quick update. We're really, really pleased and very thankful for the facilities that we have today to be able to conduct the work and Ames, it's made a tremendous difference in our ability to enhance the work that we do and to be able to collaborate.

There are three groups that are located at Ames, the Center for Veterinary Biologics, which has the responsibility for the approval of vaccines and diagnostics that are used in this country; the National Animal Disease Center, which is the intramural research arm for USDA and then, our laboratory. And

we're all collocated at Ames, Iowa at the complex. Our new facility is the large one that you see in the middle there and we've got some older facilities that were built in the 50's that were not modern laboratories that would not allow us to carry out some of the types of work that we needed to do, and we were able to modernize those facilities.

And we just moved into them in July of '09, so it's still working through things, and it's been great to be there. We also had the ability to enhance some other areas. We had rented space before for our PSC diagnostics and we were able to move in 2004 into this facility that was built on the campus. And then we built a low containment and a high containment facility there at Ames.

So, we're very appreciative having the opportunity to have these facilities to move our work forward. These are websites that more information about NVSL and NAHLN is available. With that I would turn it over to (Barb) but I'd be glad to answer any questions right now. Yes?

Committee: I was trying to write down numbers when you went by the slide, but can you maybe remind us again of actually the number of foreign animal disease investigations that are done every year?

Dr. Lautner: Yes, there can be -- and it's important to understand those were the ones that were done at (unintelligible) which would have the livestock ones, but we have a large number of poultry ones. So in any particular year, we may have -- and it varies quite a bit -- we may have between 200-400 disease investigations.

One thing I would say when the UK in the 2001 had their large outbreak of FMD and somewhat more limited than maybe in 2007, we can have - when there's heightened awareness of foreign animal diseases there can be more phone calls in to state veterinarians or federal veterinarians to say, "you know,

I've heard about FMD and I want to be sure this isn't." So, there can be increases depending on that situation. Same with avian influenza, when you have the more high profile cases around the world of avian influenza, there's a heightened awareness and more submissions done that way.

One thing, that (Barb) will talk about is, we recognize though that those are the cases that come to us when someone called and recognized it might be a foreign animal disease, but everyday there's samples going into diagnostic labs that could be a foreign animal disease and that's one reason there's been special training with people in the diagnostic labs as well as for classical swine fever that have many look-a-like diseases. They have the ability to test those samples coming into their lab when you've got - rule-out could be classical swine fever, but it wasn't detected at the foreign level.

Committee: Thanks.

Howard Hill: (Beth), in the discussions we've had with the Mexicans on the nine state region where they can export in the United States, we've talked about CSF, but what's the status of blue eye, it seems like we've kind of forgotten blue eye and are you guys doing any work on it or...?

Dr. Lautner: Actually, thanks to the new facility, you saw that BSL-3 AG facility? We just now have undertaken blue eye studies at Ames to look at the diagnostic work and the pathogenesis that and take a look at that. But that is one that is, as you know there's not live swine moved because that is one area that has an area of concern yet for the blue eye. So, we actually had to wait for a facility to get done and commissioned to be able to do the work there. But that is an area that has not resulted in live swine coming from Mexico because that is still one even with the classical swine fever addressed, that's one that still needs to be addressed yet. But it's not off the radar from a diagnostic standpoint.

Howard Hill: Thanks.

Committee: Two quick questions. One is just on terminology, at one point you were talking about pen-site diagnostics? Is that basically field-testing? Okay. And on the foot-in-mouth disease vaccine, is that still something that we have to get activated in Britain, or is that in a form that we'd be able to use it immediately here?

Dr. Lautner: With regard to the foot-in-mouth disease, what we maintain in our vaccine bank is what are called vaxes, frozen concentrate so it doesn't go to pure bright to be made into vaccine. So it can get jetted over there and then put into their production line right away to make it into vaccine.

One of the challenges with foot-in-mouth disease is you do have a shelf life of about 18 months. So if you stock pile -- and the other aspect is, there's seven serotypes of FMD but when they do recommendations for vaccine banks, there's over 20, because there's subtypes within the serotypes and there's not any really good cross protection between serotypes and even between like an O or an A, you might want more than one O or A to have good protection. And that's one of the challenges.

The other aspect is worldwide, you know, we're doing a good job of eradicating foot-in-mouth disease, and what that means is there's not the manufacturing capacity for foot-in-mouth disease vaccines. And in general the vaccine companies are producing it when they have a contract for someone that wants it, so there's not - if you don't have a stock pile or a vaccine bank yourself, if you just went on the market to buy some, it's - there aren't inventories of it.

Committee: With our vaccine bank out, about how long would it take for us to be able to start deploying vaccine if there were an outbreak?

Dr. Lautner: What we're able to do is we can ship it, obviously very quickly, overnight to the UK, they can bring it on, and our original - our contracts with them start looking at our first supplies in three days.

Committee: Thank you.

Committee: Does the vaccine - does it just prevent it or does it cure the virus?

Dr. Lautner: That's a good question. The vaccine will provide effectiveness against the clinical signs, but it may not prevent infection of the animal. And the Holy Grail for a foot-in-mouth disease vaccine is a universal vaccine that would work against all serotypes and would prevent the animal from actually being infected.

One of the reasons that we're working on that DIVA test to differentiate infected from vaccinated animals is so that we have a more accurate test to be able test a vaccinated animal and be able to distinguish is it tighter just from vaccine or is it tighter from also being infected? There are tests available that could work on a herd basis for that distinguishing but not on an individual animal basis yet.

Committee: Have you worked on scenarios, and I'm not sure that's your job, but has there been a scenario for how long to contain if indeed there was an outbreak in the United States? Figure all the time it's going to take to get the vaccine concentrate to Britain, get the vaccine back here, and then, I mean, has there been some kind of work done?

