

**FTS-USDA OFFICE OF COMMUNICATION**

**Moderator: RJ Cabrera  
July 22, 2011  
11:00 am CT**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode for today's call. I would also like to remind participants this call is being recorded. If you have any objections, you may disconnect at this time. Thank you and you may begin.

Michael Doerrer: Good afternoon everybody this is Michael Doerrer from USDA in Riverdale. We'll start out with a quick roll call from our facilitator, (Jan Grimes), and then we'll go to our committee chairman, Dr. Don Hoenig for words of welcome. So, (Jan)?

(Jan Grimes): Okay good morning or afternoon. The roll call will begin now so if you are here, please just say here, nice and loud. Mr. Maximiliano Fernandez, I think I heard you already.

Maximiliano Fernandez: Yes.

(Jan Grimes): Okay. Dr. John Fisher? Dr. Andrew Goodwin?

Dr. Andrew Goodwin: Present.

(Jan Grimes): Ms. Vicki Hebb?

Vicki Hebb: Here.

(Jan Grimes): Dr. Hill? Dr. Howard Hill?

Dr. Howard Hill: Here.

(Jan Grimes): Dr. Donald Hoenig? Okay. Mr. Morris Johnson? Was that a yes?

Man: (Unintelligible).

(Jan Grimes): Dr. John Kalmey?

Dr. John Kalmey: Here.

(Jan Grimes): Dr. Charles Massengill?

Dr. Charles Massengill: Here.

Man: (Unintelligible).

(Jan Grimes): Ms. Judith McGeary?

Judith McGeary: Here.

(Jan Grimes): Mr. David Meeker?

David Meeker: Here.

(Jan Grimes): Dr. Boyd Parr?

Dr. Boyd Parr: Here.

(Jan Grimes): Ms. Genell Pridgen? Okay, Dr. Willie Reed?

Man: (Unintelligible).

(Jan Grimes): Mr. Charles Rogers?

Charles Rogers: Here.

(Jan Grimes): Dr. (Phillip Spayer)?

(Dr. Philip Spayer): Here.

(Jan Grimes): Mr. (Gill Stockton)? All right, Mr. Brian Thomas? Dr. Elizabeth Wagstrom?  
Dr. Cindy Wolfe?

Dr, Cindy Wolfe: Here.

(Jan Grimes): Okay. So I want to go, run through the folks that I have still not as on the call yet. I have Dr. John Fisher. Did I miss you? Dr. Hoenig? Okay, Mr. Johnson? Ms. Pridgen? Dr. Willie Reed?

Woman: He may be a little late.

(Jan Grimes): Mr. (Stockton)? Mr. Brian Thomas?

Brian Thomas: Just got on. Good morning.

(Jan Grimes): Okay, welcome. And Dr. Elizabeth Wagstrom?

Dr. Elizabeth Wagstrom: I'm on.

(Jan Grimes): Okay. Thank you, welcome.

Michael Doerrer: Well we definitely have a (unintelligible). I think our chairman, Dr. Hoenig is having some technical difficulties. I'm sure he will join. In the meantime, Judith, as our vice-chair, do you want to say any words to call the committee to order and welcome us?

Judith McGeary: I'd like to welcome everybody for giving up their Friday afternoon for this call. And one of the things that has been touched on in several emails and I want to encourage folks to bring up on this call is, you know, where can this committee actually start focusing its attention and providing recommendations.

We have a lot of topics on today's call and all of them are important and all of them are things that, you know, different people on the committee expressed interest in hearing about and getting involved in to some degree.

And I personally would like to see us start to set a priority list of where we're going to dig more deeply as we set our eyes on an in-person meeting sometime in October or November. So, welcome everybody. I look forward to this afternoon.

Michael Doerrer: Thanks a lot Judith. And now we'll just run through the agenda briefly.

(Jan Grimes): Yes. Again, Dr. John Clifford will be speaking to us for just a little bit, offering some opening remarks and talking about 2015 which I know you all are aware of that whole initiative and a new perspective, just giving some updates on that.

We are going to be covering administrative issues. Judith and (Donald) will be handling those. The next item after that is getting an update on the tuberculosis and brucellosis collaboration on the regulatory framework.

Dr. Alecia Naugle will be onboard to talk to you about that. We're going to talk about vaccine challenges related to emergency preparedness and response.

Dr. Darrel Styles will be offering thoughts on that. Then we have a scheduled break that will start at 2:30. However, if we end these first items more rapidly, we'll just continue until I, you know, sense that we need a break or we hit 2:30.

At any point though, if it feels like folks are, would like something, please speak up and let us know and then we will make those proper arrangements to go on hold for 15 minutes and then come back together.

After the break we'll have an update from Dr. Elizabeth Lautner and Dr. Bob Martin on the NAHLN, which is the National Animal Health Laboratory Network.

Dr. Diane Sutton will be talking about scrappy. And then we are going to get a conversation going about modernizing the general disease database, the surveillance instrument that we're going to be using. And Dr. (Viconso) and Aaron or (John Viconso) and Aaron Scott will be talking about that.

Finally we'll be getting an update on the national veterinary stockpile. And we have Rodney White listed for that. And then we'll wrap up and talk about next steps.

Anything missing from the agenda that you expected to see that you didn't?  
That you don't see?

Michael Doerrer: I just want to note for members of the public, both the agenda and all informational materials, the committee is going to have, is available on our Web site. So, do take a look at that and you'll find everything that you need to follow along with us.

(Jan Grimes): Okay. All right, so, Dr. Clifford, are you on?

Dr. John Clifford: Yes (Jan), I'm here.

(Jan Grimes): Okay. I'd like to welcome Dr. Clifford and let him go ahead and begin talking.

Dr. John Clifford: Thanks Jan. And I want to begin by thanking the committee and the members for your continued support, commitment and service. I was unable to join in on the last call and I'm pleased to be with you all here today.

I understand others have joined us on the public line as well, and are taking time to listen as the committee explores various animal health topics, and I want to thank you all for joining our conference call today as well.

Before I begin discussing Veterinary Services 2015, I'd like to point out just a couple of things. First, regarding the status of the proposed animal disease traceability rule, because of the importance of the proposed rule on animal

disease traceability to America's livestock industry, additional review time is warranted.

So we hope to move forward with the proposed rule as soon as possible. And as soon as it's scheduled for publication, a press release will be issued.

Second, the aquatic animal health subcommittee membership review is fully underway. VS has proposed members for the subcommittee and we're seeking the administrator's concurrence and then those appointments should be confirmed sometime this summer.

So now on, with regards to the new perspectives document for 2015, I'd like to share with you the latest on our strategic roadmap for Veterinary Services 2015.

I'm glad that we can finally talk about the details of 2015. We already know some of the basic ideals that have brought us to this point, flexibility in writing, interpreting and carrying out our regulations, transparency as we make decisions and interact with stakeholders and one other, and collaboration, both internal and external in how we develop and carryout our programs.

These ideals led directly to the creation of the detailed new plan that maps out the future direction of VS. Calling that document, Veterinary Services, a new perspective, and I'd like to take a few minutes to walk through the document with you today.

It begins with the primary focus of VS 2015, which is to enhance the core strengths that made VS a leader in animal health. Some of you may ask how we do that. Well the document specifically lays out not only our refocused

vision and mission, but the five goals that will ensure our role as the nation's animal health leader.

Our first goal is to transform the culture of VS to meet the evolving needs of the animal health community. For me, culture change means including more voices and more diversity of thought and opinion in our decision-making.

A critical piece of our new perspective is to focus on our individual strengths and use those strengths in a very goal-directed way within our organization. It means moving from a way of doing business where we say yes to everything, to one where we say yes only to those things that clearly align with our strategic goals and resources.

In many ways, goal two is similar to goal one. It calls on VS to build new collaborations and partnerships while sustaining existing ones. For working to do things like formalizing relationships, doing a better job of cataloging information about stakeholders and stakeholder events, and getting better communication products into your hands so you can reach out more effectively to partners.

External collaboration is a large component of our new perspective. One of the themes of VS 2015 is that VS cannot work in isolation. We'll leverage our skills by partnering with agencies and organizations whose expertise complements our own.

For example, we have a pilot underway that encourages VS employees to identify short-term detail assignments with potential one-health partners.

The services VS offers are the focus of our third goal and centers on enhancing our core strength and surveillance, diagnostics and import/export.

Goal four, which specifically addresses our core strengths in the area of emergency management. It states that VS will support readiness and response, balancing the needs of animal agriculture with the interest of people and the environment.

Both goals three and four recognize the history as our nation's veterinary authority and we've earned that reputation because of the knowledge and expertise of our employees.

However, these goals call on VS to expand and enhance its traditional skills in more strategic, purposeful ways, which brings us to our fifth and last goal. We will invest in an integrated technical infrastructure to support our mission.

How we adapt and use technology is a central theme of the new perspective. Effective information technology's at the heart of our core programs. Goal five requires VS to adopt, use and retire legacy IT systems more strategically.

We'll continue to follow our IT roadmap, a document which is on our webpage. And it contains specific milestones we'll use to measure our success in meeting this goal.

These goals require our organization to be proactive and not reactive. It's important to note that not everything in our new perspective is new. VS 2015 is and always been about carrying out on what we do well, improving things where we can while finding new opportunities to bring our services to the forefront of the animal health community.

Now how do we go about implementing the goals and priorities I just described? Our VS management team has chosen to get the ball rolling by

identifying 18 short-term priorities for fiscal years 2011 and 2012 that our foundational to our strategic goals.

So let me just offer a few highlights. Going forward, you'll see more flexible, transparent regulatory framework such as for animal traceability and other issues.

As you know, a proposed animal disease traceability regulation for livestock moving in an interstate will be published soon and this is a significant milestone for us.

It's a move toward performance-based rather than prescriptive type regulations. You'll also see new approaches to animal import and export. As another example, VS is evaluating and refining the concept of export centers.

We're considering whether that concept can be expanded to cover the U.S. and to eventually include other services such as facility inspection and approvals for select agents, biologics, laboratories and other export facilities.

We're also developing electronic inspection and certification processes starting with export product certification. In terms of emergency management, we're focused on developing new emergency management tools.

For example, we're developing plants to secure our milk supply. We're looking at new swine euthanasia technology and ways to expand mobilization of non-federal employees to respond to emergencies.

Next in the area of surveillance, we'll continue our work toward implementing a comprehensive, integrated surveillance plan for swine health. The plan will

include broad ranging data for analysis and decision-making, and generating timelines that address commodity specific surveillance plans.

Finally, you'll be seeing expanded services related to one health and wildlife. For example, cost-benefit analysis for reducing wildlife diseases and the risk of transmission are essential items for us.

We expect our first analysis of this kind to focus on brucellosis in the greater Yellowstone area. In addition, we'll be working more and more to integrate one health initiatives into daily VS activities and continue building new collaborations throughout the one health community.

Keep in mind that these immediate priorities are only a start to implementing our goals for 2015. I've asked all VS employees working with you, our customers and stakeholders to develop and implement specific solutions for improving our service at the local level.

And I want to emphasize that no good idea is off the table. In addition to asking VS employees to find ways to make our organization more efficient and more responsive, I also welcome your ideas and suggestions.

Our partners in the states and tribes and our stakeholders in the industry and academia have been vital sources of inspiration and support throughout the 2015 planning process.

I hope that spirit of collaboration continues and we will build and establish mechanisms to allow you to get your ideas and comments directly to me and my staff.

So for example, we have a 2015 mailbox where you can send your ideas. The address is VS2015@aphis.usda.gov. VS' new perspective is intended to be a baseline for us to grow and adapt in the changing animal health landscape and prepare our workforce and organization as a whole to flourish as we move forward.

This isn't a radical departure from VS' longstanding history. But it is a new strategic posture to begin addressing our most pressing priorities. It represents a fraction of our plans to evolve VS in this dynamic environment.

We welcome stakeholder participation in the process particularly in those areas that will affect you most. I believe this committee will be instrumental in helping VS addressing these priorities.

And I look forward to working with you on these and other important matters through 2012 and beyond.

I'll also mention to those of you listening in that the new perspective document may be found on the Veterinary Services Web site. I think it's under the secretary's advisory committee for animal health and the Veterinary Services Web site.

Again, thank you for listening and I'd like to use the rest of our time together to answer any questions you may have.

(Jan Grimes): So I guess we'll open for general questions to Dr. Clifford.

(Gill Stockton): Hello, this is (Gill Stockton). Dr. Clifford?

Dr. John Clifford: Yes.

(Gill Stockton): On that document that you sent us, the veterinary service, a new perspective, chapter three, page 11, there's a list of 18 items that you're working on. And item 7 and 8 deal with exports, but I don't see any dealing with imports. And I note that you share responsibilities with other agencies within APHIS, but when or why not dealing with some import issues?

Dr. John Clifford: Well I think the document as a whole deals with import and export. But these are basic priorities we feel are critically important for us to accomplish in the initial phases.

So the item, which item number is that that you were looking at (Gill)?

(Gill Stockton): Seven and eight on page 11, evaluates the exports, you mentioned that.

Dr. John Clifford: Right.

(Gill Stockton): And in fact you mentioned both of those.

Dr. John Clifford: Right, so...

(Gill Stockton): But...

Dr. John Clifford: ...basically...

(Gill Stockton): ...simply, the import surveillance isn't on this list of 18.

Dr. John Clifford: No it's not. I mean, so, what are you thinking (Gill) that needs to be on here?

(Gill Stockton): Well, that's our first line of defense for new diseases in this country is preventing them from getting in here.

Dr. John Clifford: Yes and we do that on an everyday basis and there's no doubt about that. We continually evaluate diseases through our risk assessment evaluations for regionalization of countries and those are things that we continue to do.

Recently we've been meeting with customs and border patrol with regards to making sure that we have the right kind of messages. We're trying to increase our messaging to people traveling to and from countries that may present a risk of disease here, into the U.S.

And so those are critically important things. But as far as what we've identified as what we feel are most currently important for us right now, today, are these 18 things for us to accomplish.

(Gill Stockton): Does that mean that you feel that your resources for import surveillance is sufficient?

Dr. John Clifford: When you say import surveillance, I think our resources are sufficient for us to do analysis of animals or regions and countries abroad for us to be able to adequately assess those countries for movement of animals and products into the U.S.

In addition, we do not allow live animals directly into the U.S. with the exception of our borders on Canada and Mexico. And all other live animals coming into this country would have to go through a quarantine facility that are adequately staffed, yes.

(Gill Stockton): Okay.

Dr. John Clifford: I think our (unintelligible)...

(Gill Stockton): But then, for instance, the BSE and from Canada and stuff, that's a different agency that...

Dr. John Clifford: No.

(Gill Stockton): ...who looks at the cows, or?

Dr. John Clifford: No. When you say looks at the cows, that's not a different agency. APHIS has a major role to play there. The FDA has the component of dealing with feed bands, so we have done an analysis of Canada and we consider Canada to be in that same risk category for the OIE of that moderate or lower risk category.

But we have been able to address those issues because of the processes that are put in place both in this country and in Canada to address those. So we have done a tremendous amount of work on BSE through a lot of assessment and a lot of external analysis as well.

And BSE is declining worldwide. And it's declining worldwide because we know how to address this disease.

(Gill Stockton): Yes but of course there's still major concern, out here, in whether or not any older Canadian cattle should be coming into this country at all.

Dr. John Clifford: Well we have a date in which cattle that are more adapt to that date are allowed to come into the U.S. And those animals are required to be permanently identified both with an identification as well as either a tattoo or a brand.

(Gill Stockton): Yes.

(Jan Grimes): All right, other questions from the group to Dr. Clifford?

(Howard Hills): Dr. Clifford, this is (Howard Hills). You mentioned putting resources towards improving euthanasia, humane euthanasia measures, are you prioritizing any species with that?

Dr. John Clifford: I think the, some of those initial ones were for the swine activities for that. I think that, you know, we're looking at that more broadly, but in addition we're also looking and I think you'll have some discussion with that later on with others, about more use of vaccine and trying to look at how we can effectively salvage more animals with the least amount of destruction possible.

If you have a large outbreak of FMD into this country in certain areas, we will not, probably even have the ability to get all those animals effectively destroyed and in the ground if we don't look at other uses and measures to be able to address some of the concerns we have.

So basically part of that would be using vaccines. And whether we vaccinate to live or vaccinate to kill would depend upon the situation and how many animals we're talking about.

But the most important thing in an outbreak situation like that, as you know, is to stop - get the movement stopped in that area, get animals vaccinated and protected and stop the spread of the virus.

Charles Rogers: Dr. Clifford, this is Charlie Rogers. I guess our, the plan includes working more closely with private veterinary practitioners, is that correct?

Dr. John Clifford: It's not - yes, private practitioners, but it's also others.

Charles Rogers: And you - there's probably, there's some areas in the country where the veterinary, large animal veterinarians are in short supply. There's not enough of those people around probably, or maybe not adequate number, is there - how do we address that issue?

Dr. John Clifford: Well, I think, you know, that issue's trying to be addressed on a number of fronts and you've got the American Veterinarian Medical Association trying to address that.

I know that that's an issue for Congress that they're looking at it. They've been providing some funding to help try to address some of that. I don't, you know, we all know what the funding situation currently looks like.

But I know there's a number of initiatives going on at the schools through the American Association of Veterinarian Medical Colleges as well as the veterinarian profession to try to address some of those concerns.

And I think, you know, in some cases there may have to be incentives of loan repayments and things like that to veterinarians to move into some of those areas.

Charles Rogers: And Dr. Clifford would it not also be in your asking for suggestions, possibly a bigger role for vet techs and veterinary assistants through this program?

Dr. John Clifford: Well, I guess, you know, that's really a question probably that needs to go more to the state licensing boards because, you know, our federal veterinarians and the state animal health inspectors and veterinarians would

fall under - the state animal health inspectors and veterinarians would fall under the state rules.

Our federal veterinarians would fall under a different set in what we do and don't do within states. And the private practice acts are controlled by the state themselves.

So if you wanted to see greater involvement from animal health technicians within states in the private sector, that's something that would have to be taken up at the state level.

Charles Rogers: I see.

(Jan Grimes): Anyone else? Okay so Dr. Clifford thank you very much for your opening remarks. I assume you're going to hang on the line and continue to listen to the conversation.

Dr. John Clifford: Yes (Jan) I will be listening. I have a couple of meeting in between I have to go, but I will be staying on the phone for the majority of the time. I appreciate the comments and questions and I do request that you all, if you have suggestions, that, provide those to us and we'll be happy to take a look at those.