Dr. Lautner: There has been and I can give Jose a heads up that you need like to have some discussion of that. One of the challenges is, even if we had the vaccine right in our hand, we still have to determine where we're going to use it. I mean, there

still has to be a plan of understanding where's going to be the best use of that vaccine.

Doing a ring around where the infected herds are and then part of that is knowing epidemiologically what herds are linked, where could the spread of all been, where are the populations, and where are we going to make the best use of that vaccine. So it does take a period of time to understand where the disease is, where it isn't, where it's been moving to, to make the best determination of where are we going to vaccinate versus where do you need to depopulate.

Committee: So do we think that we would be able to get the timing down better in the United States since what happened in the big outbreak in Britain? I mean are we going to lose as many -- of course we have more animals, but I'm just trying to figure out if we're going to lose as many animals.

Dr. Lautner: And I think that would be a good discussion to have with Jose. I could say basically when we've looked at it in the modeling work that's been done, one of the factors is how easily can you - how quickly do you detect it? Is it a strain that shows a lot of clinical signs, so it's very easy to detect. Is it reported right away or have animals moved and then you've got to trace all that movement. So it depends on how widespread it's become and how much animal movement has taken place before you find it to how quickly you're going to be able to get it contained.

Howard Hill: (Beth), I think we don't want to leave everybody with the impression that if you have an outbreak of FMD that you're automatically going to vaccinate, it's going to depend on the outbreak and where that outbreak occurs. If it occurs in Don's state in pigs, we're most likely going to slash and burn. If it ends up in North Carolina or Iowa or Illinois, than it's a different scenario. So, it's not an automatic that we're going to vaccinate an outbreak. That fair?

Dr. Lautner: That is, and one of the decisions has been made is as soon as we know -- the other thing you have to do once you have FMD, you have to match it to know which vaccine you want to activate. So there is a period of time and it depends of the serotype how quickly you can do that. So you do still have to match and know, but the decision's been made by all three countries that if we have an FMD detection as soon as we know which vaccine we would likely want to use, they would ship it and start the activation process, even if you then chose not to use it, but you would have that jump on it already.

But that -(Howard's) exactly right, you're going to have look at the individual scenario to make the decision of what combination of policies that you'd use. Exactly.

Dr. Martin: I want to echo what (Beth) said and tell you it's a privilege to be here, to be able to provide you with an overview of the National Animal Health Laboratory Network. What I'd like to do since I'm not really certain how well versed you are in the NAHLN, is provide you with some history and background, we'll go over our current capabilities, how we've applied those in surveillance programs, and then we'll talk about some of our activities to enhance our capabilities this year.

The Network was founded in 2002 and it really is a group, it's a partnership between our state and federal partners. If you look at the bottom of every single slide you'll ever see me present, it says, "NAHLN a state and federal partnership to safeguard animal health." It really is a partnership. We've made tremendous progress over the past eight years, but none of that progress would have been possible if it hadn't been for our state partners and the federal partners working together.

So what we're doing is we're looking at exotic diseases, zoonotic diseases, emerging diseases, and I'll give you some examples of those as we go through the presentation. But that partnership is between a couple of groups in USDA, APHIS, and NIFAA, formally CSREES, AAVLD, which is the American Association of Veterinary Laboratory Diagnosticians, and the NAHLN laboratories.

There are three purposes for NAHLN. When it was first founded, the major purpose was rapid response. We wanted to have that surge capacity that's necessary to do the testing of samples in an outbreak. But what we quickly realized that we really needed to look at early detection. If we look at early detection in surveillance programs, and you'll hear (Dr. Granger) talk tomorrow about NSU, then we'll have an opportunity to get ahead of something. So we can detect the disease quickly and minimize the impact to animal health and to the economy.

But those two aside, I think I was rather naive when I took this position because I thought that our surge capacity would by far and large be the biggest strain on our laboratory capacity. That's not the truth. As we've seen with exotic Newcastle outbreaks in California, the real push for our capacity is in recovery. So, proving to our trading partners that we're free of the disease is going to be a large drain and we need a huge capacity to be able to do that.

Now if you think about those purposes of NAHLN, and what animal health diagnostics has been like for the past very many years, you realize that what we're talking about when we're talking about testing for foreign animal diseases in a state laboratory is a real shift in our paradigm. And we needed factors that would help us increase the confidence in those laboratories overall. So what we had to do was come up with founding principles, and those are all listed on this slide.

But basically what those founding principles do is provide us with that foundation. They provide us with a confidence that those results are going to be acceptable and that whether we ran them at NVSL in Ames or at Plum Island, or at one of non-laboratories, we would expect the same results. We'll go through these as we go through the presentation.

But I wanted to talk with you just a little bit about the laboratory structure. We started out in 2002 with 12 laboratories, those were the core member laboratories, those laboratories received infrastructure support from NIFAA and they also received support from APHIS for doing testing, so surveillance testing. They have a fee for service and we provide them with that funding.

Our member laboratories receive some funding either from NIFAA or from APHIS, and on top of that they also do fee-for-service testing. Our contract member labs are labs that are only performing service - fee-for-service testing, so they don't receive any infrastructure support, and then we have our adjunct member laboratories. You can see the adjunct member laboratories in Georgia and it in Wisconsin. They are the blue diamonds. It's the FSIS laboratory in Athens Georgia, and the DOI laboratory in Madison, Wisconsin.

Now, we have the core member laboratories seen there in the red, and we have the member laboratories, but a year ago what happened was we took some of those contract member laboratories; all of those that were AAVLD accredited and they became member laboratories. So we then provided them with the funding to help maintain their quality management system and to message into our information technology system.