(Jan Grimes): Great. Thank you Dr. Clifford. So the next item that we'll move onto, and Judith, I don't know if Dr. Hoenig's on yet, but I'm going to leave the committee administration issues to you if you're prepared to talk about that.

Judith McGeary: First, Don have you joined us? Okay it's (unintelligible). I think the only piece that I had on my list was the planning for our in-person meeting and setting a date.

From the emails that have gone around, it looks like first week of November is the most likely. We have two options. One we can try to set a date right here and now and see if the first week of November is workable for everybody.

The other would be, of course, to set up some sort of calendar survey. I assume we can do through SGA if that would be an easier way to handle it.

RJ Cabrera: Judith? This is RJ. Michael and I talked a little bit about this earlier and if we can settle on a two-week frame, I'll send something out and let the committee choose dates and we'll put something together that way. I think that would probably be the easiest.

Judith McGeary: That sounds good. So, and one question for y'all is, I know we were looking into October because of budget issues, would it be possible, I mean, some people had suggested an early October meeting, would that be possible with the budget? What's our early cutoff?

Man: Early October is when the U.S. AHA meeting is, so.

Judith McGeary: Okay. Sorry, I missed that one.

Man: Yes.

Judith McGeary: So, judging from the emails, the week of October 31/November 1 appeared to be certainly one of the options. Would the week of October 17 - the week before and the week after it though had quite a few people saying it wouldn't work - would the week of October 17 be enough of an option that people would like to look at specific dates?

Let me rephrase, who couldn't do the week of the 17th? That might be...

Dr. Boyd Parr: This is Boyd. I only have a couple of days and I would have to be gone during our state fair to do it, which is kind of tough for a state vet.

David Meeker: This is Meeker. I wouldn't be able to do it that week.

Dr. Elizabeth Wagstrom: This is Wagstrom, I couldn't do it either.

(Howard Hill): (Howard Hill) and I couldn't do it that week.

Charles Rogers: Charlie Rogers, I couldn't do it that week either.

Judith McGeary: Okay, I think we've got enough to...

Michael Doerrerr: But we surveyed though, the first weeks in November...

RJ Cabrera: First and second.

Michael Doerrerr: ...the first and second weeks in November, we'll just put that on the survey?

Judith McGeary: I can tell you right now, I can't do the second week and I saw a lot of no's actually on the second week, that week of the seventh.

Michael Doerrerr: The third?

Man: The third doesn't work for me at all.

Vicki Hebb: Yes this is Vicki, I can't do the week of the seventh, but I can do the first week.

Judith McGeary: Well what about the third week? I think Michael, was that what you're suggesting?

Vicki Hebb: Oh I'm sorry.

Michael Doerrerr: Yes the week of November 13.

Judith McGeary: Fourteenth.

Michael Doerrerr: Thirteenth, fourteenth, yes.

(Liz): This is (Liz) (unintelligible) and I can't do that third week.

Dr. Boyd Parr: Yes, this is Boyd, I can't either.

(Andy): Yes, this is (Andy), I can't. With this many people, there's not going to be...

Michael Doerrerr: Yes we're not going to find a date that we're...

(Andy): ...weeks that there aren't going to be lots of conflicts, so. Yes.

Michael Doerrerr: So, Judith we'll get in touch with you and Don. We'll just pick a few weeks, maybe two or three or even four to survey.

RJ Cabrera: Yes and go from there.

Michael Doerrer: And we'll just see where we get the greatest numbers and we'll just go from there realizing that we're going to have to have a couple absentees. That's okay.

Judith McGeary: Yes it is. Location wise, I hate to break it to you (Andy), I think Cozumel's out. We could also handle it by survey. I just wanted to, you know, did folks have specific locations that they would like us to look at besides DC.

There were some general ones had been mentioned like the south. But, were there very specific locations that anybody had in mind to propose?

Maximiliano Fernandez: This is Max Fernandez, I believe Washington DC is an easy place to get in and to get out, you know, during the early morning or late afternoon. And I think it (unintelligible) more economical at the moment if you fly there.

Judith McGeary: And Max, I agree with you, I think, you know, I have a lot of preference for D.C. and I think Don does as well. We're also hoping certainly if we have it in D.C. that we'd have the opportunity for Secretary Vilsack to spend some time with the committee members, which is really only an option in D.C.

So I think there are a lot of thoughts about D.C. What I wanted to ask though was does anybody have specific alternative locations that they'd like us to consider in terms of, we could set up a survey to address the location. Were there specific alternatives that folks wanted to look at?

Man: The only problem with D.C. is it's very expensive. I mean, if we're cost-conscious, we may want to look at going into central, a more central location where hotels aren't as expensive, like Kansas City or St. Louis or something like that.

Maximiliano Fernandez: This is Max Fernandez again, I believe the USDA have a contract with many of the hotels over there and they have very reasonable rates for the government.

Judith McGeary: Certainly USDA, you know, there're government rates, I think at hotels all over the country, but I think probably still the D.C. ones are higher. I mean it's a good point to be made about the cost, which actually, RJ and Michael does it look like - what sort of budget are we looking at in terms of whether we'd be able to have a second or a third meeting during the course of our second year of existence? I mean, how many or...

RJ Cabrera: Judith we'll know more about that sometime in September.

Judith McGeary: Okay.

RJ Cabrera: We're working with our committee management official and we've got to put together some projections, but we'll have a firmer idea about that in September.

Judith McGeary: Thanks RJ.

RJ Cabrera: I know that we'll probably be able to do at least one but we're looking into other options as well.

Judith McGeary: Okay. So how about if anybody - you know, if anybody wants to pipe in quickly, feel free to. Otherwise I'll suggest that if you have, if you come up with a specific suggestion, I've heard Kansas City and, you know, a sort of a centralized, you know, physically more centralized location and less expensive.

If there are other ones, you can send them over to email and we'll create up a survey for everybody. Will that work?

Man: Yes.

Judith McGeary: Then we'll go with that. RJ do you know if there were other administrative issues other than schedule that because I don't remember.

RJ Cabrera: I think it was just, I think you're right. We're just looking at dates and venues, unless you have anything else.

Man: One question I would have to the committee is, if we're waiting for our next in-person until November, or even perhaps later, do we want to do another call between now and then?

Judith McGeary: I think that's a good point. I think I assuming that we'd probably go with another call if we got - if the in-person meeting gets pushed back much.

RJ Cabrera: We would definitely -- this is RJ -- we would definitely need to have a prep call of some sort before that in-person meeting, but in terms of another public call...

Judith McGeary: Well I think with animal ID - I mean, presumably - well actually I won't say presumably, we, I would think that we'll probably have the animal ID rule out and, you know, if we want to have time for a substantive discussion on this committee providing comments during the comment period, pushing that into November could be difficult, depending on when exactly the rule's published.

Dr. Charles Massengill: And, I agree, and I think we do have a rather large number of items on our agenda, so I think another phone call with a reduced number of agenda

items that we can go deeper into would be a good idea before our face-to-face meeting. This is Chuck Massengill, I'm sorry.

Judith McGeary: Thanks Chuck. Other comments or thoughts on another conference call between now and what's looking like November?

Dr. John Clifford: Judith? Hey, this is John. I'd just like to add one comment to the group. Depending on the location you're picking, if you all are going to be depending upon having a lot of interaction with a number of staff people, it does increase the cost considerably if we have to do things at another location. So I just wanted you all to take that into account.

Judith McGeary: Thanks John, good point. Either we fly to D.C. or the rest of y'all fly out too.

Dr. John Clifford: Well and in this case, both of you, we'd all be flying versus just you all.

Judith McGeary: Exactly. Thank you.

Dr. John Clifford: You're welcome.

Judith McGeary: Other thoughts from the committee members on a second call? Presumably we'd plan something in September.

Michael Doerrer: Yes that's what I was going to suggest Judith, do another public call in September and then do another purely informational prep call immediately before the face-to-face.

Judith McGeary: So how does, any objections or specific thoughts about a call in September from the committee?

Man: Sounds find to me.

Man: Sounds good

Michael Doerrer: Okay we will work that out and get dates out, et cetera to everybody.

Judith McGeary: Michael thanks for bringing that up. I think that takes care of administrative pieces.

(Jan Grimes): Okay. Thanks Judith.

Judith McGeary: Thanks.

(Jan Grimes): So we have here in Riverdale is Dr. Alecia Naugle and she is going to give you an update on the TB brucellosis combined rule and what the progress that working group's made. So here she is, Dr. Naugle.

Dr. Alecia Naugle: Good afternoon everybody. Again my name is Alecia Naugle and I am currently the program manager for USDA's TB eradication program. And I'd really like to thank everybody for inviting me to participate in your call this afternoon to give you both an update on the status of our program as well as on the status of the regulatory draft framework document that we recently published and took out and did some public meetings on.

So what I thought I'd do this afternoon is start with a brief update about the status of the program and then move on more specifically to the regulatory framework and the proposed rule that we're developing for the future.

A handout has been developed and posted on the Web site that has additional details regarding our TB program update that I'm going to start with first. So I

thought the approach that I would take is just highlight some of the key points that are in the handout then give everybody an update on where we are with the regulatory framework and then finally open it up to you all for your questions and comments.

So with that we can start out by saying that the national bovine TB eradication program is one of USDA's longstanding disease eradications programs. It's a cooperative effort about the federal government, state government and industry.

And our ultimate goal is one of eliminating mycobacterium bovis, that's the organism that causes bovine TB from U.S. livestock. And a little bit of history as to how we got into this business and how we're doing.

In the 1900s, tuberculosis was both the chief cause of deaths in humans as well as the most economically devastating disease of livestock in the U.S. In cattle, again we've talked about this disease is caused by the bacterium mycobacterium bovis.

However, this same agent can also infect people. So it's a human health concern. During the early 1900s, more than 5% of all cattle were infected and about 15 to 30% of all human TB cases were actually caused by m-bovis.

And the understanding was that these people most likely contracted the disease from drinking raw milk from infected cattle. So to respond to this public and animal health threat, the bovine TB eradication program was formed in 1917.

Since that time, we've had success in reducing the prevalence of this disease in cattle herds from approximately 5% to less than 0.001%. Many consider

this to be one of the greatest animal and public health achievements in the United States.

However, we continue to occasionally, sporadically detect TB in livestock herds. So our ultimate goal of eradication remains a bit elusive.

The next section on the handout that you were provided discusses the current TB affected herds. In the handout we provide some information about the herds that we've detected in the last two fiscal years, fiscal year 2010 and so far in 2011.

To give you a little perspective, since the mid 1980s, the number of TB affected cattle herds that we detect every year in the U.S. has been relatively constant.

We tend to detect about 10 affected herds per year. When we detect these herds, we either depopulate the herd or manage it using what's called a test and removal plan.

And we base the decision on which approach we're going to use in a herd, for each herd, and we consider a number of factors. The things that we look at include the apparent prevalence of infection in the herd, meaning how many animals are infected within that individual herd, the risk that the disease could be transmitted if we kept the herd under a test and remove plan, either to other animals in the herds or potentially to other herds or even wildlife.

We consider the effectiveness of different management practices that allow us to mitigate disease spread. And we also look at the cost-effectiveness of depopulation for each herd.

The next section in the handout talks about state status. And to give you a little background here, an underlying concept for the current TB program is one where we classify states according to a system where we have five status levels.

And each status level has associated with it different moving requirements. Currently we have five status levels and the lowest ranking has the most restrictive movement requirement.

Man: (Unintelligible).

Dr. Alecia Naugle: In addition to having an individual state having a status, there's also the option of states identifying a zone within their state that could have a different status. And this happens on a case-by-case basis and we commonly refer to this as a split-state status.

We give each state a separate status, one for cattle and bison and the other for captive servants. And the handout gives you a summary of the current statuses for the state.

I think you'll note that the majority of states are at our highest level of status with regard to cattle and bison, and that status level is called accredited free. And then we also have several states that are at a lower level.

For captive servants, all of the states currently are identified as modified accredited.

Because of the linkage between state status and interstate movement requirements, there is a considerable economic incentive for a state to have the highest level possible under this system.

However, in the recent past, many states have expressed concerns, either about the inflexibility of our system and as a result, in April of 2010, APHIS issued a federal order that made, that suspended some part of our code of federal regulation.

The purpose of this federal order was to address some of the concerns that states had as well as ultimately to make it easier for producers, even if they're in a state where there's been TB identified, to still be able to move their livestock.

Man: (Unintelligible).

Dr. Alecia Naugle: A key change of this, of the federal order, was that we would not downgrade an accredited free state or zone if a TB affected herd was identified, as long as that state or zone continued to meet certain criteria to control the disease.

So that's a bit of an overview about state status. The next section on your handout talks about surveillance that we do for bovine TB. And in our surveillance program, we have components of slaughter surveillance as well as live animal testing.

Slaughter surveillance is our major case finding tool. And to give you an idea of how this happens, during the inspection process at a slaughter establishment, as you know, food inspectors actually observe each individual animal.

And during this process they look at certain lymph nodes, in the head and the chest cavity to see if they look abnormal. And if inspectors see a certain type

of abnormality that's often found in animals that are infected with TB, this sort of abnormality is called a granuloma, they collect that tissue and they submit it to the laboratory for evaluation.

And that evaluation is either under the microscope, and we call that histology. Or they do other testing such as putting the tissue in culture and trying to grow the bacterium.

So that's what we mean when we talk about the process of slaughter surveillance. And to make sure that our slaughter surveillance is effective, we actually have performance standards in slaughter establishments that kill adult cattle -animals called cows, called bulls, those kind of things.

APHIS works very closely with our sister agency, the food safety inspection service, to make sure that each individual slaughter establishment meets these criteria.

So every year we, through our slaughter surveillance, we have approximately 10,000 granulomas that are submitted and from those 10,000 granulomas, we usually identify about 10 to 15 cases a year.

And then through our EPI investigations and our trace investigations, we usually identify somewhere between five and ten affected herds, directly through slaughter surveillance every year.

As I mentioned, live animal testing's also an important component, particularly for captive servants where we don't really have established slaughter surveillance standards.

We test over a million head of live cattle...

Man: (Unintelligible).

Dr. Alecia Naugle: ...every year for TB and over 10,000 head of servants every year for TB.

Man: (Unintelligible).

Dr. Alecia Naugle: An important part of this live animal testing is what we call the coddle fold performance standard. And accredited veterinarians that conduct this testing, we have a performance standard that we've set up for them.

We expect them to report a certain number of animals to be what we call reactors.

Man: (Unintelligible).

Dr. Alecia Naugle: Many of you have probably had a TB test. It's a similar principle. We inject the tuberculin and then approximately three days later we go back out and look at the area where the tuberculin was injected. If we see any swelling there we call that a reaction, so we expect veterinarians to identify reactors.

And we hold them accountable for doing that and that allows us to increase the effectiveness of our surveillance program.

Man: (Unintelligible).

Dr. Alecia Naugle: And I think we have information about how the states are doing with regard to our CFT response rate in your handout.

Finally, the last area that we cover in the handout is one that I understand that you're very interested in hearing about and discussing, and that is our collaborations with Mexico and our efforts to reduce the risk of importing TB cattle from that country.

Man: (Unintelligible).

Dr. Alecia Naugle: APHIS works very closely with our colleagues that our Mexican animal health officials to reduce the risk of importing either TB infected or TB exposed animals into the U.S.

We do this through a couple mechanisms. One thing that we do is we conduct reviews to make sure that the requirements for the control of TB are equivalent between the U.S. and Mexico.

What this means is that every year we send a team of APHIS employees to various states or zones within states to Mexico to evaluate their TB program to see if it meets our same criteria for a status.

For the past several years we conduct these reviews in between four or five states or zones, each year, in Mexico. And just like for interstate movement here in the U.S., this status level that we give a Mexican state or zone determines what kind of testing has to be done and what other requirements might exist in order for those animals to be imported to the U.S.

Again, the lower the status, the more restrictive the requirement for these cattle to come into the U.S. Currently Mexico has one zone that's classified as modified accredited advanced, 12 modified accredited states or zones, nine accredited preparatory zones or states, and 11 non-accredited states.

You may be aware that Mexico is, excuse me, that APHIS is going to reclassify the status of Chihuahua, an A zone to accredited prep. And that change is scheduled to become effective on August 18.

One of the reasons that we're making that change is because efforts that occurred in Mexico to address some issues that came up on a recent review in Chihuahua have not been effective in reducing the number of cases that were seen in the U.S.

Specifically, since February of this year, there has been five TB infected cattle that have been identified in the U.S. that originated from Chihuahua. Additionally, Chihuahua has reported to us that they've identified 15 new TB affected herds during the last year.

Both of these measures exceed the allowable standards that we have for Mexican states for MA status, so we intend to downgrade them. And there have been some changes in our imports for those cattle in the interim until they're downgraded as well.

This is important because Chihuahua is currently the largest Mexican - the state with the largest volume of Mexican cattle coming into the U.S. So we believe that this is an important step to take to reduce the risk of importation of TB infected cattle into the U.S.

Again, one we that we monitor how well we're doing with our efforts to reduce the risk of importation is by looking at the TB cases that we see come through our slaughter surveillance program.

And some of the information in the handout gives you some additional details about what we've seen in those cases in the last year.

So briefly I just, I think to be able to kind of let you guys have good free discussion, I think I'll go right into the update on the proposed framework, proposed rule, and then we can just open it up for general questions at the end of that.

Since Dr. Thomas joined you on your last call in May, the USDA has held four public meeting to receive comments about our framework, in May and June.

These meetings were in Michigan, Georgia, Montana and Texas. As you knew at the time of your last call, we did publish a notice in the Federal Register on May 6 where we published the draft framework.

And we accepted written comments through July 5. At this point, the comment period has closed and we received 37 written comments. We are in the process of thoroughly reviewing both the written comments and the transcripts from the public meetings.

And these comments are definitely being considered as we draft the proposed rule and the program standards.

The plan is to publish both the proposed rule with the program standards in the Federal Register. And as of now, our goal is to get this done early in calendar year 2012.

In preparing for the meeting, I understand that there was a lot of interest about the indemnity element that we included in our framework, so I wanted to give you a little, more specific information about the comments we received about indemnity.

You'll remember from your discussion with Dr. Thomas, some of the key components or approaches around indemnity that were in the framework document, included the idea that there would be a calculator that would be potentially used to determine an animal's fair market value.

And then we also talked about not having a provision for appraisal or appeal. Well, as you can imagine, the indemnity element generated a large number of written comments and we had very robust discussion at our public meetings about the language that we included in the draft framework document.

While I won't go into detail about all those individual comments, I can let you know about a few themes that emerged. First of all, many people view funding for indemnity as essential for the continued success of both the TB and the brucellosis programs.

Secondly, virtually all of the written comments that we received supported paying the current market value for animals that are to be indemnified for either disease. And there were several comments that indicated replacement value should be paid.

We had quite a bit of mixed opinion expressed about the use of the calculator. The majority of written comments did appear to favor the use of an appraiser. However, many agreed that a calculator may be able to work in certain situations.

One comment that came up several times was, perhaps the calculator can be used when we're removing individual or small number of animals so that they can be tested further to determine if they have TB or brucellosis, but when a whole herd needed to be depopulated, that an appraiser should be used.

And finally I can say that in the written comments that we received and in the public meetings, there was unanimous support that there needed to be an appeals process included for indemnity in the event that the owner chose to dispute the valuation of his or her animals.

Again, we take these comments seriously and we are reviewing them and considering them as we develop our regulatory test and our program standards. So thanks to all you on the line that may have submitted comments in one form or another.

So at this point (Jan) I'm done with the formal, kind of presentation I was going to give and I'll just turn it back over to you to facilitate any questions or discussion that folks might like to have either about the handout, about the status of TB or about our proposed rule.

(Jan Grimes): Okay so....

Dr. Donald Hoenig: (Jan), (Jan), this is, can I interrupt for a second, this is Don Hoenig.

(Jan Grimes): Sure.

Dr. Donald Hoenig: I just got on a few minutes ago.

(Jan Grimes): Okay.

Dr. Donald Hoenig: I apologize. We've had a power outage up here where I'm staying, and, so I had some issues in getting on until now.

(Jan Grimes): Okay, well welcome.

Dr. Donald Hoenig: So, I don't know. Thank you. I assume Judith has sharing the meeting and if it's okay, I can...

(Jan Grimes): Yes, Judith has done a fine job of...

Dr. Donald Hoenig: Great.

(Jan Grimes): ...keeping the group going, so.

Dr. Donald Hoenig: Thank you.

Judith McGeary: But Judith is also very happy to hand the meeting back over to you Don. Welcome back.

Dr. Donald Hoenig: Well I sincerely apologize for not getting on but we, believe it or not, it's 98 degrees I think in Portland, Maine right now, which is highly unusual for this area. And I guess we just had a huge, big power outage. So I've had some issues here.

So I listened to the end of the TB presentation and but I missed the rest. So, I guess we'll open it up for questions for the committee.

(Jan Grimes): Yes please. Questions for Dr. Naugle.

Dr. Willie Reed: Yes, this is Willie Reed and I have a question. I'd like to ask, in those states where we had positive herds in fiscal year 2010, how much wildlife testing or (unintelligible) testing has been conducted? Not in the captive facilities but in the wild.

Dr. Alecia Naugle: That's a good question. I would say that what we encourage to happen in those cases is during the time that a, what we call an epidemiological investigation is being conducted, that means that, you know, we have veterinarians or animal health technicians that are onsite at the herd, they're evaluating not only issues associated with the disease and disease transmission such as, you know, doing the testing of the animals in the herd, identifying traces either animals that came into the herd, animals that went out of the herd, determining the period of time for which we need to follow up on those traces, all those kind of hardcore EPI actions within the herd, one of the things that is also evaluated during this process is the potential risk of wildlife exposure and/or transmission.

So we do not necessarily require that in every situation there be wildlife surveillance conducted after the detection of a TB infected herd. Our recommendation and our suggestion there is, base that decision on a good epidemiological investigation and the information that you receive.

And by that, an example might be, you know, if you have a highly concentrated, confined dairy herd in which, you know, the cows are never out on grass, they're, you know always maintained in the building, the risk of wildlife exposure there would be very, very low, relative to, you know, a beef herd say in a state where there's been, where there's a really high density of let's say white-tail deer for example.

So, Willie, in response to your question, the first thing to keep in mind is, doing wildlife surveillance might not always be necessary in every situation. So we've got to base that on the science and what we're seeing going on with the epidemiology there.

That being said, I think if you look at the list of herds that we have on here, I can confirm for you that there was some wildlife surveillance, the herds in 2010, there was some wildlife surveillance performed in Kentucky, Nebraska, Michigan, obviously we have an ongoing wildlife reservoir there and there's extensive surveillance in white-tail deer going on in Michigan.

Off the top of my head I can't confirm whether wildlife surveillance was performed in Colorado, Mississippi, Ohio or South Dakota. For the 2011 herds, there has been wildlife surveillance in white-tail deer performed in Indiana, in Michigan again.

I cannot provide that information, I can't confirm about Colorado, California or Arizona.

Dr. Willie Reed: You know, I guess what you said makes sense that, you know, we need to do, you know, test wildlife on the basis of science, but it would seem to me that particularly with these beef herds that we give strong consideration to testing the wildlife.

And, you know, the testing is not that difficult if it's done during normal harvest of deer. So I would encourage you to really give a strong consideration to working with these states to make sure that at least some sampling is done.

Dr. Alecia Naugle: Yes I think that's a very good point and to that we have actually provided cooperative agreement funding to, obviously we do - we have been and continue to do that in Michigan for wildlife surveillance. And many of the other states that I named, VS and APHIS actually provide a cooperative agreement funding to them to conduct wildlife surveillance because we identified that that was an important action to take.

So you're point's very well taken. Thank you for that, for that suggestion and comment.

Dr. Donald Hoenig: Willie just as a follow up to that. I mean, I think it might be appropriate if the committee actually make - might want to make a recommendation on that. And there may be other recommendations that we might want to make on this particular issue.

So I just, you know, make a note of that that perhaps that might be and if we can do that in the form of a recommendation.

Dr. Willie Reed: Yes, I would certainly agree with that Don. You know, I have, you know, a lot of experience working in Michigan with the deer.

Dr. Donald Hoenig: Yes that's right.

Dr. Willie Reed: And it seems to me that if we identify these positive beef cow herds and we depopulate them and then don't really check the wildlife and they repopulate and they become positive again, we've just spinning our wheels.

Dr. Donald Hoenig: Right.

Dr. Willie Reed: We ought to know what's going on in the surrounding wildlife.

Dr. Donald Hoenig: Exactly.

Dr. Charles Massengill: Dr. Hoenig this is Chuck Massengill.

Dr. Donald Hoenig: Hi Chuck.

Dr. Charles Massengill: And, I have a question about the plans or considerations that have been given to dealing with the calf crops from herds as we move from depopulation as a primary means of dealing with affected herds over to a test and removal program which obviously is going to take a number of reproductive cycles through that herd.

Is there are a plan or are there provisions being made to deal with the calves that those producers either beef ordinary are going to need to be able to market to be able to stay in business?

Dr. Alecia Naugle: So Chuck, this is - I'm assume - is that direction, is that question directed to Dr. Hoenig or myself, or both?

Dr. Charles Massengill: To (unintelligible).

Dr. Donald Hoenig: I hope it's not directed to me.

Dr. Alecia Naugle: I was hoping it was.

Dr. Donald Hoenig: No that's yours.

Dr. Alecia Naugle: So Chuck, I think you bring up a really good point, and, you know, the one thing that I will say is that we, all of us really, whether we're a government agency or a private individual, we need to learn from the experiences that we, you know, have in our lives.

And one of the things that I would say is we had some valuable learning when we implemented the kind of switch from our policy of automatically

depopulating the herd to, you know, moving more toward a test and removal plan.

And one of those, that valuable piece of learning really was this issue of in a beef herd, implementing a test and remove plan proves to be perhaps a little more difficult in some situations and one of the key issues is how deal with marketability of the calves that are born into that herd.

So yea, I mean, I think we've realized Chuck that, easier said than done. That's one area that we, we consider when we make the decision about whether we need to depopulate the herd or put it under a test and remove.

Additionally, I think we're learning now that it takes a little more background work to kind of set up even feed lots or slaughter houses, et cetera, et cetera, that may take cattle from a herd under a test and remove plan.

So I know that in the local area offices that's one thing that they've really done to try to, you know, facilitate a test and remove plan in these herds.

And finally I would say that, you know, with regard to monitoring the infection status of these calves, should they remain in a herd under a test and remove plan , they're considered members of the herd so they're, you know, tested under the same protocols that we would any adult animals in that herd.

That probably isn't the answer that you wanted to hear, but I do think that we recognize that that's a problem and as we're moving forward, we're just trying to identify better ways to address that.

Do any of you on the committee have any thoughts about how we can address dealing with the calf crop? Should a beef herd be identified to be placed under a test and remove plan?

(Gill Stockton): This is (Gill Stockton). It's not a question but, I mean, I do have a question, excuse me. What is the prevalence of the TB in the calves and the feeder calves as they become yearlings?

Dr. Alecia Naugle: So (Trey) is an epidemiologist. I would tell you that that's a really difficult number to quantify. I think what we can tell you is we can look at the number of, and this not a, this a measure of incidents, not a measure of prevalence, but I think we can look at the number of TB cases that we've detected over, you know, a given period of time, like fiscal years 2010, fiscal year 2011, and as far as number of cases, you know, we're usually identifying, like I said, around 10 or 15 slaughter cases and usually about 8 to 10 of those are in fed cattle, either steers or heifers.

So that's the best quote number I can give you because coming up with a true prevalence estimate for TB in feeder cattle is something that's very difficult if not impossible to do based on, you know, the current surveillance system that we have.

Dr. Charles Massengill: Alecia this is Chuck Massengill again. Understanding that there may only be one or two or no infected calves, the calves are also going to be restricted. With brucellosis we can spay the heifers if somebody will deal with that. That's just adding cost to the producer.

But the heifers can be spayed, steers can be sold unrestricted, that's not such a big issue. However, with tuberculosis, expecting that test and removal

program's going to take, what do you suppose, four, six, eight years maybe to get completed?

Dr. Alecia Naugle: Oh yes, not at this time. You know, right now we develop these test and remove plans based on epidemiological modeling. In the past we had a very rigid process that would take up to six to eight years.

But under our current system where we actually utilize data for that specific herd, utilize data about the accuracy of the diagnostic tests that we use, most of the herds that we have under a test and remove plan now, the estimation is that probably within two to three years, they'll be out from under quarantine and there's a period of assurance testing, usually for five years after that.

So I think now most of our quarantine periods have been significantly reduced from the six to eight years that you cited.

Dr. Charles Massengill: Okay so if I understand right, now we're looking with TB at maybe a two to three year quarantine so that's two to four calf crops we'd need to deal with. And again, I still think we need to get really serious about finding a way to deal with these producers because that's their revenue, that's their source of income and that's the only place their paycheck comes from.

I mean, that's, obviously quoting the obvious, but...

Dr. Alecia Naugle: Understood.

Dr. Charles Massengill: ....that should be a really necessary part of a plan like this.

Dr. Alecia Naugle: And, you know, perhaps a question for you all is, are there management practices that we could utilize in these herds that would reduce the risk either

of transmission to those calves or transmission of disease from infected calves to other animals that might allow us to address this problem.

Dr. Charles Massengill: I think we're starting to get into some really tough details there, but I'm not quite sure what a rancher with 400 or 800 cows on pasture or grazing national forest might be able to do to reduce the risk. I guess that would be one of those challenges for our western ranchers for the people in the south and the southeast and the Midwest.

We might have multiple small units or we may still have some big herds out in the flint hills.

Dr. Donald Hoenig: Chuck this is Don. Do you think that here again this might be an area where the committee might want to consider a recommendation...

Dr. Charles Massengill: Yes sir.

Dr. Donald Hoenig: ...that we can work on...

Dr. Charles Massengill: Yes sir.

Dr. Donald Hoenig: ...okay. I agree. And, I mean, this is an important topic and I really think that the committee needs to devote some serious time deliberating on it. So I've made note of two issues, you know, the two issues that have come up so far. Wildlife surveillance and the issue that you've brought up.

And, you know, we ought to be thinking about crafting a recommendation on it. So I would ask you to consider how that might, you know, be drafted.

Michael Doerrer: And Don this is Michael, before you joined during the administrative portion of the call, we agreed to aim to have another public meeting of the committee in September.

Dr. Donald Hoenig: Okay.

Michael Doerrer: So, just FYI, because we might be able to use some of that time to further deliberation.

Dr. Donald Hoenig: Right. Okay, thanks Michael.

Charles Rogers: Alecia, this Charlie Rogers. I got a quick question, if a new outbreak, and let's say it's in a confined dairy herd, will we start with just a quarantine of that herd and then expand to a zone if necessary, is that the new plan on how you would start at this point?

Dr. Alecia Naugle: Thanks Charlie. That's a good question. So yes, as we do right now, again, we would rely on our epidemiologic investigation to guide our actions in that situation.

Remember that a quarantine authority typically, generally I think in all states, lies under the state's authority. However that is usually what occurs. When you identify a TB affected herd, there's usually some type of quarantine or hold order that's placed until we're able to get in there, do some preliminary EPI investigations, conduct testing, et cetera, et cetera.

You're correct in that under the new plan, the concept of zoning really focuses on using that epidemiologic investigation to identify the risk of transmission or the actual transmission of disease to other herds.

We again are still kind of working on the language about what zoning would like under the new plan, but under the scenario you mentioned that'd be a perfect situation for zoning, right?

Where you have one dairy that's a TB affected dairy and through the course of your EPI investigation you identify other TB infected dairies, either in the same geographic, most likely in the same geographic proximity.

So yes, that's a possibility under the framework that we're thinking about for the new program.

Dr. Willie Reed: This is Willie Reed again. I wanted to ask you Alecia, how, you didn't mention the gamma interferon test. How much of that testing is going on in these infected herds?

Alecia Naugle: That's a good question. Thanks Willie. So the gamma interferon test, let me back up a little for those that might not have all the science to this situation kind of under your belt. It takes a while to get use to because it can be quite complex.

So as we talked about, one of the frontline test, if you will, is what's called the coddle fold test, that's the tuberculin test. If an animal responds to that test, in other words, you know, when the veterinarian injects the tuberculin, goes out three days later, feels the area, there's a swelling, we identify that animal as a responder.

When we've identified an animal as a responder then we do follow up testing to better determine the infection status in that animal. We call the next set of tests supplemental tests.

And right now we have two supplemental tests that we can use in TB. The first is the comparative cervical test. The second is what Willie referred to, the gamma interferon test.

In the comparative cervical test, it's another skin test. The gamma test is actually a blood test. Yes, you're correct, we do use the gamma as a supplemental test in the TB program.

And really quickly, let me pull an exact number for you for 2010. In FY 2010, we conducted approximately 13,000 gamma tests, actually 13,314 gamma tests.

Dr. Willie Reed: Okay so are there any plans to increase the amount of gamma testing or it just depends on?

Dr. Alecia Naugle: So right now, one thing to keep in mind is that the gamma test is only approved for us as a supplemental test. That means to use the test as an official test, the animal has to already have responded to the CFT.

At this point the company that makes the test, Preonix, has started to have conversations with us about other uses of the test, and we're still really in discussion about what those other uses might be.

I would remind everybody that in order to be approved for use as an official test, the test has to be licensed by the CVB, our Center for Veterinary Biologics, and it also needs to be approved for program use.

Right now, the gamma interferon test is not approved as a primary test. So we're not in the situation where we can go out there and use it, say as a, you know, as a surveillance tool, as a frontline test.

We are working with the company though to explore is that use possible in the future.

Dr. Willie Reed: Okay thank you.

Dr. John Kalmey: This is John Kalmey. I've got a question about the coddle fold test and resulting quarantines, or quarantines that result from that test. We've had an accredited herd for several decades and the last few years when we've done our test, which we've had some positives, which you're supposed to have with that test...

Dr. Alecia Naugle: Correct.

Dr. John Kalmey: ...even if you don't have the disease. But those tests have resulted in a quarantine of the herd. We've never found any TB but from the time from the initial test until two or three tests down the road when they find out it's not TB, it quarantines our herd and we lose several sales.

And I've complained to the state vet about it and the response I've gotten is, well drop your certification, it's a TB free state, so why are you worried about it. So I guess the rules are, is that a reasonable response to my concern?

Dr. Alecia Naugle: So thanks John. I think, that's an interesting question for sure. I guess I would start my answer by saying, you know, ultimately as a producer, your decision to start a fire herd or any array of diseases really is yours and yours alone, right?

And ultimately that has to work in with what your business plan, what your management practices are. So in your particular situation, I can't tell you yes you should or no you shouldn't continue to be an accredited herd.

Obviously that's your prerogative and that's your decision. I will speak to the need to quarantine a herd after we've identified a few responders. You know, we know TB is out there and we do occasionally find herds.

I think it, when we have a long history of herd testing in a herd, you know, I think we have a lot more confidence that this probably was a false positive result as opposed, you know, to truly an infected animal, but the premise of needing to quarantine that herd and conduct a series of test to confirm the infection status of the animal is really critically important to our ability to prevent transmission of the disease further.

So I would urge you to, you know, recognize that that process of placing the quarantine or the hold order and following through on the appropriate testing to confirm the infection status of the animal is a necessary and important one, at least from a regulator veterinarian perspective.

Dr. John Kalmey: Yes I think I do understand that. But I think you need to understand also that as a result of that, and being less flexible, I mean, you know, if it's a herd with no history of testing, that's one thing, but if it's a herd that's been tested for, you know, decades, then, and you've got one positive from a test and you know you're going to have some false positives, you expect to have false positives, because of this response, there's a lot of animals that would normally be tested and you'd be, you know, finding the disease because of this response, there's a lot of animals that aren't going to be tested, so.

Dr. Alecia Naugle: That's a really interesting observation. I appreciate you bringing that up John. I don't know that I can - well it's not that I don't know, I can't give you a final answer or anything more definitive today.

But I would offer that, you know, I'd be interested in hearing some thoughts about changes to the current accreditation process for herds under the TB program, particularly along this idea of those herds that have had a long history of testing under the program and are there changes that maybe we could do to make the program a little more appealing.

Dr. John Kalmey: There's a lot of us who have accredited herds. You think it's a good idea to continue testing but because of the burdensome nature of being quarantined for two or three months every two or three years, we've decided it's not worth the effort and although...

Dr. Alecia Naugle: Right, sure, sure.

Dr. John Kalmey: ...we think it's not a good idea to not test, we're pretty much forced into not testing.