As you can well imagine, the more money you get for infrastructure support, the more responsibilities you have. So, if you look at this list you can pretty much see, and I know that you all have access to our news letter, there's a link there where you can find this slide and it'll explain everything, we don't need

to go through it line by line. Not to mention the fact that I can't read from here.

But, there is one unifying factor in all of this. Each laboratory that is participating in NAHLN activities has to have a quality management system. And we'll talk a little bit about that laboratory approval process. But that is one of our strong partnerships with AAVLD is to recognize their accreditation process and recognize the strength of that. It is consistent with OIE and with 17o25.

So if we go through and talk about our founding principles, the first one on the list is diagnostic techniques, and I would be remiss if I didn't mention the NAHLN methods technical working group right up front. This is a group of state volunteers as well as folks from NVSL, we also have FSIS and DOI representation and we've had Canadian representation in the group. They look at the methods, they look at where we have diagnostic methods, what the performance characteristics of those methods are, try to identify gaps.

This group has been instrumental in coming up with the validation processes that we go through. And also what we call methods comparison. So if we've been using one platform for a long period of time, one thermocycler and all of the sudden the manufacturer decides they're not going to make it anymore, how can we quickly and efficiently switch from one piece of equipment to another without having to revalidate an entire assay.

They also look at continual performance of assays, monitoring the performance of an assay over time, so that we have a better idea about what a test result means. We currently have standardized methods for each of the agents listed here, avian influenza, exotic Newcastle, BSE, CWD, foot-in-mouth disease, classical swine fever, pseudo-rabies, swine influenza virus, Scrapie, and vesicular stomatitis.

Dr. Lautner went through a lot of these, so I won't spend a lot of time on these, just so that you understand what we're really doing is looking at where our gaps are and trying to address those gaps. So we look at how enhance our capacity, we look at where we have a gap if we don't have an assay with the performance characteristics that we need, how we could enhance that and work with other partners to develop those assays.

The NAHLN IT system, I have - I've heard from (Dr. Parr) that he's going to question me on this, so I have to be really careful here, that was - it was really established so that we could take information from individual lab information management systems and message it through a message broker into a USDA database and we would be able to get the results out.

Now the most important part of that, from my perspective, is that we have data standards and that we're doing this in a consistent manner. So, you're lymph system might be different from my lymph system, but because we're using the same different components of a message, we can put it all together and have a better understanding very clearly and in a very straightforward manner.

We now have 13 labs that are sending electronic test results messages for classical swine fever and 12 for avian influenza. That might not sound impressive to you when you see a map of 60 laboratories, but let me tell you that's a huge accomplishment. There is no other network, including public health in this country that is electronically messaging diagnostic test results. We're the only one that's doing it. And that is because of that partnership. We would not be doing this if we didn't have state experts helping us get this job done.

We are now looking at expanding messaging capability; we're looking at swine influenza virus message, as well as a CSF ELISA message. We've had a pilot project with one of our labs in Texas and we can now successfully message CSF ELISA results. Now, another thing that we'll help you in all of this, as we look at CSF we can draw a comparison to that with FMD serology. So, because we've done this message in a very defined manner, what we can do is switch out components, if we've shown the capability for doing the serology messaging, we can switch those components for FMD and quickly be able to message FMD serology also.

Our Train the Trainer program has been just an absolute joy. In 2002, I actually took a job and I was working on validating assays that would be used in this network, and boy I'll tell you, we thought that we were on top of the world because we had 12 laboratories, we took two people from each of those 12 laboratories and we trained them and we proficiency tested them. And I thought, my gosh, are we prepared. The next year we went back to do it again, more than half of those people had moved on.

So, I was, you know, we were devastated because we were going, you know, how are the people at NVSL either at Ames or at Plum Island going to be able to do their job as a reference laboratory, if what they're doing is continually retraining people. So what we looked at was an incremental process where we developed a program where we're training people to conduct the assay and then we're training them to train other people. So once we've trained them, they go back to their laboratories, they're proficiency tested, when they pass that proficiency test then they can train other people who then have to be proficiency tested.

That has changed, if you look at this slide, what we have from twelve to fifteen laboratories for AI, E and B, CSF, and FMD to 50 some laboratories for AI, 39 for CSF, 50 for E and B, and 40 for FMD. And the number of

analysts that we have trained is tremendous compared to what it was before. We still see that turnover but we have people out in the laboratories that can help provide that training.

And we actually - it's built a lot of camaraderie between the laboratories, because initially when we started it, you had to go back to your individual laboratory and work with the personnel in your laboratory. Now we have people from other laboratories come in. So we've done this in a very incremental process and I think we're all quite comfortable and quite pleased with the result.

We also have a proficiency-testing program as Dr. Lautner said; NVSL is the National Reference Laboratory. They provide those proficiency test panels and the reference materials. And what you have to think about proficiency testing as a competency assessment. So what we're really doing is looking at the competency of the individual analysts that perform those assays.

We're also looking at our ability to train those folks. Okay, so if you put me in a lab right now and I trained a bunch of people, they might fail the proficiency test but it's probably because of the quality of their trainer. So we have multiple ways to look at that information so that we can determine where problems and issues are and how best to make sure that we have a group of well trained proficient people, should we have an outbreak.

We have a laboratory review and approval process, this was developed in conjunction with AAVLD. When the NAHLN was first created there were 12 laboratories, they were all AAVLD accredited. Because of BSE and E and B, that number quickly expanded, and it expanded to laboratories that aren't accredited, so we needed a process to go through to approve those laboratories to participate.

And as I said earlier, we now have a requirement that all laboratories have to have a quality management system. If they're not AAVLD accredited, they have to participate in site visits, they get a report back, there are non-conformances that they have to address, if they don't address those non-conformances they don't participate in NALHN activities and their NAHLN status is removed.