Dr. Alecia Naugle: I appreciate that. I hate to say it, but might that be another recommendation?

Man: (Unintelligible).

Dr. Donald Hoenig: Yes, I mean, certainly that's added to the list here. I'd like to at some point, probably talk to John a little bit offline and find out what the exact situation is with that because generally when we get a coddle fold responder we get out pretty quickly and do a comparative cervical test and if it's negative, it's done with.

So we rarely, and we have a fair number of coddle fold responders, but we rarely get comparative cervical positives. If we would get a comparative cervical positive then that certainly would change things and we'd probably have to quarantine herds.

But generally in our case up here, you know, in New England when we get a (unintelligible), sometimes we get out within about seven days and do a comparative cervical and they generally negative, so we don't end up with that situation. But yes, we'll certainly add it to the list.

Who else has questions on the tuberculosis issue? I have one myself but I'd like to let others weigh in.

Brian Thomas: Yes this is Brian Thomas.

Dr. Donald Hoenig: Hi Brian.

Brian Thomas: With the grantors and producers on reservations, some of the producers do run their livestock on forest service with BLM, (unintelligible) ground, for gravy. And the question that brought up to me on the TB and brucellosis was, say for example we haul out mineral salt blocks to the livestock for supplemental feed and it's needed for livestock to prevent other diseases, and they found an infected her with TB or brucellosis, and they quarantined the livestock on the reservation, would the wildlife also be tested for example if they were in the forest service area, if they were near (unintelligible)?

Maybe using and licking the same salt block or out of the same salt watering pond or et cetera? You know, there's that with the question brought up to me was, you know, what do we do in that case?

Do we work with both the state vets here and then also the fish and wildlife or how do we get control if something like that happens you know, and breakout?

Dr. Alecia Naugle: So, thanks Brian, this is Alecia. That's a really good question. I'm going to, I'm not sure if you were on a little earlier. First I would kind of respond similarly to the original question from Willie is that you would need to decide if wildlife surveillance was appropriate based on the findings of your epidemiologic investigation.

And then those details of whether it's necessary and how it would be worked out, really those would occur at the local level for the most part. So just for fear of getting in over my head really quickly, I'm just going to defer and say, that really would be a conversation that I would imagine would occur between your tribal leaders, the folks in the state, as well as if it's a public, you know, wildlife or a public land, probably the department of the interior.

I know that brucellosis has had a lot of experience in that area with regard to a similar kind of circumstance in Yellowstone. But I can't speak anymore specifically to that question today Brian.

Brian Thomas: All right thank you.

Charles Rogers: Alecia this is Charlie Rogers. You know that our initial test that the veterinarians perform that creates a certain amount of false positives, what's the possibility of any time soon having a test that eliminates that situation?

Dr. Alecia Naugle: Good question Charlie. I'm pausing so I can gather my thoughts. I think one thing to keep in mind is that regardless of what kind of test you have,

there are always going to be what we call false positives, which you know, you point out that in with the case of the coddle fold, that would be an animal that 's a responder on the initial test.

And then we go on to find out she's not infected to TB. We also have false negatives, right? And that's an animal that's truly infected but it never shows up on the test.

And, you know, as an epidemiologist, I would argue that it doesn't matter what kind of test you have, you're still going to have to deal with the issues of a false positive and a false negative.

Certainly we try to identify tests that have, depending on how we want to use them, either the highest sensitivity or the highest specificity that we can get them to have.

I think your question is pointed toward, do we have any new diagnostic technologies on the horizon for TB.

Charles Rogers: That's Correct.

Dr. Alecia Naugle: And I would answer that there's been a lot of exciting work in the last couple years with regard to that question. Here in Veterinary Services we have established what's called serum bank and what that is is we went out there and have basically created a bank of serum that's well characterized, meaning we know the true infection status of the animal.

We have coddle fold tests, comparative cervical tests, gamma test results, culture information on all the infected animals and all the non-infected

animals that are in our bank, we know came from accredited free states, where we have no reason to believe that there was infection in those animals.

So that has really been helpful in evaluating some of these new technologies as they come on board.

You may be aware that the Chembio Cervid STAT-PAK was recently licensed for use in, I believe, elk and red deer. Currently in veterinary services we're in the process of evaluating the use of that test in captive cervids, specifically in elk and white tail deer and reindeer.

Our hope is that dependent on the performance of that test we'll be able to provide program approval for that test in those species, so we're working on that and that's on the horizon.

Another comment that I made earlier, the manufacturer of the gamma interferon test has come to veterinary services and we're working with them regarding the possibility that that test could be used in other ways in our program.

And then finally, many of you may have seen the press release regarding (IDAX) making available a serum test for use in TB diagnostics in other countries.

Because of confidentiality reasons I can't provide a lot of information regarding our work with that test here other than to say that, you know, we've had discussions with (IDAX) and we're working with that company in regards to their developmental diagnostic tests for TB. And again, that's a serum test; a blood test.

So (Charlie), do we have anything today that we can turn around and use in these herds? No. But I think we have a couple of really exciting technologies that are pretty close to us being able to use more widely in the program.

Now I would caution you, and remember, you know, no test is perfect. You're still potentially going to have false/negatives and false/positive results and, you know, we need to be cautious when we talk about using a new testing methodology in a nationwide program. But with those caveats we've seen some exciting developments.

(Jan): Okay. Anybody else have other last questions for (Alicia)?

(Alicia): Don't you mean anybody else want to grill (Alicia) some more?

(Jan): Yes.

Don Hoenig: Well, yes, this is Don. I have - I want to get back to the issue of indemnity and all the discussion that surrounded that and I was wondering whether the committee might want to add that to the - to our laundry list of recommendations to the Secretary.

We don't need to, you know, come up with anything formal right now, but I know it has been an area of concern amongst the state veterinarians and so I think, you know, I'd like to add that to the list of possible recommendations. And I just wanted to know if there was another discussion on that amongst committee members.

I will say that the experience that I had with foot and mouth disease ten years ago in England with respect to indemnity involved they had a calculator that

they used for grade animals and so it was fairly straightforward in my experience in dealing with grade animals, both dairy and sheep.

But if they were pure bred animals, they always brought in an appraiser and in the herds that I was involved in we were able to come to an agreement pretty quickly because of that.

And I'm not sure whether there was an appeal process over there but, you know, in the case of a disease like foot and mouth disease, time delay is crucial and you don't want to have that. So you want to build in a system that's going to be fairly easy, fairly quick to work through.

And my experience over there it worked fairly well with those two types of - with the calculator and then bringing in an appraiser. So - and I know that (Alicia) referred to that.

So I just like to have some more discussion on that, if we could or any comments.

Chuck Massengill: Don, this is Chuck Massengill and that absence of indemnity is why I'm so concerned about how ranchers and dairy producers are going to deal with their calf crop. I mean without the indemnity it puts the complete onus on the producer to take those losses and take the beating.

So I think that definitely needs to be on our discussion list.

Don Hoenig: Okay, good. Other comments?

Man: Don, I was going to ask, are there other issues even besides indemnity, you know - I think this is the second or third presentation the committee has had

on TB. I think your - you as a group are as well educated as any stakeholder (ZF) has on our TB program.

Unfortunately you got in on the ground floor in terms of our regulatory development for the new TB/brucellosis framework so I think the committee is well positioned to be able to offer some recommendations after some further deliberation maybe in September.

Don Hoenig: Yes. Are there other issues?

John Clifford: Hi Don, this is John Clifford.

Don Hoenig: Hi John.

John Clifford: Hey, and to Chuck's comment and to you all on the indemnity issue, as you just deliberate and discuss that issue, you know, I think it's important to know and note whether the committee is in support of the options we have for the approach we take with test and removal with regards to tuberculosis looking at potential actual risk of spread.

And I know what we can say historically but unless we want to depopulate thousands and thousands of animals that may not be infected, I understand what Chuck indicated and I know that's an issue that we've got address on the beef cattle side especially. In dairies you can move - you can still move your milk, but in the beef animals we need to move - be able to move feeders and things in order to keep business going.

So just consider that. Appreciate it.

Don Hoenig: So John what you're asking is does the committee support the approach that you're proposing to take with test - with (unintelligible).

John Clifford: We're already doing it, yes.

Don Hoenig: So you're already doing it, right.

John Clifford: And for example, if you don't then what's the alternative because it's - I understand the issue around indemnity, but, you know, that comes with a lot of resources needed to do that.

Don Hoenig: Okay. Any other discussion with respect to the TB issue?

(Jan): Okay. This is (Jan). We have Dr. Darrell Styles here and he is prepared to share an update on emergency preparedness and response vaccine challenges. So I'm going to, with your permission Don, have Darrell go ahead and share with us.

Don Hoenig: Sure, that would be fine. Thank you, (Jan).

Darrell Styles: I'd like to thank the committee for this opportunity to give you some - an update on APHIS preparedness and the challenges in terms of vaccine when it comes to FMD mitigation measures and I'm going to confine my remarks specifically to FMD because it's the disease of primary concern that we have.

What I'd like to do is first of all discuss some of the ongoing research work at Plum Island by the Ag Research Service areas, DHS, Department of Homeland Security in terms of mitigation strategies.

Then I'd like to talk about APHIS's policies, changing policies on the use of FMD vaccine, potential strategies and the challenges we are going to face because of those decisions.

Naturally I'm going to be covering these topics in a very (gressorial) manner because we don't have time to get into a lot of the specifics and in terms of how we manage the vaccine itself, I can't be completely candid about some of that information because it is somewhat of a sensitive nature but I will provide you with what information I can to give you some direction.

You're aware that we've had an ongoing research program for some time with foot and mouth disease. All of that work is ongoing at the Plum Island facility. And APHIS and ARS has worked together for a number of years to try to move forward research in that area.

To talk about some of the more pertinent research projects to date, I think the first of all we want to discuss the vaccine efforts that are ongoing now on Plum Island and that is an ARS idea which has been translated into a DHS project and that is the adenovirus vectored FMD vaccine project.

If I oversimplify some of this information to some of you, please forgive me but I want to be sure that everyone on the phone understands what's I'm trying to describe.

Traditional vaccines which are inactivated or killed are simply vaccines in which the virus has grown in some (media) or perhaps in eggs and then is concentrated and then inactivated by some chemical or physical process.

That material is then refined into a vaccine and then that vaccine is used in the animal or human to protect it from a specific disease.

There are advantages and disadvantages for these types of inactivated vaccines. The advantages are is that they are by comparison relatively inexpensive. The disadvantages are they require large facilities in order to grow virus and the process can be somewhat prolonged depending on what types of methods are used to grow the virus.

Not to get too depth far into the weeds with epidemiology, suffice it to say that most inactivated vaccines and specifically FMD inactivated vaccines have a very short activity or protection period.

If you're using FMD vaccine, you would need to booster on a minimum of every six months if you're in a vaccinate-to-live kind of situation because the immunity just simply isn't very long-lived.

This is a characteristic of most inactivated type of vaccines that immunity is generally readily short-lived. The advantage the adenovirus vectored vaccine is that it is actually carried into the animal on an artificial viral platform and therefore actually emulates or mimics an actual viral infection.

What this does is stimulate different parts of the immune system that will encourage a longer term protective immunity over each dose given to the animal.

How this particular vaccine works is the adenovirus is an innocuous virus that is simply used as a vehicle and the replication parts of that virus are replaced with key proteins from the FMD strain of concern that we're trying to vaccinate against.

And so it's inserted into that virus and then that is inoculated into the animal as a sort of semi-live culture. The animal's immune system perceives that it's actually undergoing a viral infection, replicates all arms of the immune system which does not occur with an inactivated vaccine and therefore you get a stronger, more robust and longer term immunity.

The other advantage of this is that these types of vaccines can actually be created without the benefit of having to grow the virus in large quantities. So in other words, all you need is a master seed clone out or replicate the proteins that you wish to use in your vaccine that will protect the cow or the swine, put those into the vector and then use that as your vaccine.

So this also offers the alternative of a multi-candidate platform. So if we had an O-serotype and then all of a sudden due to some reason we suddenly get an A-serotype of FMD in the country, we could quickly switch gears.

With an inactivated vaccine, that would require growing up large quantities of that A-serotype very quickly in order to meet that challenge.

So this type of work which has been a Department of Homeland Security, although it's built on Agriculture Research type of work, has been ongoing. The status of that project is is that they are now in the safety testing phase and probably within the very near future they will reach a conditional license. And by the very near future, I'm saying that it will probably occur within this calendar year, if not, early next calendar year.

The problem with this vector vaccine is not necessarily in its potency or in its type of delivery system. The issue is with cost, as well as the volume of vaccine that must be injected into the animal in order to bring about the level of immunity required to protect it.

Those two technical aspects have not yet been overcome and so that's been a challenge for the DHS scientists to try to surmount those particular obstacles to make this vaccine more practical.

Other work that has gone on and related to the vaccine and I'll get into how the two are related is the area of biotherapeutics. On the previous call, the issue of gamma interferon was brought up during the tuberculosis session.

Well interferons are a family of chemicals produced by the body in response to an infection from either bacteria, protozoa, fungi or viruses. And these interferons all do different jobs within a cell in order to protect the cell or to fend off pathogen.

Something that ARS has looked at has been looking at biotherapeutics using interferons because interferons, if given to an animal early in the infection or pre-infection can actually mitigate or even prevent that animal from contracting clinical disease.

So what they looked at was actually using this same adenovirus platform using the gene for alpha interferon Type 1 and what they were able to do with that is actually prevent swine from becoming infected with any strain of FMD that they had tested.

And this has an advantage of delaying infection or preventing infection, this type of biotherapeutics but it's still in its infancy stage. This is very early work at this point.

They've also looked at constructs and this where the vaccine comes back in where they would insert both the interferon gene, as well as the FMD proteins

into the adenovirus vector, such that the interferon would protect the animal up until the time that protective immunity can be established.

When a vaccine is given, you are not automatically covered and neither is the animal. There is a ramping phase in order to build sufficient immunity. That depends on the agent, the type of vaccine and any number of factors but generally that can take anywhere from 7 to 14 days before protective immunity can be established.

And by the insertion of this particular interferon gene, what we do is essentially protect the animal because the protein immediately starts becoming transcribed or produced in the body, protects the pig or the cow up until the time that the vaccine can actually begin to manifest and effect.

Unfortunately, this work has not been shown to be as effective in cattle as it has in swine, and so ARS now is focusing on looking at this kind of construct with interferon and the FMD vaccine - adenovirus vectored vaccine in swine and that work is ongoing.

Other types of work going on on Plum would be just basic virology into the area of how the disease itself works. But I want to give you a benchmark for that - our lead investigator from ARS in FMD is Dr. Luis Rodriguez. And Dr. Rodriguez is always challenged with trying to flesh out his budget.

As of about last year, his yearly budget consisted of about \$1.8 million. We would expend that amount of money probably within the first 10 to 15 minutes of any FMD outbreak. So it's a travesty that one of the most dangerous diseases that we are tasked with is given such a pitiful budget but that's the reality of our current environment and I'm afraid that it's only going to get worse.

So I think you do need to be aware that ARS is doing a tremendous amount with a very limited budget.

So what do we do - how is the vaccine kept and stored? Well we do have vaccine in country. We do not make it here but we keep the vaccine in the form of a concentrate (engine) which is simply just an orange juice concentrate you'd think of that's kept frozen a virus itself that then is refined into a usable vaccine.

We have some quantities of those viral concentrates stored at Plum and how that is determined is by a technical council of experts made up from DHS, ARS and APHIS looking at what strains of FMD out there are actually challenge us with the greatest threat.

This is all housed within a group called the North American Foot and Mouth Disease Vaccine Bank which is quite an old entity and this is a trilateral agreement between the United States, Canada and Mexico. And each of those countries has a variable degree of investment in this vaccine bank but all of the material and the work goes on at Plum for storage and for validation of those vaccines in terms of potency, safety, as well as testing for any kind of (adulterines).

So in the event of and FMD outbreak, the North American FMD Vaccine Bank would be activated. There would be requests going out from CVOs of the member nations and the vaccine would be refined for use and then made available for delivery.

However, the crux of the problem is that there is not a sufficient amount of vaccine antigen that would even address a small outbreak. Now I don't want

to get into specific numbers here because some of this information is sensitive and we have an open forum on this call.

But suffice it to say is that we definitely need more vaccine in the bank in order to meet the challenges in the future should we be tasked with an FMD outbreak.

One of the questions that's arising in your mind right now; well how much more, and that gets me into the point where I want to discuss strategies.

The idea that we in the United States would use a vaccine for foot and mouth disease is only a recent decision and by recent I mean within the past probably year to year and a half.

The emergence of an essential epizootic around the world of different strains of FMD virus have shown how dangerous this particular agent can be, and the alarming situation that occurred in the UK, as well as South Korea and Japan underscore to us as regulators that we needed to more strongly consider the use of vaccine as a response tool for mitigation.

In the past our policy had always been stamping out without vaccine in order to preserve the sanctity of our trading status. Given the numbers of animals that we have and how rapidly this virus could potentially disseminate, we no longer have the luxury of automatically selecting that option.

So depending on the size, magnitude of the outbreak and its breadth, we may have to elect to use vaccine in order to mitigate and control or perhaps even for longer term use.

So the four decision points are no vaccination and stamping out, vaccinate to eradicate, vaccinate to slaughter and vaccinate to live.

APHIS is in the process of trying to work with its stakeholders and you remember we had the May 2 meeting to discuss FMD vaccine. APHIS is in the process of working with its stakeholders to try to come to a rational strategy on how to approach this very difficult problem to look at trigger points that would allow us to move from each - from one step to another or move through them in unison.

For example, it may be determined by our epidemiologists that this outbreak is so large and encompassing that vaccinate to eradicate simply is not an option at this time, that we may immediately have to move to vaccinate.

Other situations may be that the outbreak is small and perhaps others are undetected and that we would move forward with an eradication policy until such time we saw that it could not be controlled in that manner. We do not want to make the same mistake, unfortunately that was made in South Korea where that decision came far too late in the process.

So we want to be very proactive in this. And you may question this, well why hasn't APHIS been working on this in the past. The fact is that emergence of these strains around the world and a virtual epizootic at this point, plus the fact that we've had a standing policy for many years in place to eradicate rather than vaccinate has precluded much advancement in that area.

So this recent decision that we must look at some manifestation of vaccination and the trigger points by which we move forward on these decisions in order to protect the industries themselves has been a relatively new development.