We have done an annual report on this, I'm kind of big on annual reports, we do reports, we talk about what our goals were for that, we talk about what worked well, what didn't work well, and then set up goals. So, we've been doing this for a couple of years now and we keep getting input from the stakeholders and trying to improve the process every time. And also work very closely with AAVLD on this.

One of the things we found as we went through our training was that the non-conformances that we were seeing were very similar, whether a laboratory was accredited or not accredited, you have to look at accreditation as a continual process of improvement and we saw similar non-conformances no matter where we went.

So what we decided to do was do training and this was quite an accomplishment for us. We worked with members of the AAVLD accreditation committee and developed this training module, it was three days, and we went through very interactive lectures and games and helped people have a better understanding of what quality management systems are and how to implement them. And then we had a wet lab where we had all kinds of non-conformances, and they had to find those non-conformances and help us figure out how to address them.

We had 87 participants from 52 different labs and again we had a summary report and recommendations, and you'll hear later about what we're going to

be doing with that this coming year. This one might be the one that's the most interesting to this group. We had a series of FMD table top exercises this past year, it was inspired by our 2007 high path AI exercised series, and if you're not familiar with that you can find that on the NAHLN website under our publications. That report was released through the secretary's office.

So with this, what we wanted to do was really start looking at our policies, so we had a policy level exercise where we sat with Dr. Diaz's staff, we had NAHLN folks there, we had NVSL folks there, and talked about policies. Talked about what happens 'if' and had a whole list of a matrix of questions about if you had this question, what policy do you go to, where do you find that, who's responsible for updating that.

Worked through that, we then did a pilot exercise in Kansas and then had 15 follow-up exercises. We are going to be having NVSL tabletop exercises, the first ones we've ever had. So we're pretty excited about that. We'll be doing that not - in March, early March. And then we'll have a follow-up policy exercise to try and tie it all together.

Each time that we do this there's an individual report for each of the exercises, and then we do a summary report, so what you would find on the web would be the summary report for the avian influenza exercises, with all the identifying information removed so you can't point issues back to a single laboratory.

We had five general areas in our preliminary findings for this scenario testing; we're just working on finishing all those reports right now. NAHLN laboratory preparedness, we've made tremendous progress in our preparedness, but we still have a long ways to go. I think Dr. Lautner would agree with me we have - we've made incremental gains in all of these things,

but every time we do another exercise or another exercise series, we find other things that we need to address. So, we're working through those issues.

Communication - our communication has improved tremendously, and we'll talk a little bit about that when we talk about surveillance. But the important part is testing those communication chains and understanding that you're going to call when we discover that there's some diagnostic development needs, as Dr. Lautner said, we need a DIVA assay we need to deploy serology - FMD serology to the NAHLN lab, and we also need more transparency around decision making. So our stakeholders are very interested in knowing how decisions are made, so the more we can help them understand that, the better off we'll be.

I'd like to talk a little bit about application of those capabilities. (Dr. Granger) is going to talk with you about the National Surveillance Unit. That group was created about the same time NAHLN was created and when the NAHLN laboratories are doing testing, it's through a surveillance program. So, it's a surveillance plan that was developed by NSU and then those things are implemented. It sounds really pretty simple, we're doing surveillance testing, but it's not at all.

What it's done is implementation of these surveillance programs has helped us communicate across VS and across APHIS lines because instead of us working individually, we're all working together. So we have opportunities to work with (Dr. Meyer's) staff, we have opportunities to work with the staff of (NCAHAM), we're working with the National Surveillance Unit with NVSL, so it's really been very, very helpful and I think it has improved our capabilities by having us all working together on these surveillance plans and programs.

Some of the other benefits of surveillance are early detection. So, we're doing surveillance of high-risk populations and we can detect an agent earlier. Some of the biggest benefits I believe, as I talk with other networks, because we're doing testing on a regular basis and a lot of other networks aren't, like Public Health, they're not using their assays on a regular basis. So, I believe our proficiency, our technical proficiency is higher because our folks are doing these tests more frequently than just doing a proficiency test once a year.

I also think that it's helped our communication. We all know that you're going to get a presumptive test positive, so when we get that presumptive positive, we're going to have to call people, and we're going to have to do additional testing. So, we have to work through all of those protocols and it's much easier in my estimation to work through those protocols now and address issues, than it would be should we be in the midst of an emergency.

And last, I think that this overall has improved our preparedness, we're much better prepared. We know where the downfalls are to the assays; we know if there's going to be some technical glitches. We've worked through the troubleshooting; we've also built those relationships within Veterinary Services and within the stakeholders, not only in the state laboratories but the state animal health officials, the folks that are collecting the samples. So, that has really helped us tremendously.

I'm going to give you a couple of examples here. I have to mention classical swine fever, because this was the first surveillance plan that was developed by the National Surveillance Unit, it was implemented in the NAHLN laboratories and it was for a foreign animal disease. Now, that might not sound like a big deal to a lot of you, but it's huge. It's a huge paradigm shift to talk about implementing surveillance for a foreign animal disease in state-run diagnostic laboratories.

We started this in 2006, we've tested over 30,000 samples, we have 38 labs that are participating. Now all of these labs have been through that lab approval process, all of the analysts that are conducting the tests are trained and proficiency tested. If there is a presumptive positive result, they all know what they have to do. So, we're all working through this and have the same understanding about what needs to be done.