So each one of those steps has its own time clock associated with it when we can reopen the markets. For example, the shortest is vaccinate to eradicate - I mean eradicate with no vaccination at all.

But of course, that means the destruction of large numbers of animals and we not only have to look at this as a non-homogenous group of animals. We have different classes of swine and different classes of cattle, the largest two groups that we would be concerned with, that was a small ruminants.

So for example, is it really logical to go in and destroy a dairy herd of perhaps tens of thousands of animals that has a very long ramping phase in order to get that dairymen back up to speed. We may essentially cause him to go out of business, whereas maybe vaccination would be a better option until he can clean the herd and then perhaps go back to a vaccination-free status.

So we have to not only look at the disease but we have look at the individual usage of the animals. For example, would we have to vaccinate large numbers of feeder pigs that are destined for slaughter? And the answer is, well perhaps we may have to do that in an active outbreak in order to contain it, but does it make sense to do it in animals that have a lower risk of exposure, while it may make sense to vaccinate the sow herds which do produce animals to ensure that they are kept safe.

None of these decisions at this point are set in stone. These are all kinds of ideas that we are working through with our stakeholders to try to come to some sort of rational understanding of how we can move forward with a vaccine policy and the trigger points necessary to move forward in each option.

In vaccinate to eradicate - to eradicate, we would simply use the vaccine to contain the infection and then eradicate inward to ensure that we have stamped it out completely. And that point we would actually reach a free status much quicker but at a greater cost.

And at what point do we stop eradication? As many of you know, we have - and as I've mentioned on previous calls, APHIS has a tremendous challenge ahead of us in terms of depopulation and disposal. The idea that we're going to do mass burial as they did in Korea is simply probably not a feasible option.

In fact, right now many of the sites in Korea are having to be exhumed simply because they are now spilling over leakage from the decaying carcasses into the water table and contaminating the environment.

So we don't have a lot of options and so vaccine may be our only viable option in some situations when the outbreak becomes too overwhelming for us to manage through an eradication program.

Vaccinate to slaughter would be something that we have to work with our industries on to make sure that the public understands clearly and all arms of government speak with one voice that the meat supply is safe, that the vaccine - we are already consuming it because we're eating meat from Argentina and that simply we are vaccinating and that the act of the vaccination does not in any way endanger or adulterate the food supply.

This has been a problem in countries where active FMD has been ongoing. In fact, in Japan the Japanese public refused to accept vaccinated meat and that unfortunately was due to factors beyond the government's control and perhaps a poor public relations campaign. We can't afford to do that in the United States.

And then of course the last option would be if we have such an overwhelming outbreak that we simply cannot contain it, we may have to vaccinate to live. And with some sectors as I have mentioned previously such as the dairy sector, cow/calf operations or perhaps sow operations, we may be vaccinating to live to ensure that we have a consistent supply of animals for the different commodity markets.

Eventually we could go back to a free status but that may take some years. And what our stakeholders are coming to realize is that all of this would have a profound and terrible impact on our export markets.

So as you can see that this decision is not entered into lightly but we are here to assure that the survival of U.S. agriculture in terms of protecting it from the menace from FMD.

So the issue of how much vaccine we need has been a thorny one. As you can appreciate, it depends on which one of these options we elect. You might ask me by saying well why don't you just plan for the worst case scenario. Well, let me just give you a brief example.

In North Carolina alone, in Eastern North Carolina, there's about 6 million to 7 million pigs at any one time. That 6 million doses of vaccine that would have be given twice in a very short amount of time in order to protect those animals if we elected to do it and then if it was a longer term outbreak, it would have be given on a six months basis.

If that didn't occur, then there could potential for reinfection. So the amount of vaccine as you can well appreciate, if that's only one state and one state's animals - category of animals, multiply that by all the states and the swine and

cattle that we would have to protect and suffice it to say we simply do not have those kinds of resources at hand.

Your next question to me probably would be well how much do you need. And what I'm trying to convey to you is that we're trying to determine that to come to you with a rational number of what we would need to have in storage so that we can call on that in a very short amount of time and marshal that vaccine for usage and we hope to provide that, but I can only say that what we have now is in - is grossly insufficient to meet that need.

Well what do I need to move forward on this initiative and the bottom line is that we need resources and that comes in terms of funding. Preparedness has a price, but nowhere near the price it would be if we had to face a large scale FMD outbreak.

So what we're trying to is look for resources in order to increase supplies available to regulators here in the United States to ensure that we can meet any demand that we may be tasked with in terms of FMD.

And that sort of encapsulates all of my remarks. I know that was brief and quick but I wanted to leave sufficient amount of time for questions.

Don Hoenig: Dr. Styles, this is Don Hoenig. I just - since you just mentioned it, I just have a follow-up. How soon do you think you'll be able to get that information as far as the quantity of vaccine that you need?

Darrell Styles: We are working now. We do not want to rely solely on models, although models will help us come to that decision, but we also are relying on our own common sense and just looking at the challenges and working with our

stakeholders and what they estimate that their needs may be should we have to elect to do a large-scale vaccination campaign.

So in terms of how quickly that would be, I would say within the next three to six months we should have that data. And I know that seems like a long time, but remember, we had a vast agriculture production system and we have to be careful how we make this decision.

Chuck Massengill: Dr. Styles, this is Chuck Massengill. Can we talk about vaccinate to live on cattle? Are we talking about a normal lifespan following vaccination or a limited number of cycles or what are we talking about when we vaccinate to live?

Darrell Styles: Well I think that would depend on the category of cattle that you're talking about. Certainly with dairy cattle, of course, they have a limited lifespan and then they move on to slaughter or disposal. With cow/calf operations, that's a much different story where they have a much longer lifespan. And then the nation as a whole has to determine the value of getting back to that FMD free status.

Let me make one other point and I'm glad that you brought that up. Even though we may need OIE specifications for FMD free status after an outbreak, meeting the expectations of our trading partners and the high bars that they may set for us to reopen our markets to those trading partners is very challenging and that takes a tremendous amount of effort.

So we may be able to meet the OIE expectations long before those key foreign markets are reopened for our export products.

John Clifford: Don, may I say a few words here?

Don Hoenig: Sure.

John Clifford: So one of the things, too, that we're doing along this line is looking at a greater acceptance in the international community for the use of vaccines, especially in the issue of using DIVA type vaccines, so vaccines that you can tell the difference between actual fill strain type viruses versus the vaccine strain itself.

And this is going to take a good while, I think, but we've talked about it the last couple. We are beginning in the Quad countries which is Australia, Canada, U.S. and New Zealand and I think we have others, as well.

We're beginning to have these discussions and trying to push this issue forward so that we can as technology develops and hopefully it will develop for a lot of these that we can use that technology to all of our benefits and if we can - as long as we can move product in animals safely and let them live safely so that we can move to that type of a situation versus having to kill everything in order to regain free status.

Genell Pridgen: Hello. This is Genell Pridgen. Do we have any kind of estimation as to the time that it's going to take to gather this information and be able to say whether the titer is from an actual FMD outbreak or is from the vaccine? Have we got a projected timeline to determine that because I know it's very easy in some of the human diseases to be able to tell, you know, what the titer level is, whether it was, you know, wild or vaccine induced?

John Clifford: Well I was talking - I'm going to let Darrell answer this more specifically of vaccine, I'm talking about things that might happen in the future, not things that are going to happen necessarily today.

In some diseases we have that capability like pseudorabies. We have a gene-deleted vaccine where you can tell the difference, but one of the things about FMD, as well, is we're going to be looking at clinical evidence, even if we have a titer we're also going to be looking for clinical evidence of disease.

So Darrell, would you - also you might want to respond.

Darrell Styles: Thank you Dr. Clifford. Yes, the DIVA strategy that Dr. Clifford mentioned, the differentiated vaccinated from infected animal has been put forward as part of the adenovirus vectored vaccine program. There are proteins within that particular vaccine that will cause an antibody response that is not found within a wild type infection that will signal that yes, indeed, that this has been a vaccinated animal and not one that has been naturally infected.

With inactivated vaccines, that's a more complicated issue. We can differentiate by looking for proteins that are not produced by an active replicating virus within the animal so that would indicate a vaccinated animal. And if those antibodies to those proteins were detected in the animal, that would indicate that it had been exposed to an active virus.

However, those are not necessarily recognized by our trading partners as DIVA strategies and those tests can be expensive and may not be validated for every species or every situation.

Liz Wagstrom: Hi, Darrell, this is Liz Wagstrom. I have a quick question about communication to the state regulators. I know a lot of the state emergency plans are still operating under the assumption that there will be a massive depopulation after around any positive findings of foot and mouth disease.

What's the strategy for communicating to the states so that they can begin to take second looks at their emergency plans?

Darrell Styles: We've been working through our stakeholders including the National Association of State Animal Health Officials. Representatives are on that working group for developing a rational strategy from NASAHO. And this is one mechanism by which we hope to reach out to our state stakeholders.

We plan a subsequent meetings, in fact, in November we will have one on continuity of business and animal movement control issues in which we will have a much greater representation from our state regulators and these types of issues will once again be brought up to them and so that they understand the change in landscape for our plans in terms of mitigation.

Don Hoenig: Dr. Styles, this is Dr. Don Hoenig again. It sounds to me like there are a couple of areas that you've identified as kind of overriding concern. Number one is the inadequacy of the funding for research that Dr. Rodriguez has at Plum Island and the meager amount that he has to work on this issue as far as research goes.

And the other is the - just generating enough vaccine - more vaccine in the North American Foot and Mouth Vaccine Bank. That sounds like it's at a very low level right now.

If the committee - I think the committee - I'd like to see the committee make some recommendations on this but the issue is if we make recommendations to the Secretary, does it just involve the Secretary having to shift around more funding and take money away from other areas in animal health or what are your impressions on how that work?

And John, I'd also welcome your input into that, too, as far as how the committee could be helpful in that regard.

Darrell Styles: I think that decision is far above my pay grade, so I'm going to defer to Dr. Clifford on that.

Don Hoenig: You're a smart man.

John Clifford: Actually, Don, I think personally that we would probably under this current environment we would have to probably find those resources ourselves and make internal shifts. I'm not talking on the research side. I'm talking about on the vaccine side.

But just also remember that the North American Vaccine Bank is just that. It's a North American bank that is funded by three countries. So unless we were going to do this alone, we would also be asking contributions from Canada and Mexico to help bring the dose levels of some of these strain types in the vaccine bank to a higher level. So...

Don Hoenig: So basically you're saying that - if you were to do that, that would involve some internal shifting of money.

John Clifford: Yes.

Don Hoenig: Yes.

John Clifford: There is no other money.

Don Hoenig: Right.

John Clifford: I mean the Secretary could do what you indicated, but that - I think we would have to really be looking internal.

Don Hoenig: Yes. And with respect to the funding for research at Plum, is that a DHS issue or an ARS, Agricultural Research Service, issue?

John Clifford: An ARS issue a DHS issue, both.

Willie Reed: Don, this is Willie Reed. I don't know if anybody can answer this question. It would be kind of nice for me to know what the target would be in terms of research funding. I think I heard, if I wrote this down correctly, that from Dr. Styles that 1.8 million was going for FMD research at least to Dr. Rodriguez's lab.

And I mean I don't know if anybody knows what is an adequate number to make the progress that we think we would need to make over a reasonable period of time.

John Clifford: I think that's a very difficult decision. Having come from academia let me give you a benchmark for comparison. Many of the NIH grants that I was a party to, although I was not the primary investigator, I may have been a sub-investigator, a single NIH grant to a large university for, say, a pharmaceutical project or project in molecular biology could amount to \$2-1/2 million to \$3 million. And we're talking about one university out of many, one investigator out of many.

So the funding that comes from the National Institute of Health and the National Science Foundation is enormous by comparison to what comes in to NIFA and ARS.

Willie Reed: Yes. It's just that, you know, from our perspective, before you ask for, you know, funding, we need a real plan and - of how much and what it would accomplish and that sort of thing otherwise, you know, we're not likely to get very far just asking for more money without a well thought-out plan of the deliverables that would come from increase funding and, you know, if the impact on a timetable and all of that.

I don't know if that can be done but it certainly would be the way that I would approach it...

John Clifford: I would...

Willie Reed: ...for that.

John Clifford: I would agree with Willie. I think that you've got the - you got to have a laid out plan before.

Willie Reed: I think any - it's about - you ask any investigator working on any problem, any disease condition, you know, there's never enough money. But if you have clearly goals that you'd like to achieve, somebody ought to be able to put some numbers down in terms of how much it would cost to achieve some goal or some objective.

Darrell Styles: I feel confident that ARS and counterparts could provide that information to us as to what they would need in terms of a long-term strategy. In fact, they tend to plan their research in five-year cycles.

Willie Reed: Okay.

Don Hoenig: So is that something that perhaps we could be provided with for the next public call in September? Or is that too soon?

Darrell Styles: Yes.

Don Hoenig: Okay, thank you.

Willie Reed: Does think as we, you know, advocate for more research for FMD, we ought to have something specific in mind, a certain amount or certain objective that we think we need to achieve in a reasonable amount of time.

Don Hoenig: Well we'll look for that then on the September call and we can follow up with that. As far as the North American Foot and Mouth Disease Vaccine Bank, I mean, do either - John, do you have any other thoughts on how we're going to solve that shortfall or...

John Clifford: We were actually...

Don Hoenig: It seems like...

John Clifford: ...been having - beginning to have some discussions around that Don, but I don't have anything at this point in time that I can share.

Don Hoenig: Okay. Well if - I know that Dr. Styles said within three to six months you might have a better idea as far as quantities, you know, target quantities. So maybe we can continue to keep that, you know, on the front burner.

John Clifford: Exactly. It's an extremely important issue and it's one that we all care much about. You know, it wasn't very long ago we started the outreach and

initiation on this and I think we've got to develop some strategies and gain some internal support for those strategies, as well.

Don Hoenig: Yes. Okay. Other members of the committee who have questions or concerns on this issue?

Howard Hill: Yes, this is Howard Hill. Dr. Styles, you mentioned that there was a continuity of business meeting coming up in the near future. Is that going to include some ag-economists or will that be all animal health people or what's the makeup of that committee?

Darrell Styles: Yes, there will be ag-economists at that committee - at that meeting.

Howard Hill: Okay. The reason I ask that question is we had a similar meeting just concerning the swine industry and some of the information that we got from people like Dermot Hayes - Dr. Dermot Hayes at Iowa State was very helpful.

Darrell Styles: Thank you.

Don Hoenig: Any others? Okay. If not, I thank you, once again, Dr. Styles for your presentation and for offering your time to the committee.

Darrell Styles: Thank you.

Don Hoenig: I know we have a break scheduled for the - in the agenda at 2:30. What's the committee's pleasure with respect to that? Do you want to keep going along or do people need to take a brief break?

Judith McGeary: This is Judith. I vote in favor of a brief break.

Don Hoenig: Okay. I would tend to agree. Why don't we - I have about 2:20. Do you want to try to reconvene at 2:35 Eastern?

Judith McGeary: That would work.

Willie Reed: Good for me.

Woman: Sounds good.

Don Hoenig: Okay, 2:35, thank you.

Willie Reed: Okay.

Man: Ten minutes break.

Man: Hello?

Man: Yes, hello?

Man: Yes.

Man: Hello.

Willie Reed: Yes, we're on a break.

Woman: We're on a break right now.

Man: Okay.

Woman: Yes, until about 2:35.

Man: I'm having trouble here with my phone.

Man: Dr. Lautner, Dr. Martin, are you guys on line?

Beth Lautner: We sure are.

Barb Martin: We would be.

Beth Lautner: We're here together so we'll be coordinated hopefully.

Man: Are people getting back?

Willie Reed: Yes, I'm back. This is Willie Reed.

Man: Yes, we're ready.

Woman: We're here.

Man: Present.

Man: And our presenters are on line so we're ready to go.

Don Hoenig: All right. Why don't we get started with the next topic which is, I don't know, is it Dr. Lautner or Barb Martin who are on to talk about the NAHLN?

Beth Lautner: Okay. This is Beth and I'll go ahead and get started with just a quick of what we're going to present and then Barb will take over from there, the NAHLN coordinator, if that's all right.

Don Hoenig: Yes. Thanks a lot Beth. Welcome.

Beth Lautner: Okay, great. We'll go ahead and get started.

We did provide a presentation that was posted on the Secretary's Advisory Committee's Web site, however, I'm not sure if everyone has that in front of them so as we talk, we'll make sure to not just refer to you'll see on the slide, but we will let you know when we're flipping to the next slide, but we'll provide the information whether you have it in front of you or not to be able to understand and get the information that we're trying to present.

So what we have is three parts that we'd like to present today. First we're just going to give a quick update, reminder of what we talked about in January of 2011 when we presented at the face-to-face meeting in Washington, DC.

The second part of the presentation and the main part of the presentation is really to give you an update on the 2011 activities. And the third part of the presentation is to provide just a few points with regard to budget and direction of the program.

And with that, Barb will go ahead and start.

Barb Martin: Hi everybody. I'm actually on Slide 3 if you have that. And just as a brief history, I know you've probably all heard this several times over, but NAHLN was initiated in 2002 as a result of several different efforts; the Animal Health Safe Guarding Review, the FMD outbreak in the UK and the events of 9/11.

Because of that, state and federal stakeholders both recognized that our federal labs wouldn't have the capacity to test the large number of samples that would

be generated in an outbreak. And we needed to develop that capability and capacity outside of the federal structure.

So the mission and purposes of the NAHLN came from that and therefore early detection, rapid response and appropriate recovery from adverse animal health events.

It truly is a partnership. We have multiple groups within USDA, APHIS, as well as NIFA working this and our state partners at the AAVLD labs.

If you think about what happened with the creation of NAHLN, we really changed the paradigm of testing in the U.S. because we looked at testing samples from potential foreign animal diseases and then during an outbreak in our state laboratories, and we needed to develop confidence on everybody's part of the quality of testing in those laboratories.

So we established founding principles and those include quality standards, assessing the competency of laboratory personnel, having standard operating procedures and reference materials, having adequate biosafety and biosecurity, and then having a secure electronic communication. And then the last one is to have an assessment of our preparedness by using scenarios.

If you have the slide up you'll see that we have a laboratory designation map there and we basically have four different laboratory designations; the four member laboratories that are receiving a significant amount of infrastructure funding through NIFA, the member laboratories; we have 12 that are receiving infrastructure funding through APHIS and 16 through NIFA. And then the contract member laboratories and they're not receiving any infrastructure support.

We also have adjunct member laboratories. Those are federal facilities that while they're not veterinary diagnostic laboratories are interested in having access to the methods and being able to have that capability and capacity to test for samples. And those would be the labs, the FSIS lab in Athens, Georgia and the Department of Interior Laboratory in Madison, Wisconsin.

We talked last time about our capabilities and their applications and if you flip to Slide 4, we'll go over those a little bit. We talked about the NAHLN methods, technical working group. That group is a phenomenal group. It's made up of both folks from NVSL, the campus here in Ames and at Plum Island, as well as representatives from NAHLN laboratories across the country and we occasionally have international representation, too.

And what the group does is meet together and talk about the performance characteristics of assays. They talk about fit for purpose if an assay should be used and for what purpose it should be used.

And it's really become a great way for laboratories to provide input, because on the a quarterly basis we go out to all of the NAHLN laboratories and ask if they have any issues concerning the tests that they're running for surveillance, if they have any questions about proficiency testing and then they provide that feedback, we get answers for them and then provide it back to all the laboratories.

We also have standardized rapid diagnostic techniques for avian influenza, exotic Newcastle, BSE, CWD, FMD, classical swine fever, pseudorabies, SIB, scrapie and vesicular stomatitis and currently have surveillance programs for BSE, CWD, CFS, PRV, SIV and scrapie.

And I will bring up to you again as I did in January of last year that CSF was the first surveillance program initiated in state laboratories for a foreign animal disease, so that's a huge accomplishment on the part of all of the partners involved in APHIS, as well as our AAVLD laboratories.

We have a secure communications and reporting system via the NAHLN IT system. We have laboratories that are messaging their diagnostic test results from their (LIM) system into our (BS) system.

We also have a train-the-trainer program that I believe has been instrumental in making certain that we have an adequate number of people that are trained and proficiency tested and ready to go should we have an outbreak.

We have quality standards in place and a proficiency testing program. So by that I mean that we have the materials available for the laboratories to use as references and we also have a proficiency testing program so the laboratories that are participating in our surveillance programs have to have trained and proficiency tested personnel or they will not be participating in those programs.

We also have a laboratory review and approval process and we work very closely with AAVLD on that.

We'll go over a few of our 2011 activities and give you a brief update of what's happened since our presentation in January.

I'm on Slide 6, for those of you who have the slide deck in front of you.

I think one of our biggest accomplishments over the past year has been the development and implementation and actually improvement of our quality management system training.

We developed this training in partnership with AAVLD Accreditation Committee. We recognize as we went out and did site visits at the laboratories that every laboratory has non-conformances whether you're an accredited laboratory or not and this is all about continual process improvement.

And we work together with the accreditation committee to develop a quality management system training course. We delivered that in August of last year, the very first time. It was a very interactive environment. We stuck with the international standards, so we have AAVLD, (ISO-1725), OIE standards, we talked about document control, records, internal auditing, management review, corrective actions, root cause analysis.

And then what we did was reinforce that in a wet lab. So we took the folks that had participated in these interactive lectures in a game format and took them into the laboratory and had them find non-conformances and then talk with us about what they would do to address those non-conformances.

This year we've been very active in the development of distance learning modules for quality management systems. We actually have our initial module developed on corrective actions and right now we're getting both national and international feedback on that.

We also did a collaborative training with (PPQ)s, National Plant Disease Network in April of this year and had 26 participants. So we actually took what we were doing on the animal health side and applied it to the plant health side and it was received very, very well.

We are now in the process of getting ready to have another training next month, early next month. We have participants from ten different NAHLN laboratories and then we have 16 international participants from five different countries; Kazakhstan, the Ukraine, Russia, Kenya and Tanzania.

I think one of the most important aspects of this training to me is that we're not only helping the laboratories, but we are getting feedback on this training every time we present it and then improving our training materials and trying to keep moving it forward.

And it has applicability across the board, so not only is it applicable to animal health, it's applicable to plant health and it's applicable both nationally and internationally.

If you go to Slide 7, there's some information about diagnostic development that we're working on right now between NVSL FADDL and the National Animal Health Laboratory Network.

In April of this year we completed negative cohorts for FMD, African swine fever and rinderpests. We had 11 different labs that participated. And we tested over 6000 samples for foot and mouth disease, 1100 for African swine fever and 1350 rinderpest samples.

We'll use that information for assay validation and the other important part of this is sharing results and communication protocol. So I think one of our big advantages with the NAHLN is the fact that we do things like surveillance and we do negative cohorts.

So as we were doing these negative cohorts, we spoke with the AVICs and the state animal health officials and explained to them what we would do should we find a positive and developed those communication protocols and actually had opportunities to test those communication protocols.

And I believe that that makes us much better prepared. Not only do we know more about the assays themselves, but we understand some of the problems that come about as you're trying to work through a positive test result.

We currently have several different projects with collaboration between NVSL, DHS, (FASI) and NAHNL labs. We're developing an (RT-PCR) for FMD in milk. We have completed the optimization of the (R&A) extraction and we're getting ready to do a negative cohort. So we were on the phone just earlier this week trying to talk about the negative cohort and how that will work.

And again, as I said with FMD, ASF and rinderpests negative cohorts, there'll be a series of communications with the state vets and the AVICs and none of this will go on in a vacuum. Labs will not be testing unless they're a state animal health official and their AVIC are supportive of it.

We're also looking at an FMD pen side test and we'll conducting a negative cohort with that. There have been a lot of questions about that test and we need to look at a negative cohort for that.

And then we have collaboration between NVSL, DHS and the NAHLN labs. We're getting ready to deploy FMD serology to the NAHLN labs. The first thing that we need to do there is do a negative cohort.

And it might sound really simple when we say do a negative cohort, you know, go out and test negative samples, but let me give you guys a little bit of background about what happens out at FADDL when they have to do this.

We need control samples. So we need controls not only when we're running the assay but also when we're proficiency testing people. And that can take a great deal of resources not only the serum samples themselves, but the people to get those samples harvested, bottled and then tested and shipped out the door. So it is a huge, huge project.

And we're also working on completing negative cohorts for lumpy skin disease and contagious bovine plural pneumonia. And DHS has provided funding extensively for validating these tests.

If you go to Slide 8, we'll talk a little bit about our laboratory capacity estimation program. This is a collaboration between NAHLN and FAZD with DHS funds and AAVLD.

What it really is is a software of tools for evaluating and monitoring non-capacity. So what we're hoping is that we'll be able to use this to provide daily testing and search capacity, not only on an individual laboratory basis, but overall NAHLN diagnostic testing.

It will also help us to work at prioritizing resources and it will help us manage a large number of diagnostic tests simultaneously. One of the most positive things about this from my aspect - from my perspective is that we're going to be able to use this to process map and determine where our rate limiting steps are.

And then if we have that information from all across the country and we know what the rate limiting step is and see some frequency more than another, then we can address that issue and hopefully increase our overall capacity.

That is currently in a pilot phase in 11 different NAHLN laboratories and we're expecting that that will be released in mid-August of this year. It also has great applicability for other networks. So as we look at this, it's the process that we're mapping, it's sample receipt, it's extraction, it's amplification and there are serologic tests in there, too.

So as you're mapping those processes, there's nothing that says this is strictly for animal diseases, so we're hoping that this will have widespread applicability to other networks.

On Slide 9 we talk about the NAHLN portal. We have several different modules that are in development for a NAHLN portal. So what we want to be able to do here is have a secure web space and this is built on the FoodSHIELD or CoreSHIELD platform and we want a mechanism to electronically comment on and release our standard operating procedures.

We also want a laboratory directory that includes information on physical space, personnel and equipment and we'll use that information in that to help feed the information into the capacity estimation software.

We also need a mechanism to monitor the performance of assays over time. So this will provide the laboratories a way to provide us with information on their controls because all the laboratories are using the same controls. They can enter that information into the secure Web site and then we can track it over time and it will help us. It will send us alerts if there appears to be a problem with something or if we see a trend in a negative way.

It's also going to be a mechanism to train others on the validation process and a mechanism to submit and receive proficiency testing results. Proficiency testing has become a huge, huge process for us. We have almost 300 people that are proficiency tested for avian influenza, exotic Newcastle, classical swine fever and foot and mouth disease.

And if you think about that and then thing about the number of samples that they're doing and it's anywhere from 12 to 20, that's a huge amount of data. And the possibility of making a mistake and duplicate data entry is just huge.

So will hopefully increase our efficiency and will also give us a way to have standardized reports for all of our proficiency testing process.

We have a workgroup and collaboration space so that we can post documents and schedule meetings and calls. We're going to be using this for the various NAHLN committees and hopefully the NAHLN coordinating council, too, and it will also be a mechanism to schedule meetings and training.

It's currently in the pilot phase and we're hoping to have user acceptance testing in the NAHLN labs by this fall.

Willie Reed: Barb, before you go on, this is Willie speaking.

Barb Martin: Hi Willie.

Willie Reed: Hi. How are you?

Barb Martin: I'm okay. How are you?

Willie Reed: Okay. I wanted to know, Barb, this sounds really interesting here. I wonder if the LRN has any or perhaps all of this already developed and whether or not we have to reinvent the wheel.

Barb Martin: Yes, that's a great question Willie. The LRN does not have this already developed. In fact, I went to the integrated consortium of laboratory networks and explained what we were going to do with this, so it's not already developed, nor is the capacity estimation software.

So these are new initiatives that will be applicable to others. In fact, because it's being built on CoreSHIELD, we're going to be able to take some of the modules that they had previously developed for the food emergency response network and tweak those slightly for our use.

So part of the laboratory directory was already built and there's other things that were built, but then we're personalizing this, if you will, for us because we're trying to make certain that all of our state veterinarians and AVICs and folks out in the field are aware of non-cooperating agreements, for example.

So they'll be able to go in and see that information.

So while there are bits and pieces through CoreSHIELD, this is not something that the LRN has already developed there. I think they're interested in seeing how this works for us.

Willie Reed: Yes, I think it could be very useful to other networks. I'm very excited about this. It's great.

Barb Martin: Yes, I agree completely.

Willie Reed: Sorry for the interruption.

Barb Martin: Oh, that's okay. That's okay.

Okay, and then on Slide 10 if you remember back to January, we talked about FMD tabletop exercise series. This all started because of the 2007 high path avian influenza exercise series and what we did was to look at the recommendations and the final report and try to make progress on all of those and we wanted to show that progress through another series of exercises, so initiated the FMD tabletop exercise series.

That was a five-part exercise series. We started with a (VS) policy level workshop so we went to Riverdale and met with a bunch of folks, had folks from Fort Collins join us by TBC and we talked about laboratory or we talked about policies, existing policies and how they apply to laboratories and tried to assess where we might have gaps so that could work on those.

We then did 16 different tabletop exercises. We followed up with NVSL tabletop exercises and those were pretty fun because we hadn't had the opportunity to have exercises at NVSL so we did both an avian influenza exercise here in Ames and then did an FMD exercise out at Plum Island.

Last month we had a follow-up policy exercise that was just great from my perspective because we were able to really close the loop on some of those policies and talk about what we found as issues and were those things consistent between the AI exercises and the FMD exercises.

And now what we're doing, DHS is helping us through FAZD to have a (con-ops) meeting in October of this year and what we'll be doing is really working

on fleshing out those policies and getting input from our stakeholders on the impact of those potential policies to them.

On the next slide, Slide 11, it's the non-coordinating council. That was established in 2009 and it's made up of both state and federal representatives. We have regular meetings. We've had a couple of face-to-face meetings. We actually have our next one scheduled for September of this year. And then we have monthly conference calls.

We're currently reviewing possible options for enhancing the network structure, as well as looking at the NAHLN strategic plan and we're planning to get input from state, federal and industry stakeholders prior to finalizing those plans.

Now we'll go over the budget just briefly. A little bit of history first, on Slide 13 the NAHLN budget in fiscal year '10, NIFA had \$4.4 million through the Food and Ag Defense Initiatives and that funding supports NAHLN lab infrastructure.

And remember back when we talked about laboratory designations, there are 12 core and 16 member laboratories? And that funding is used for personnel, both technical QA and IT personnel, as well as equipment.

And then APHIS in 2010 provided \$6.5 million through arms in the vet diagnostic line and that funding supports the laboratory review process, but NAHLN program staff, IT infrastructure, training, surveillance. Surveillance is a big part of that, so all of those different surveillance programs that I mentioned earlier are paid for through APHIS funding.

It also provides reference materials, proficiency testing, maintenance of equipment, infrastructure support of quality management system and IT systems in 12 of the member laboratories.

And then when we get to 2011 on Slide 14, you can you see that NIFA had a 39% cut to the (fatty) bill and through the NAHLN coordinating council it was determined that that would be spread evenly across the lab, so each of the labs lost 39% of their funding.

And APHIS funding remained stable at \$6.5 million. Now that's an approximation because as I said, that includes our surveillance testing so it's an approximate number and we think it's going to hold pretty close to true.

And then on Slide 15, NAHLN budget in FY12, most of you are aware that the House of Representatives zeroed out the (fatty) bill and because of the work of AAVLD, AVMA and AAVMC there was an amendment to restore \$4.4 million to integrated programs. And now they're preparing to have the senate address that with ag appropriations.

APHIS funding, the president's budget showed a decrease for both CWD program, as well as avian influenza and wild bird surveillance.

And then on Page 16, in conclusion, those of you that have heard me talk before know that I will beat this drum for forever. Partnerships are key to the success of NAHLN. We would not be able to do this if we weren't working together.

We've had numerous accomplishments in 2011 and our upcoming activities in 2012 will be used to increase our preparedness and to improve the functionality of the network.

And with that, I'll open it up for questions.

Man: Thank you Barb.

(Geo Stockton): This is (Geo Stockton). I have one question please. When you were doing the - what you said completed negative cohorts and those different tests, what was the criteria for choosing the diseases that you were developing the testing protocols for?

Barb Martin: Okay. That all started several years ago, excuse me. I believe it was 2002 ARS received money to validate various assays and that included the majority of the agents that were listed there, so FMD, classical swine fever, African swine fever, contagious bovine pleuropneumonia, rinderpests, lumpy skin disease.

So they determined they received that funding to do that and then we're carrying that out. ARS actually provided part of that money to APHIS then to complete the validation of those assays.

(Geo Stockton): All right. So that funding is coming to an end?

Barb Martin: It is. It is, but one of the things we talk about when we talk about validating assays is that we have an initial assessment of the performance characteristics of that assay as we complete the validation studies. But as we use that assay, whether it's in the NAHLN laboratories or whether it's at one of our campuses either here in Ames or Plum Island, we're adding additional information, adding additional data points and increasing our confidence in the performance of that assay.

Beth Lautner: And maybe - this is Beth Lautner. Maybe I could just add one comment. Currently we have an active surveillance program for classical swine fever that uses the PCR, the technology that's been developed and that we've developed for these other diseases and that's currently deployed to the NAHLN laboratories and they're able to use that in the classical swine fever surveillance program.

So if look-alike diseases come in to a NAHLN laboratory where classical swine fever is a possibility, it's probably PRRS or salmonella but classical swine fever could be a possibility, they have that test to be able to use.

The other test that we have in place like the foot and mouth disease, that one has been available to the NAHLN laboratories to use in the event of a foreign animal disease investigation.

So if a producer thinks that, you know, foot and mouth disease might be a possibility and their practitioner looks at it and they call a state or federal veterinarian to come in and take samples, at that point, the samples can be split between a set that goes to Plum Island to the Foreign Animal Disease Diagnostic Lab and a set that would go to the NAHLN laboratory so they can conduct that initial screening test for foot and mouth disease.

And that's what these tests are. They're the screening test. Not a confirmation but a screening test.

The other diseases, the contagious bovine pleuropneumonia, the rinderpests, the lumpy skin disease and African swine fever, they're just getting through the point through this testing process where we would have them available to deploy in the face of an outbreak.

We don't have plans to have an active surveillance program for those diseases, but they would be available and ready to use. For example, African swine fever has been on the move in the world. So if we were to have an introduction here, we would have a test that would be ready to go.

The rinderpests we would hope we would never have to use. That one has just been recently declared eradicated from the world. But it is a test that we started to develop and we wanted to be sure to still have a rapid test for it.

(Geo Stockton): Thank you.

Howard Hill: This is Howard. I got a question for Barb or Beth. A meeting I was at earlier in the year, the subject of NAHLN came up and there was still some concern about the ability to electronically transfer data to a central coordinated area in the case of an outbreak of foreign animal disease.

And I got interrupted during your talk Barb, so maybe you covered this and I didn't hear it, but where are we with that? Do we feel like we have a good system now in place if we had an outbreak we would be able to electronically transfer data?

Barb Martin: Okay, Howard. We currently have 15 laboratories that are routinely transmitting diagnostic test results electronically to a (VIA) system. We are having training the second week of August and bringing in representatives from I believe ten additional NAHLN laboratories to help them on the messaging process.

But that doesn't quite answer your question about do we have that capability and I'm going to defer part of that to (John Vaconso) when he talks. I know that we can message into our NAHLN IT system. It would not automatically

go to VSLS, so there is still an issue there and we are working to get that resolved.

Howard Hill: And I would assume that the speed at which you can resolve that probably revolves around funding, right?

Barb Martin: Exactly.

Howard Hill: Yes, okay. Thank you very much.

Don Hoenig: Other questions from the committee?

Willie Reed: So Barb, what happens if NIFA doesn't come through with funding?

Barb Martin: Well Willie, we continue to operate as we can with the existing APHIS funding. But NIFA funding covers a lot of personnel.

So even though we would be able to continue to pay for surveillance testing, the laboratories wouldn't have the personnel levels that they had had before and it would decrease our overall capabilities because we wouldn't have as many proficiency tested people.

So that means that translates into we're not going to have the capacity that we have and we may not even have the capability to test in some laboratories.

I'm getting on my soapbox, aren't I?

Willie Reed: Well we essentially lose or waste millions of dollars of investment that we've made over the years which is really unfortunate if it should happen, yes.

Barb Martin: Yes.

Man: (Unintelligible).

Boyd Parr: Don, this is Boyd. I appreciate Barb and those comments. As an action item, I don't know, we obviously advise the Secretary and not Congress. But is there an item, an action item to put - for the committee to consider at the next meeting or now recommending or affirming our concurrence with the importance of the NAHLN and continued funding of it as far as it depends on the Secretary as far as animal health?