I want to bring up SIV, really quickly too, Dr. Lautner mentioned that our laboratories had to quickly develop and validate and deploy an assay to the NAHLN laboratories. We worked very closely with the folks from Southeast Poultry, from NADC, from NVSL, and then our NAHLN Methods Technical Working Group to get this assay out the door and in the hands of the laboratory and have the folks start testing. So, that sample matrix and the algorithm that Dr. Lautner described is the one that (unintelligible) is using currently.

We're not going to spend much time on this, we have surveillance programs for avian influenza, we've worked very closely with wildlife service's on wild bird surveillance. That has been really important to us because it's helped increase our messaging capabilities, and we wouldn't have had a lot of opportunities to work with some of those laboratories if we hadn't been able to do this testing.

BSE we have six labs that are trained - have personnel that are trained and proficiency tested. They've tested almost a million samples since June of 2004. I guess that shows you what you have to do in recovery. Yes. We went to maintenance surveillance in September of 2006 and we're currently testing approximately 40,000 samples per year.

Chronic wasting disease, we have 23 labs with personnel trained and proficiency tested. They're testing in excess of 250,000 samples per year.

Pseudo-rabies, we just started in 2009 with a pilot in ten laboratories. We've now expanded that to 16 laboratories that are participating.

And vesicular stomatitis, this is a little different because of the performance characteristics of the assay, it's a compliment fixation test, and it's not an assay that you would really use for early detection of an assay. So what this is, is it's used only after confirmation of an outbreak.

This is probably one of the biggest accomplishments I think we've had with our preparedness. We have a VS memo; VS memo 580.4, Dr. Diaz is going to share with you about it tomorrow. That memo was modified a couple years ago. And it describes the procedures that we go through for foreign animal disease investigation or in an emerging disease investigation.

The changes to that mean that we can split samples and send part of that to a NAHLN laboratory and part of it to NVSL, either the campus in Ames, or at Plum Island. Those samples are always going to be confirmed if it's a new outbreak, it's always going to be confirmed at NVSL, but it does give decision makers an early - early information because sometimes what we've seen is we have the results from the NAHLN laboratory before the sample even gets to Plum Island. So it gives the state veterinarian and the ABIC to make decisions and to get things done sooner.

Dr. Diaz will also talk to you about some of the tools for implementation. We have some 580.4 flow charts. The memo, previous to 2008 was pretty simple and straightforward; it's very complicated now. So we needed some help to help us get through it and help people understand it.

When we look at what we're doing in the coming year, we have a lot of work that we're doing in conjunction with (SADL) and NAHLN on diagnostic tests. We're working on negative cohorts in the NAHLN laboratories and

optimizing several different assays a long with hopefully deploying FMD serology to the NAHLN lab sometime this year.

Our NAHLN IT priority activities -- you ready (Dr. Parr)? Okay. We are going to be working on training other laboratories so that they are ready to message, but one of the key things that we have to do and one of our biggest roadblocks to capacity in the laboratories is an order message. And by that I mean, what happens when a sample comes in the door of your laboratory?

Currently, laboratory personnel have to enter all of that data into a computer. An ID is assigned to that sample and then it goes into testing. You don't want to test it until it has that sample ID and that takes a good amount of time. What we're hoping with this order message is that we can get that information securely transmitted from the field to the laboratory, so the laboratory has that background information, it can populate into their IT system, their IT system can give it an accession number or an ID number, and then we can eliminate that roadblock and increase our capacity. Okay? Good.

So, right now we're working on trying to integrate our databases. So, trying to make sure, just like we've done with our surveillance programs where we have a lot of different people working across lines that we typically didn't in the past. Now what we're looking at is integrating those databases, so that our databases are more robust and we have the architecture to support putting multiple diseases in a database. And the reason that's important for you is because if we have an emerging disease, we want a place to store that data quickly and efficiently. We don't want to have to rely on spreadsheets.

We're also messaging for additional diagnostic assays and technologies, so ELISA immunohistochemistry, virus isolation and sequencing. We're also working with (FASSI) to develop a software tool for evaluating laboratory capacity.

We have worked on this and what we're doing now is a process map, so we're looking at all the different parts and how much time those take and trying to determine what the roadblocks are so that we can better address the problems and issues. If we know where those roadblocks are we can hopefully address the biggest ones to our capacity, and then hopefully increase our capacity. Right now, we're working to get NAHLN labs involved in this and we'll be - we're hoping to have that done by the end of this year.

Okay. We have a NAHLN portal that we're working on with NSU; this is going to give us -- with KSU and the University of Minnesota. This again will be a partnership with other folks and we'll be working to develop the different modules and then make them available to the laboratories. We are taking our quality management system and are training and expanding that. We're looking at distance and online delivery, and potential involvement of other networks so that they can have consistent training that way. We've also been asked about the possibility of international delivery and participants.

We're working on our NAHLN operational plan. All of things on this are from our exercises, their follow-up items and documents that we need to address from the findings from our FMD exercises. So, we'll be putting those out there, working with Dr. Diaz's staff and trying to make sure that everything we put out is consistent with their response plans. We also had some training that we're developing for VS memo 580.4, even with the flow charts we need to do some additional training and work.

So, in conclusion, we really believe that what we've done with this partnership is increase our capabilities and capacities throughout the country to address adverse animal health events. We've implemented national standardized surveillance for high priority for diseases with classical swine fever. And increased levels of coordination and collaboration have really

increased our capabilities overall. And the last line there is the most important to me. Partnerships are key to the success of NAHLN, we wouldn't be where we are today if we hadn't partnered with our state folks. That's it. NAHLN information and you should have a bunch of handouts and background information too.

Committee: Thank you.

Committee: I have question. I would compliment you on that. What you said a partnership, with my role as state veterinarian, we have - I have to be responsible for one of the NAHLN member labs, diagnostic laboratories. And it truly, they mean what they say, which is not always the case sometimes; the partnership has been a pleasure.