Don Hoenig: Boyd, this is Don. I think there is. I think it's a really important issue that keeps coming up over the years and so I think it's a minimum a committee should consider a recommendation on supporting the concept of the NAHLN, supporting funding for the NAHLN and in fact supporting perhaps increased funding for the NAHLN.

But one issue that I also think that we talked about over the years on US Animal Health Association and AAVLD is this concept that the funding for NAHLN comes from NIFA and from APHIS. And I believe we actually met with the Secretary of Agriculture four or five years ago, perhaps Secretary Johanns at the time and the one issue that we discussed with him was trying to get some movement on perhaps transferring all the funding to APHIS.

And I don't know, you know, NIFA is part of the USDA so - and it could be a recommendation or something that we could at least consider discussing and possibly making a recommendation.

So there's a number of issues there, but I think the - yes, I agree Boyd, and I think we ought to consider some sort of recommendation.

Boyd Parr: Yes. I'm certainly not well-informed enough to know the intricacies on whatever will make it more stable and more useful I'm in favor of. I have not investigated whether leaving it in NIFA or moving it, you know, whether that's the problem.

Congress cut that line item, you know, whether they would have done it if it was under APHIS or not. I'm not involved enough to know.

Don Hoenig: Right, and I think, you know, we could perhaps inquire of any of the other lab people on the call. Willie, I know that you've been involved in this over the years and anybody else from the lab end of it who have some wisdom on whether the NIFA versus APHIS funding is a problem and whether we ought to make a recommendation on that.

Willie Reed: Well I can just, you know, speak from my experience and being involved with this, I would have much preferred to have dealt with APHIS than NIFA. And even this whole concept of how NIFA categorizes laboratories has been problematic and a point of contention amongst the laboratories in terms of fairness.

And really - so my recommendation would be to do that but Barb, I'm not sure what you've heard from the other labs or the other lab directors. But that would be my recommendation that if all of this funding was under APHIS' review, I think it would work much better.

Barb Martin: Yes, Willie, I think that that's a conversation that we need to have with the NAHLN coordinating council.

Willie Reed: Yes. But just, you know, just from one person's experience over the years dealing with both organizations and, you know, APHIS is much more nimble in being able to get things done and this process of, you know, with NIFA is I just find it very - I did find it very cumbersome.

Don Hoenig: Well maybe we should be working on a recommendation for the September call, drafting a recommendation. So I would ask the people who have most intimate knowledge of that on the committee perhaps Willie and Boyd and one or two others if we might want to consider something for the September call in the form an action item.

Willie Reed: But like Barb said, I would, you know, like to get some comments, feedback from the Council before we acted on that because we wouldn't want to do anything that would go against their wishes I think.

Barb Martin: Yes, Willie the other thing I would suggest would be to get some input from the (USAJAAVLD) joint NAHLN Committee.

Willie Reed: Yes.

Barb Martin: Because that's a big group and they could provide some good feedback.

Willie Reed: That's a good recommendation and I guess that committee won't be meeting until USAJ meeting, you know, later...

(Barb): Yes, that - yes. That committee has monthly calls.

Willie Reed: Okay.

(Barb): Yes. I can forward you information on that.

Willie Reed: Okay.

((Crosstalk))

Willie Reed: ...feedback sooner then.

Beth Lautner: This is Beth Lautner. One thing that might be helpful for you is we have sat down and had good discussions with NIFA with regard to roles and responsibilities. And I think perhaps some of the discussion in the past has been related to when we didn't always have maybe as much clarity around roles and responsibilities.

One thing that we could share with the committee if you'd like is the charter for the coordinating council. And from that that's co-chaired by myself and Muquarrab Qureshi from NIFA. And as part of that coordinating council charter we reviewed and reaffirmed the roles and responsibilities of APHIS and NIFA and that would be something that might be a helpful document for you to see how we've allocated out those roles and responsibilities.

Willie Reed: Yes, I agree Beth. That would be great...

Beth Lautner: And Gary Anderson is the other co-Chair with that committee, the coordinating council. So to try to have all the three partners represented there. So we'd be glad to share that charter as a public document. Be glad to share it.

Man: That'd be helpful. Thanks.

Willie Reed: Yes. I would love to see that.

Dr. Don Hoenig: Okay. And that would - you know, it might be helpful for you to bring back to that coordinating committee our discussions and find out what their feelings are about the idea of this now being all this split funded I guess. I'd be interested in their feedback on that.

I don't - haven't been involved in that committee at all. I just remember that when I was on the USAHA Executive Committee and we met with the Secretary, it was the one issue that we brought up with him and that was brought forward by AAVLD and USAHA Government Relations Committee and it was in D.C. several years ago, so.

Well, thanks Beth and (Barb) for your update and we will look forward to hearing back from you. And we probably ought to continue on to our next agenda item unless there's anybody else that has a burning question.

Okay. Thank you.

Man: Yes. Thanks (Barb) and Beth. Thanks.

(Barb): (Unintelligible) for inviting us.

Dr. Don Hoenig: Sorry. I think the next topic is scrapie update on Scrapie Program from Diane Sutton.

Alan Huddleston: Good afternoon everybody. This is Alan Huddleston. I am Diane's associate. She was not able to join us today so I'm stepping in for her. I'm hoping everybody can hear me.

Dr. Don Hoenig: I can hear you.

Man: Yes.

Alan Huddleston: Okay. Very good. I'm going to go ahead then. Thanks for inviting us today to give you a quick update on the Scrapie Program. We're just going to give you a couple of stats about what the program has achieved so far but also talk with you a little bit about budget and what we might be having to think about doing in the next year to make up for some of our decreasing funds.

So first of all, as many of you are aware, the goal of our National Scrapie Eradication Program is to identify and eliminate the last remaining classical scrapie cases in the United States by 2017.

And after that maintain surveillance at high levels for seven years to minimize the risk of delayed detection of any undisclosed cases and also so that by 2024 the United States can meet OIE requirements for scrapie freedom.

So through the hard work and cooperation of the sheep and goat industries, the states and the USDA, the United States is well on the way to eradicating classical scrapie from the country.

Between 2003 and 2010 for example, the prevalence of classical scrapie in the United States has decreased by 85% from 0.2% prevalence in 2003 to just slightly less than 0.03% prevalence in 2010.

The percent positive black-faced sheep detected at slaughter has fallen on average 26% each year since fiscal 2003. And for those of you who might not have this knowledge in your head, the black-faced sheep population or subpopulation of sheep is where we find the greatest concentration of scrapie and as that prevalence has been going down, the prevalence in the black-faced

sheep has started to come close to matching that of the white-faced sheep and the (model) faced sheep.

So there's been quite a good closing of that gap in the last seven years. Also during fiscal year 2010 we discovered that the number of new infected or source flocks have decreased by 37% from the previous year. And if you look at on average from when it was at its highest in 2005, it has decreased in average - that number has decreased in average of 33% each fiscal year.

So we're almost there. And as we get closer, each case that we find will be a little bit more challenging to find because it's becoming to be more like a needle in a haystack. And each case will - each individual case will appear to look more expensive in terms of how much resource we had to devote to finding just those smaller and smaller cases.

So let's shift from that into budget. So due to the current economy and our large government deficit, since APHIS is taking critical looks at funding for all of its programs, I'm sure I'm not the first person to bring that up today. The Scrapie Program has sufficient funding for the remainder of this fiscal year in 2011 to continue our program operations especially providing official ear tags, those free ear tags to sheep and goat producers.

Also we're going to be able to meet our slaughter surveillance numbers that come in. Part of that is that we would be able to have the funds but also because our numbers are expected to be a little bit lower, we refined our sampling criteria in this past year from where we based it on science of not trying to take older animals or too many older animals because those tend to be a population where you find the zero to very, very few cases.

So we asked our field to stop bringing in some of our really ancient sheep or gummers so that we would target more specific animals. And as a result of that, we're seeing a little bit of a drop this year.

So in fiscal year 2012 the President's budget calls for a \$2 million 30 thousand reduction in scrapie funding. So our total proposed Scrapie Program budget would be 15 million 876 thousand. And that would be as part of the new Equine Cervid and Small Ruminant Health Line. So in 2012 despite the proposed reduction in APHIS because that does sound like a significant chunk; but we expect to be able to sustain our current service levels for a couple of reasons.

We have a declining need because the disease is decreasing. The prevalence is decreasing. So we have to spend less money on disease response and indemnity. And also we have been building up a small trust of funds for our - in our indemnity account, which has been able to pass over from year to year. So if we have any - if we have a gap in 2012, we would be able to use those unused indemnity funds to cover that gap and face any critical shortfalls.

So as we look into the future though if this continues, we won't always be able to tap into that indemnity fund. So we are looking at as a program - Scrapie Program ways of focusing our energies, our resources on those aspects of the program that have the greatest impact towards scrapie eradication and looking at those that have less impact and figuring out how to shift resources away from the less impactful to the most impactful.

And what we have found is that the regulatory or mandatory component of the National Scrapie Eradication Program is in the accelerated Scrapie Eradication Program, which is what started in 2001. And within that that applies to all sheep and goat producers across the United States.

And there's two elements of that that where we find the greatest muscle, the greatest strength for finding the last remaining scrapie cases are in surveillance and in ID compliance. So in surveillance that has to do with our targeted slaughter surveillance where we try to get up to 44,000 animals healthy, non-clinical animals at slaughter for testing each year.

And ID compliance, a key to that is the compliance with official identification requirements, which we believe is quite well linked to the provision of free tags to producers. So those are two areas that we want to protect with our resources.

And so we've looked - we've turned our eye at some components that are less efficient at - toward our goal of eradicating scrapie. And so we have found that the Scrapie Flock Certification Program is one area that we need to look at for reducing our resources in.

So that is for a few reasons. One of them, the SFCP is a sort of small voluntary component within the greater National Scrapie Eradication Program. For example, there are currently 1546 flocks participating in the program and that makes up just slightly less than 1% of the total number of sheep flocks and goatherds in the United States. So that SFCP the total participation actually represents a very small part of the industry.

Since 2007 in addition to that, participation has been declining. It's declined 25% since its height in 2007. We believe that that has to do with some other options that producers have namely that they can use genetic screening and genotyping strategies to help reduce the likelihood of exposure to scrapie in their herd.

Since the inception of slaughter surveillance, the majority of our scrapie-infected flocks in the SFCP flocks were actually detected through slaughter surveillance. Either through directly at slaughter so they would have been tested anyway through the regulatory scrapie slaughter testing or through tracing exposed animals.

So we actually weren't finding them through the SFCP but rather through the mandatory program. So no cases have actually been detected through flock inspections that they have every year and only through - a few through reporting to clinical suspects by owner.

And one of our more troubling statistics is that within the SFCP there is the opportunity to become certified, which basically says to by your trading partners either both within our country and externally that your flock is certified as being at a much less reduced risk of spreading scrapie to the person purchasing your animals.

And we have found that 0.5% of all the flocks that have ever been certified were determined to be infected after certification. Sometimes up to a year after they were certified, which meant that they were selling their animals as certified scrapie free for at least a year.

So from this we're concluding that the SFCP inspections are not efficient in detecting scrapie infected SFCP flocks. And we need to come up with a way of producing resources to that aspect of this program. So with that, we're considering four different options for revising the SFCP.

One of these is to eliminate two of the less restrictive categories of the SFCP called the selective and complete categories. And we would maintain the export category so that those who - those participants who want to - or those

producers in the United States who still want to become an export certified flock still have that avenue for marketing their animals and germplasm internationally.

What we would do in this instance if we eliminated the selective and complete categories is allow those current participants in those categories to grandfather in to the export monitor category and then just start with their same sort of - (age) their time in moving toward export certified status. We imagine that there would be approximately an 80% decrease in participation with the result - as a result of that.

And in a second option, Option 2, we'd keep all three of the current categories. But instead of veterinary services or our state partners running the annual inspections, we would place the responsibility on the participants, the producers in the program to arrange for and pay for accredited veterinarians to do the annual inspection for them. So obviously that would shift the main expense of the SFCP, those annual inspections to the producers.

In Option 3 we would maintain all three categories but we'd modify them so that the inspection regime or inspection schedule would be decreased while at the same time we would institute a point system based on animal sample so that those who are moving toward a higher status would actually be submitting more animals for scrapie testing.

So it'd be contributing more to our surveillance stream than it currently is while at the same time we would be expending less resources on inspections and that would - from some of our feedback from some of our SFCP participants, that would be less of a burden on them.

So they would only have to fill in a form verifying what they had done in the last year and not have to arrange a daylong inspection each year. And again in this the export category would be unchanged.

And the fourth and most recent option that we've put on the table is we're considering is to eliminate just the complete category within SFCP so that folks who wanted to stay in the SFCP but maintain their status at a little bit less restrictive or much less restrictive protocol would join the selective category whereas others could if they wanted to move towards certification they'd only be able to move toward export certification with a more rigorous export certification.

So I would just like to say that in each one of the four of those options, we maintain the export category as is so that our U.S. sheep and goat producers would still have an avenue by which they could demonstrate that their flock was export certified or met OIE recommendations as a scrapie free establishment and once we recognize them as export certified.

So what we've been doing - we started in May doing some stakeholder outreach. We're trying to get some input on these possible changes and also to solicit any other options that we haven't thought of. And so so far we have talked with some of the members of the sheep and goat industries. We've also held some Webinars with our field folks and our state partners.

And coming up in the next couple of weeks we have four more Webinars going on with SFCP participants as well as sheep registry presidents. And we're also publishing a notice in the Federal Register to give the public a chance to read a concept paper on this and comment.

Probably what we're looking at in terms of down the road is that we would be coming up with a decision or recommendation for Dr. Clifford sometime this fall with implementation in fiscal 2012.

Some of the comments that we've received back so far - some of the feedback especially from - I'll start with some of the input that we've received from industry so far is that, you know, in their opinion ideally funding for the SFCP wouldn't need to be reduced. (They'd) be maintain the resources as they are.

But if our choice is to either maintain current funding for the SFCP and see a decrease in the funding for our surveillance activities or providing those official ID tags to producers that they'd rather see is focus on the latter more effective components of the program.

Almost universally we've heard some serious concerns about Option 2, the use of the accredited veterinarians. People in rural communities note that it's very difficult to find a small ruminant practitioner who's willing to see their animals. So being able to find and accredited veterinarian to run their annual inspections might be an insurmountable challenge.

And also we've heard from our field folks that training accredited veterinarians to be able to manage the flocks and the SFCP and then overseeing that they're doing it correctly will take just as much of their resources as doing it themselves. So we have some - we are fairly skeptical about Option 2 but we will keep in on the table so we can hear back from anybody who might feel differently than that.

And in terms of our field force, well, what we're hearing back from them is well about half of them feel that just eliminating that Option 1 - eliminating

the selective and complete categories would be the simplest and most cost effective option.

We have another half that does express a concern that in doing so we would really be reducing the inner action between some of the APHIS field force and sheep and goat producers. It's one of the few opportunities that they have - they expressed that they have to get out and reach out to this growing component of animal agriculture.

And if I could shift gears, I have just one last bullet point. I did want to bring up that APHIS is planning - this is one of our other down the road things. We are in the process of attempting to publish a proposed rule that will do a few things.

It will address gaps in identification requirements including making the requirements for goats similar to sheep. It would also update program procedures to reflect new scientific information. And that's just a sort of legal speak for saying that we would start using what we know about the genetics of sheep to scrapie to be - to go into our regulations. It's already being utilized in sort of a pilot program form but actually making it official.

And also requiring states to meet some surveillance targets to remain consistent states. And with that, if anybody has questions for me, I'm willing to take them.

Dr. Don Hoenig: Thank you Alan. Any questions for Alan on scrapie?

(Janelle Criggins): Yes. This is (Janelle Criggins). Can you hear me?

Alan Huddleston: I can (Janelle).

(Janelle Criggins): Yes. Okay. So I have a comment more than a question. I wanted to say the stakeholders that I represent here in North Carolina there has been an ever increasing complaint about the Scrapie Certification Program. APHIS or USDA I believe changed the source of their tags maybe two or three years ago. And these producers are having an increasingly - an increasing problem keeping those tags in.

And those people that have been in the Scrapie Certification Program are having problems tracing back their animals because they can put tags in and those same animals two or three months, four months later when they bring them out of pasture if they bring up 100 there may be 18 that are missing tags. And it's not always easy to trace those animals back.

So actually some of the producers have opted to get out of the Scrapie Certification Program and just go to the mandatory - the Eradication Program. And, you know, even some that were involved in export and have run the risk depending on what countries they export to that they would not be able to export.

You know, I think that that was kind of a shame because it did, you know, it did offer more close control or contact or monitoring than what is with just the Eradication Program. But there seemed to be some problems particularly in North Carolina with the area vets as far as trying to help them work through the process and find a tag that would stay in these animals.

Alan Huddleston: Thanks (Janelle). That's certainly - we always are looking at what might be going on with some of the technology that is in there. And certainly there have been some issues that have come out of the field with replaced tags. That was sort of under a contract bid. And so we are looking at effectiveness. That does

become something that we evaluate when we go back to re-contract with others.

So we always - we certainly will be taking your comments as well as we've heard that before - with others as we go into the future with this. I would point out -- and unfortunately this is the free tags that we're talking about -- producers do have an option to pay for tags from some of the other companies that are approved and those - if they were more comfortable with those retention rates, they certainly do have that option.

Though again, that's unfortunately not the free one. The free one is the one that we are - we're currently evaluating. So thank you for that.

Dr. Boyd Parr: Alan, this is Boyd Parr. I appreciate your presentation and I think the process you described of analyzing the program and trying to maximize the dollars and looking toward eradication is certainly sound and I applaud you for that process. Certainly familiar to lot of us in several states that have to prioritize things in similar ways.

Just one point that - and it may be just me that doesn't know. On one of the points at the end, could you provide for the committee later or maybe the answer's simple or Cindy Wolf may know the answer immediately. You know, it sounds minor but it can be major to states' efforts and the expansion and the rule consideration.

You know, all the evidence that I see is largely sheep. And yet we're planning- seem to be making sheep and goats synonymous. Can you provide us with some incidents data in goats and the research data on the transmission from goats to sheep possibly as far and then maybe some cost effectiveness as to

how much effort it would (clude) to do everything we're doing with sheep with goats and what our benefit would be from that large effort?

Alan Huddleston: Sure. If I - I could give that - let me try to do that question in sort of a greater international economic/political response and then maybe a little bit - well, I'll start with the scientific actually.