Dr. Martin: Oh, thank you.

Committee: And they have worked together to do some of these things. And we have partnered with them; especially on the IT because of some unique expertise we have in our laboratory. And it was eye opening to me, it's kind of related to what we talked about this morning, the standardization of things and the messaging sounds finer, but it's the real key to everything. It's get out of the software problems if we have the standards in messages you can use off the shelf software, everybody doesn't have to use the same thing, and you don't have to change the programming.

It's all in there and it's eye opening to me some of these - the reason that messaging -- it was my IT guys that reviewed the stuff and said I need to be sure you drove home that point, but it's really not how many tests we can run in these labs, it's how many we can accession, which just means logging them in. So it will be key if that information can go in, one, for how many more samples we can run, and two, how much more accurate we will be, because

every time something is entered there's room for error and there will be error, well for humans.

So if you can enter it once and use it everywhere, which goes back to our traceability discussion this morning, that same thing where we can get electronic, we're so much more accurate, we don't reenter the same thing. Thank you.

Kim Ogle: Any other questions Dr. Martin?

Committee: Yes, okay. The lab in Ames, Iowa, I know that there have been like, in particular one disease, brucellosis, there's been some numbers of false positives and then when the test would be run again, they would come back negative. Could you maybe elaborate a little more on that?

Dr. Martin: Sure.

Committee: And also, I guess my concern more than I'm not as concerned about a false positive and going back and finding out it's negative, as what's the possibility of a false negative and something about it is positive.

Dr. Martin: You have to develop a testing algorithm, so the first test you use is typically a screening test with the highest sensitivity possible, because you don't want to miss a positive. Okay? So then when you send it on for additional testing, b. ovis is a - I used to work with brucellosis on Dr. (Masinko). Yes. So, I'm real familiar with those tests. When you send it on, you're doing a more specific test, so you get rid of those tests that might have a cross-reaction.

As you go to those more specific tests, there's always the possibility that you're going to get a false negative, that - nothings' a 100%. But they do multiple tests and they have a testing algorithm that helps increase your

confidence that that final diagnosis is accurate. (Beth), is there something that you want to add to that?

Dr. Lautner: I think that the b. ovis has been a subject of quite a bit of discussion at USHA and AVLD and I know Dr. (Wolfe) just asked if we would convene a group to relook at that test, so we will do that. This is a test that's given, I think all of us, some kind of fits and starts and is one that we're continuing to work on.

And I think that's probably a valid point you're making is that test results themselves, this is just a general comment, you want to take that in combination with your epi information and the other things you that know as well, because a test result there are the potential for false positives and false negatives in any testing scheme. You know, there's -- and we do these multiple tests. So, to confirm like a foreign animal disease in this country, we're going to do multiple tests before we would say, "yes, that's it." It wouldn't just be one test and that's good and we're done.

But this particular one has been one that's been challenging for all of us to work through and I know we've had some collaboration in the past, but it's one that needs further work yet. And actually Dr. (Wolfe) and I just had the discussion, she raised the issue and we'll make sure to get a group together to look at that particular one.

But again, one of things overall for diagnostic tests, is you look at the fitness for purpose of what you want. Screening tests you want highly sensitive, you willing to live false positives, because you can't live with false negatives. You don't want to miss, with a foreign animal disease, you want that test to be more apt to give you a positive than a negative - miss a negative.

Later on, in eradication programs you can change what the type of test you have, that's the challenge, the whole picture I guess and that's the important

part of this, it's what the field says, it says what the epi's out in the field say, the diagnosticians, and the history of the herd and knowing the links, what been the - animals moved in and out of the herd, and those types of things that all go into the whole picture.

Woman: Okay.

Man: I had two questions. One was on funding and the other on reporting. On funding avian influenza, you get a lot of federal funding support the commercial industry, and it's been, I think, very successful I don't know if there's an issue with that -- tight budgets. Can you address that first on funding?

Dr. Martin: I don't know if T.J. wants to comment on that. We do provide some reagents for the avian influenza for the AGID testing, I don't know TJ if you want to make a comment on that.

T.J. Myers: Every year, for the last few years we've seen our avian influenza budget decrease. And I think in the current climate, we'll continue to see that. I think that budget was very, very large because of the H5N1 issues we were having a number of years ago, and as a concern over that has died down, so has the budget.

But what we've tried to do and we'll continue to try to do is to maintain as much support as we can for the states laboratories that do that testing and the reagents that come from NVSL. But, I can't really predict what might happen with the new budget in 2011, we're still under a continuing resolution.

And then 2012, the president hasn't issued his budget yet. So there's a lot of unpredictability over the next couple of years, but we recognize that the funding to support that testing is critical. We'll try to continue to support it as

best we can through cooperative agreements to the states, but as far as dollar figures for the next couple of years; it's a bit up in the air right now.

Man: There's been a case recently, there's this commentary within two weeks on routine serology that there was found influenza in a commercial herd - flock. And that was the result of - we encouraged a test, otherwise there's really no economic, other than trade, for us to test.

Then on reporting, goes back to influenza again, with our trading agreements with some of our international partners, I know a case that we get in Texas, there was a report that got outside of Texas before it was sold to the state of Texas that came out of NVSL. There was a positive result that was not reported back to the constituents in Texas. Now there's a reporting issue there, not exactly how that flow went, but it was through TVMDL, and then around, but it didn't get back to the commercial industry until after we were told by our trading partner that we were on a watch list.

Dr. Martin: One thing I could - the comment was about the reporting process. What we do at NVSL, we report back to who submits to us, so if it's the veterinarian, whoever submitted it to us, that's who the report goes back to and they're relied upon to pass it on through that system. We don't provide reports to others that may be interested in the results and those types of things. It goes back through the submitter. I'm not familiar with that particular one, but I'd be glad to talk to you about it.

Man: It might be an off-table discussion.

Kim Ogle: Okay. Yes, one more question please.

Man: One for (Barb). The laboratories in the network, do they provide the information the test results, just what you all have funded them supported or

other information on other tests that they are conducting there too? Because this is a problem we always deal with on data ownership and data sharing, and really the only way to get those results is to pay for them.

Dr. Martin: You're exactly right. With SIV, I would say that what we've seen as we've gone to anonymous surveillances, that the laboratories are actually reporting more information. So we have laboratories that are reporting the test results from our testing algorithm, but they're also reporting their sub-typing results for no extra money.

What we've found is that these people are very interested in taking care of their stakeholders in the industries in their states. And they will do what they need to do; they're very good about reporting results and telling us when there are problems and issues. If they're testing a sample for CSF are we getting other test results? No, we're not. But they will work collaboratively with us and give us pretty much any information we ask for.

When we started with SIV, Dr. Lautner and I were contacting (Lance) on a regular basis saying how many samples have you tested for SIV in the past year, you know, what sub-types did you see, and they were providing that information to us at no cost.

Kim Ogle: Let me do a quick check in, because this is a portion of the agenda where the public is allowed to comment and ask questions, so let me ask of the folks that are in the room that are visiting as a member of the public or the media, a non-committee member, if you're interested in having the microphone and making a public comment or asking a question, could you please raise your hand so I know how much time to allow for that?

Okay, I just have one. That's good. I'm going to go ahead and allow a couple more questions than to the Ames folks and then I'll allow you time for your comments, okay ma'am? Thank you. Okay.

Man: Dr. Martin, thank you very much for - that was a comprehensive update. And I'd also like to just congratulate and complement everybody that's worked on this project, because Chuck and I, I think can remember back to 30 years ago when we sent out the first pseudo-rabies proficiency test. It was a like a car without a motor, you know?

My question, in your slide, and it may have just been an omission, but in your proficiency test, and the reason I'm interested in this is what's going on in Russia right now with ASF. You've got a proficiency test for ASF, but you don't have a standard method recorded.

Dr. Martin: We are in the process of completing validation for the ASF assay. So, right now we have trained and proficiency tested our laboratories to conduct the assay and they are running that assay on samples collected throughout the United States. So, we do have a standardized assay, it's more that we don't have an assay that's been deployed on a formal basis to the laboratory network.

Man: Okay, all right. Thank you.

Woman: Quick question, do your core - you talked about the difference of reports between your core laboratories and the member laboratories. Is there a method or is it maybe resource restricted for a member laboratory to become a core -- start serving those functions of core laboratory and reaching that level of support?

Dr. Martin: Yes, if we had additional funding.

Woman: Okay, for sure.

Dr. Martin: Our budget has been flat. What we did initially was to provide that infrastructure support on that side and then we worked at building up our equipment inventories and making sure that we had people trained and proficiency tested, and all those sorts of things that are that foundation. But we would expand that if we had the funding.

Committee: Okay, thanks.

Committee: One of the hot topics out there in the countryside is this proposed moving of the laboratories from Plum Island to Kansas. Is that a good idea, a bad idea, or does it not matter?

Dr. Lautner: The discussion is about the replacement for Plum Island. The Plum Island facility was commissioned in 1954 with laboratories, it's very difficult to continue to remodel laboratories with that HVAC systems that you have in place and the other requirements that you have to operate safely.

The Department of Homeland Security once they - had the responsibilities for maintaining Plum Island in June of 2003 undertook studies to take a look at that Plum Island area. They submitted - provided for expressions of interest for anyone who was interested in running a laboratory and building a laboratory, so they looked at about 29 different submissions that they had.

They had a site selection process that put that down to about six sites including Plum Island, then they had many site visits, there were public meetings, they did environmental impact statements and then made a record of decision to move Plum Island in the future to the Kansas facility. And as a

part of that, they did a site-specific risk assessment as well as had a review by the National Academy of Science to look at that.

Biocontainment exports around the world would say that you can, with the proper facilities in place and the proper operational procedures that are adhered to, can operate those types of facilities safely, not just on an island, but also on the mainland. And there are other countries such as Winnipeg, Switzerland, Belgium, Spain that have those types of facilities on the mainland.

Right now, the Department of Homeland Security is in the process of working through the funding to be provided for that facility, but the decision was made to move it to Manhattan, Kansas. Congress and the Farm Bill provided that the Secretary of Agriculture has the final say with regard to permitting for foot-in-mouth disease, because it's a select agent. The Farm Bill directed the Secretary of Agriculture if all requirements were met, and there's very specific requirements that are surrounding FMD, if all the requirements were met that the Secretary of Agriculture would issue a permit for a single successor facility to Plum Island.

So at the present time continued discussion about that, there is site preparation that's going on presently at Kansas. No construction, but the preparation of the site on the Kansas State University campus.

One thing that the other capacity that's being looked at was the new facility, in addition to the BSL-3 lab, that you have to have the high-containment for foot-in-mouth disease. One of the gaps in this country is we have BSL-4 capacity. BSL-4 is to address like the NIPAH and the HENDRA and the only difference between the three and a four is at a four, you have the air hoses to protect the workers, because you don't have a vaccine to be able to protect the laboratory workers.

With other diseases that have a potential for zoonosis to infect people, we have such as Rift Valley Fever, you have a vaccine that is able to give to individuals, or if you work with Japanese encephalitis. Things like that there's ways you can protect the workers without having to have the air hoses and the white suits with the air hoses. But with certain diseases like NIPAH, that's been seen in Malaysia, Bangladesh, and several other countries, there is no vaccine for people and it has a very high fatality rate in people.

So the BSL-4 is seen as a gap in our national preparedness. Winnipeg has a very small BSL-4, but we currently do not have the capability in this country to do the work and create the diagnostics so that we actually have the diagnostics or the vaccine. A limited amount of work can be done in Canada, but extremely limited. So that was one of the other enhancements that was being looked at in the new replacement for Plum Island.

DHS has received over time; I think about $110 million that has been used for design and some of the preparation work. Kansas also provided I believe about 100 and some million dollars to be able to do some of the central utility plant and the original site preparation for that area. But the funding would most likely be incremental, just like for our facility at Ames, we did not receive all that funding in one year. The overall cost of the Ames facility was $450 million. This would be expected to be larger for the type of facility being proposed, so they are going to need to receive in the DHS budget incremental funding.

Woman: Quick follow-up question on that, you mentioned the BSL-4 issues. What process would that take if they are looking at moving ahead on that, what are the steps involved here?

Dr. Lautner: Well, the proposal for the -- what's called the replacement for Plum Island is called NBAF, the National Bio and Agro-Defense Facility, and in the planning for that facility the design work that's been done to date, they have included a BSL-4 within that. And it's really the same kind of containment that you're building for BSL-3, with the exception for the addition of the air hoses for people.

Committee: I'm sorry; I don't think my question was clear. What approvals would be needed, or what would be sort of the policy process?

Dr. Lautner: Right. For that, the agents that you would work on in BSL-4 would be agents that would be either what are considered overlap agents that are on the list for both CDC and APHIS, so both CDC and APHIS, whether they're on the CDC list or the overlap list, both agencies would need to look at that process and sign-off on the process that's been used.

And the procedures are in place, you'd not only have to have the facility constructed to the standards, there's BNBL, their standards for that, but you actually have to have your procedures in place and your SOP's and all of those have to be reviewed and approved along with all the commissioning data for the building. So you have to know exactly how your HVAC system operates and all those types of things. So there's a very strict protocol to go forward for that, and it would include both public health and animal health.

Kim Ogle: Okay. Dr. Lautner, Dr. Martin, thank you so much for your presentation. Now this brings us to the part of the agenda for public comment and we only had one person that raised their hand for comment. So, I'm going to bring the microphone to you, ask you state your name, and your affiliation, and if there's someone in particular you'd like to direct your question to, or if it's just a comment. Okay?

Public: (Lloret Machado):Yes, I'm reading a couple of notes from my computer, so if that's okay. My name is (Lloret Machado) and I'm with the Rural Coalition, and we represent about 60 groups of community-based organizations that work with the American Indian, Latino, African-American, and other long- producers. And many, many of our producers are small-scale producers that operate mixed fresh fruit and vegetable and livestock operations.

And so, we're really concerned and interested about this issue, and our farmers all tend to know - and ranchers know a lot about livestock. And just a couple of issues that we really hope are, you know, going to be addressed. You know the farmers still they're concerned about, you know, what are you going to do with all this data? You know, what are - are there any confidentiality or privacy protections, you know, they are concerned about, you know, how these effect anything in the market place, and those are just concerns that have to be answered.

And then another one is not only confidentiality, but liability litigation. You know, what does this have to do with their liability for anything that may happen. I think most of them are very interested in, you know, protecting animal health and so forth, but that's a question they want answered.

There's also a concern about what is the record keeping burden? And I think there's also an interest, Vicki mentioned a very important point is, you know, how can you do something where all the records are, you know, at this date conform with the other things they need to do. A lot of them are doing good agricultural practices, and they have to have product liability insurance, how could this system perhaps work with that? How can you have, you know, one set of records as a win-win?

Could you also do anything with IDs through cooperatives, so that instead of having it to the individual premises, if there was, you know, a grouping of farmers and also where you could keep the records at the co-op level?

There's a need for technology and training, when you're doing the grant program through the states, one of the things we did in specialty crops in the last Farm Bill is, you know, try to put in a requirement which AMS has been doing, each state had to have a plan to outreach to the small-scale and the socially disadvantaged farmers who maybe don't work a lot with the state at this point and, you know, a lot of them are particularly the people that really need this help.

So is there a way to put something in the regulation that would ask the states to develop such a plan in partnership with the groups that are there. And, you know, again, that's going to be a partnership and, you know, to train some of the people from those communities to do some of the education work.

And the other things are language and cultural access, you know, can these be released perhaps also in Spanish, or -- there's a lot of Latino livestock producers in the country, for example. And then, you know, where do you do outreach on this system? We were just down in Florida with Latina producers talking about crop insurance; it's like where can you get information out? They suggested at the feed and supply stores and, you know, it would be worth it for the committee to really think about what are the best channels of information.

I'm sure we'll have other comments as the process goes along, but we just wanted to share those with you, so you know, the committee has access to them and I thank you for the time.

Kim Ogle: APHIS is still accepting comments. So, please continue to send them in. The address is on our website and so we'll take comments again tomorrow afternoon as it's noted on the agenda. And if you are not comfortable taking them live in person, you can send them on the website. And if you need that exact website address, just please see me. Okay?

Well, we need to be out of the room sharply by five, so I don't know if you'd like to spend any more time talking about traceability or whether you're "traceability'd" out. But you do have a little bit of time left.

Don Hoenig: So, what's the pleasure of the committee? Shall we adjourn? Let's adjourn.

Man: If we see on the news that the government is believed (unintelligible). We're starting on time, promptly at nine. I will be home asleep (unintelligible).

Kim Ogle: He has able assistance here. Thank you all for your productive day. We appreciate you being here. Thank you.

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