So we do know obviously that the goats can get classical scrapie. They also seem to be able to develop the atypical scrapies as well. What we're - what we find is that goats certainly can get it from sheep. And many of the cases that we've had, we've had - we are not up to 31 since 2001. So that is very small compared to what we've seen in sheep since 2001.

But the majority of those when we've gone in and found them they have had some sort of exposure to sheep scrapie and that oftentimes this happens within like a year or two later or before so that there was some sort of historical exposure that was unbenounced to the owners or they just didn't quite - weren't aware that their goats could get scrapie because it is a fairly more - it's a more rare thing for them to exchange or to get.

But when they do get it, they can certainly transmit it back to sheep. And they can - efficiently and they can transmit it to one another efficiently. So in the greater - in the context of that when we look at trying to eradicate scrapie from the United States if we demonstrate only that we have eradicated it from the sheep population, it will not open any new doors for us in terms of being seen as a scrapie free country.

So what we're - what we'll be looking at in terms of our goats is starting to sample them according to the way that OIE recommends that we do. And that

would be in terms of our population - our total U.S. goat population - approximately 3000 goats a year.

And they'd have to be appropriately randomized across the entire United States and across different uses so that we would say each year we're getting a representative sample to demonstrate that we actually do have sufficient knowledge and sufficient surveillance to say that yes indeed in addition to our sheep population which was - is indeed where the majority of the problem is, we're also finding - we're also looking closely enough that we are not - that we would find it in goats if it was in goats.

And to be able to do that unfortunately we do have to have the successful official identification that we've seen in sheep. Without it really we would not be able to do trace backs - sufficient trace backs should we be able - should we find a positive goat.

So it's sort of two fold. Yes there is some science behind it and it is kind of frustrating because we don't see the same incidents in the United States in goats that we see in sheep but it has an equal impact in terms of our trade relations with our - with the international community.

And just sort of as an aside, there are some - there are some examples around the world, I'll say Greece and Cyprus for example, where there are significantly higher percentages or prevalence is significantly higher in goats than you'd expect if it was so difficult for it to be transmitted as well as maintained in a population.

Dr. Boyd Parr: And I appreciate that information. That is helpful. And I understand the political sometimes. I would be interested -- and you don't have to do it now -- if you could get us the information on - and it obviously must be international

that establishes the percentage the likelihood of transmission from goats back to sheep because at only 31 cases here we can't have done much of a study. So it must be international.

Alan Huddleston: Yes. And that's very interesting. Yes. That's very good. And I will definitely get something together for you and we'll forward it on to the committee.

Dr. Boyd Parr: Thank you.

Alan Huddleston: You bet.

Dr. Don Hoenig: I think one of the difficult aspects of this from the point of view of goat owners is that if scrapie is diagnosed in their herd, their options are very limited. They don't have the ability to do genetic testing like sheep owners do. And so they're faced with either, you know, the decision to either depopulate or a five-year quarantine. And those are pretty dire consequences. So I don't know how we deal with that.

Alan Huddleston: I agree with you. That is very frustrating I think for the goat community. And there have been some nice advances I'd say in at least the last three to four years in terms of trying to map some of the genetic resistance - last genetic susceptibility in goats.

So we certainly are keeping our eye on that to see if we find something that starts to look as convincing as the evidence that exists in sheep. But again, you run into a problem because in so many of the countries where there are resources to do sufficient studies and tests, you don't have the same level of prevalence in the goats. So it becomes a little bit harder to study.

Cindy Wolf: Alan, this is Cindy.

Alan Huddleston: Yes.

Cindy Wolf: In the SFCP flocks that have been diagnosed with scrapie, is there a breed predominance or has that been kind of whatever?

Alan Huddleston: Well we have seen it more in our black-faced breeds. And that is again because that's where we found the majority of our cases through the RSSS. And again, we're finding in the SFCP flocks that have been found to have scrapie, they have been found through RSSS instead of through the SFCP related activities, if that makes sense to you.

Cindy Wolf: Yes.

Alan Huddleston: So it's more they've - they follow the pattern of the rest of the sheep population in the United States.

Cindy Wolf: Okay.

Dr. Don Hoenig: Okay. Well I think...

Man: I've got one question. This is...

Dr. Don Hoenig: Oh sorry. Go ahead.

Man: Yes. About the requirements for tagging animals in interstate commerce. On Page 4 it says in September 2001 the scrapie regulations were revised to require official identification of sheep and goats not in slaughtered channels and any sheep over 18 months of age in interstate commerce. Here in Montana they're requiring us to put in tags into the feeder lands.

Alan Huddleston: Yes. So our regulations allow for states to place additional requirements so they can expand the type of animals as well as the age of animals in which identification tags must be placed. So our regs set a bare minimum and the states do have a freedom under our federal system to add onto that if that's what the State Department of Agriculture and the legislature has decided to do.

Man: Okay. Thank you.

Alan Huddleston: Sure. Sure.

Dr. Don Hoenig: Okay. Well thank you very much Alan for that presentation. And if there are any recommendations that need to come out of this, I think we can pursue them between meetings.

So next I believe that we have John Picanso lined up for telling us about modernizing the generic database. Is that correct? John, are you there or is he on mute?

RJ Cabrera: Dr. (Scott), are you on? Okay. Don, why don't we move on to NVS, National Veterinary Stockpile?

Dr. Don Hoenig: Sure, is Rodney White available?

Rodney White: Yes I'm here. Yes. This is Rodney, Veterinary Services Emergency Management and Diagnostics National Veterinary Stockpile Director. And what I've been asked is to provide you an overview of the National Veterinary Stockpile Program and particularly this presentation will focus on a little bit of

background about Veterinary Stockpile and focus on our capabilities, mission and give you an idea of some of the activities we've had for the past year.

And for some reason everybody asks (unintelligible) National Veterinary Stockpile is national repository of critical veterinary countermeasures. You're talking about supplies, equipment, vaccines and we've incorporated (unintelligible) support services in the form of 3D contracts which are - provide the services of depopulation disposal and decontamination.

The NVS is the logistics arm for the animal plant health inspection service and we're here to assist the states, tribes and territories in the event of damaging animal disease outbreak, natural disasters and (unintelligible). Our services have been used in other emergencies.

Going on to Slide 2 for those that are following with the slides. And I will call out the slide numbers. I'm on the background slide. Homeland Security Presidential 9 established national policy to defend the agriculture and food systems against terrorist attacks, major disasters and other emergencies and therefore established our National Veterinary Stockpile. Although it established the Stockpile in 2004, we didn't go into full operation until 2006. Next slide.

Mission. NVS missions provide the veterinary countermeasure supplies, equipment, vaccines and response support services states, tribes and territories need to appropriate respond to a damaging animal disease outbreak.

And in Homeland Security Presidential 9 it requires the National Veterinary Stockpile to deploy or capable of deploying within 24 hours those resources so that the responders can appropriately respond. And we do have that infrastructure and I'll talk about that as we proceed through the slides.

The goals of NVS is deploy within 24 hours. And one of the things we've looked at is deployment in 24 hours only benefits responders in the (unintelligible) states know how to request NVS help when it arrives and quickly process and distribute it. And that's why our second goal is to help states, tribes and territories plan for the NVS. Next slide.

This slide some of you are probably used to. It is the APHIS' list of the 17 most damaging animal disease threats. It's in order of risk and it asks to enter those diseases that are impacting human health or zoonotic. And those that have it up on their computer, it shows the highlighted diseases. Those (unintelligible) of concern.

And to date they NVS has acquired a full set of countermeasures and the infrastructure to hold and deploy them against high pathogenic avian influences, high path AI, exotic Newcastle Disease and CSF, classical swine fever.

The NVS has also acquired partial countermeasures against the remaining 14 threats, which include animal handling equipment and personal protective equipment. And to say - to hold full countermeasures against these threats we must still acquire vaccines, as they can become available and mass depopulation equipment technology.

On Slide 5. Science based logistics, inputs from experts, NVS or logistics background but then NVS has to rely on veterinary experts to identify the vaccines and other countermeasures needed to countermeasures needed to counter its most dangerous threats.

And in defining those countermeasures and the quantities that must be held is a dynamic process that continuously evaluates several factors in addition to existing threats. Therefore we established the NVS Steering that meets - used to meet on a - twice a year but due to budget cuts and as the NVS has proceeded, we became very more established and understand what our requirements are.

So therefore we went to a meeting once a year. We met in (September) of last year and we're planning on meeting again in upcoming December. But the purpose of this committee is to advise the NVS on its national strategy for requiring, holding and deploying our countermeasures.

And the main purpose of the groups is to inform the Director and the technical function of groups either evaluate available countermeasures and evaluate available countermeasures. During our Steering Committee meetings we typically have (unintelligible) Research Service and Cyril Gay and a team of other experts that provide reports on certain diseases that are in the pipeline and actually disclose some of their countermeasures and their sources.

And the functional group typically we're to advise NVS on (unintelligible) methods of acquiring, holding and delivering countermeasures and working with the logistics chief. Moving on to Slide 6.

This slide pretty much for those that have it up describes our business processes. Pretty much a six-step process in which we rely on (unintelligible) damaging animal diseases, which are identified. And that's how we work to acquire the countermeasures and define those countermeasures utilizing that list.

We then focus on acquisition of those countermeasures making sure we're making the best use of available funds. And then we have the other block that focuses on location. Where do we place those countermeasures? We have our - we have several locations throughout the U.S. where we stockpile our inventory -- we don't have one location -- to make sure that we can deploy.

If anything happens to one of our locations, we have those supplies located strategically throughout the U.S. And one of our challenges is that next block that most of you don't see. It talks about maintaining countermeasures.

A lot of the countermeasures like personal protective equipment you have expiration dates and they have shelf lives. So we have to actually make sure we manage that. And typically we've been very successfully in actually getting contracts with vendors that are able to rotate our countermeasures such as our (unintelligible), our test strips and other actually and including some of our vaccines where we have guaranteed access. And I'll talk about that later.

One of the things we try and do is make sure we focus on minimizing cost and ensuring our availability. And last, we do play for deployment and I'll talk about exercise activities in further slides.

And here's something that I'm talking about. Next Slide 7, purchase countermeasures maintain (res), minimize cost. This kind of focuses on what I mentioned earlier about maintaining cost.

The NVS stockpiles large quantities of countermeasures and typically frequently - well, typically stockpiling is frequently needed the best or most cost effective method of deploying countermeasures that states need. When it makes good strategic and economic sense, the NVS partners with industry to

hold and deliver its countermeasure to reduce its cost and improve its response.

And here in this slide you can see there's four different methods we use. Critical items we want to be deployed within 24 hours. We typically maintain those in one of our facilities that we pretty much manage.

Critical items that vendors hold are those that must be processed before use and can rotate to reduce the cost of expiration. They're owned by the NVS but managed by vendors. And we've got several sites throughout the U.S. that do that for us and we pretty much coordinate with them. And they also understand that they too must be able to respond within 24 hours. Therefore they provide us all the contact information in the event that we have to deploy.

And the third bullet talks about guaranteed access. And these are items that vendors hope that we buy when we need them to save holding cost of storage. And if you look at personal protective equipment and you look at large outbreak, we want to make sure that we do have available a appropriate amount of PP available.

But then we can't predict actually how large that outbreak would need and how many supplies we need. So we have (unintelligible) contracts, which you hear indefinite delivery and definite quantity contracts where we have reach back through the contract and can request additional supplies. Next slide.

Next I'll focus on our capabilities. And if you're looking at Slide 8 it gives you an idea of some of the items we have in the National Veterinary Stockpile from our push packs which I'll talk on the next slide, which contains our personal protective equipment, decon supplies and our powered-air purified respirators for those diseases that impact human health.

And one of the things we've done is actually to increase the speed; we put most of those critical items into kits. We kitted items such as gloves, aprons and all of those smaller items into a kit so when responders arrive at the site, they can not have to sit there and wait on the receive process to be issued individual items and have to actually slow down or delay the response time.

So we've kitted certain items. We have antivirals, vaccine, poultry depopulation foaming units, which I'll talk to, portable vaccine shipment and storage containers, large animal handling equipment and I'll focus on our three contractors in another slide.

Next slide talks about our 24-hour push packets. It contains those personal protective equipment, decontamination supplies and (packers). They arrive within 24 hours of APHIS' order to deploy. They're not customized. They pretty much are what responders need immediately to respond to a damaging animal disease.

The customization can come after that initial response of 24 hours where you can over order and reorder those like items that you feel that you need or necessary. And one of the things we've done is each push pack supports ten responder changes six times a day for ten days. You might say well that's a lot but typically you got to look at serviceability and usage of some of the items.

When responders put on some of the PPE, you have the incidents where they can tear zippers. So we actually provide more than what's needed in that one push pack.

Next slide focuses on antivirals. NVS, National Veterinary Stockpile stores two types of antivirals, Tamiflu and Relenza. Have 80% Tamiflu and 20%

Relenza. Typically they're used for prophylaxis for prevention and will be issued by the medical unit at the incident command system.

And one of the things we've recently done over the past year is that our Tamiflu is about to expire, we've enrolled into the DOD FDA shelf life program where they can actually work and test our Tamiflu and make sure it's potent and defer the cost of us having to initially purchase it.

But unfortunately for the Relenza there is no shelf life program so we're going to have to actually procure additional Relenza because there's no shelf life or service life extension program set up for Relenza. And one of the reasons we have Relenza is because we found that certain responders when they arrive do not or cannot take pills. So the Relenza's in the form of a disk or inhalant.

Slide 11, vaccine. NVS animal vaccine will come from multiple locations and time of arrival depends on the vaccine and the strain. As you know, that could be several strains and we've got two vendors that provide the (FMB) vaccine based on the strains. Most vaccines that are manufactured overseas require coordination with overseas vendors.

In addition, if you look at the second half, it talks about the North American foot and mouth disease vaccine by Mr. Darrell Styles. Focused on that a little bit. And the National Veterinary Stockpile the logistics arm for not only APHIS but for the North American foot and mouth disease vaccine pack and the distribution of the foot and mouth disease vaccines that will be needed in the event the bank is activated.

And one of the things we recently did back in June was we started focus on a lot of our standard operating procedures making use that we - they were validated.

And in June we actually co-hosted with the FADDL foreign animal disease lab is a tabletop exercise in which we had - we were lucky to have Canada and Mexico available and also the vaccine manufacturer did come and participate in that tabletop.

And we were able to share information and validate that standard operating procedure that we're drafting now. Eventually we'll share that with the three countries with the other two countries Canada and Mexico to make sure everything is coordinated. Next slide. Slide 12.

For the some of you that actually have the slide in front of you focuses on our poultry depopulation equipment we have in National Veterinary Stockpile. The top right photo shows you our CO2 carts. We have two types. The one on the right shows you a 22-inch wide opening for the larger birds and a little bit larger than the one that's on the left.

We also have, as you can see the bottom left photos for some of you that have it, is our North Carolina portable depopulation - foam depopulation unit that we have in our inventory. And one of the things I mentioned earlier, we do have this deployed throughout the U.S. and we're able to have contractors that are trained and actually - and be deployed with this equipment as you can see in this photo.

And then you see on the right is our Kifco foam unit, which is used for larger operation. But there's one advantage to that - to the North Carolina unit, the portable one, is that if you're talking natural disasters which occurred in Alabama which some of the units were utilized, you cannot use the Kifco unit. So the North Carolina portable unit was used because you had (collapsed) houses. So that's the benefit of having that North Carolina unit.

Next slide talks about something we recently procured this year is our large animal handling equipment. We've got mobile corals, head gates, (squeeze) suits, swine working suits, cattle panels, swine panels. And one of the things we're doing now is working with a manufacturer because our swine panels we saw an issue as far as response that most of them are on - they're palletized.

So from a response standpoint we want to make sure that when it's - when these items arrive is that it's not a burden to the state private territory. They have to now provide or find a forklift. And we were talking about setting some of this equipment up it could become a burden.

So we worked with the vendor now and they're developing a prototype trailer that can be used for our swine panels. But all of our animal handling equipment is mobile. It's on wheels. So actually improving our large animal handling equipment by making sure that our swine panels are also too mobile.

And if you look at the slide, I mentioned indefinite delivery, indefinite quantity, that means that we have four contractors that are on contract that actually provide surge quantities if we don't have - if we actually have an larger outbreak than what is anticipated and what we don't have in our stockpile. They can actually ramp up and start providing additional large animal handling equipment in the time when it's needed.

And one thing unique about our mobile coral is (you) pretty much can deploy that system with two people. It has hydraulics. The wheels come off. And you can see the bottom it can expand to whatever configuration you need.

Next slide focuses on a vaccine ancillary supplies module. Something we originally started working with. We had a team including Dr. Larry Elsken

expertise and actually trying to look at the different needles that would be required.

And we, you know, looking at the cost. So needles are very expensive so we wanted to make sure we get a cross section of all the species making sure we had all the available needles available. And therefore we established vaccine (series) supply module, which would be - if there was an outbreak and there was approval to vaccinate.

As you can look on the left, it gives you an idea - a picture at (triwall), which is the equipment used to actually delivery our supplies and shows your dropdown flap and there's been a lot of lessons learned and we've learned over the past exercise that has improved our push packs and one of the devices in (triwall) where you can see all the supplies are packed and everything is labeled.

We've got a diagram so that the people in the warehouse are able to actually identify what is in our push pack. And it's critical when you are actually deployed and you for the first time (survey) has a person in the warehouse. And one of the things we realized that's been a (unintelligible) because a lot of states don't have these people available.

And so we actually go out and we assist them with training and identifying some of the functions and other areas that's needed. But this picture is focused on our (unintelligible) supplies. We do have a contract for additional self-(filling) syringes and other items that we do have in this module to include all weather paint sticks, sharps containers and as I said earlier, various needles.

And the two photos on the right identify the FMD paint vaccination ear tags which there large and small cattle and swine tags and appliers underneath the

(offices) of the North American Foot and Mouth Disease Bank in which we store in one of our locations and will be deployed if bank was activated. Next slide.

This slide demonstrates some of what we've been doing over the past year as far as looking at our cold chain management process. And that's one of the things we test during our exercise is, you know, you have the vaccine, what does it require to make sure that vaccine arrives at the correct temperature? Typically it's two to eight degrees.

And when I first came onboard as the log chief prior to becoming the Director, we had an exercise and we utilized a refrigerated truck and most of you realize that that refrigerated truck can cost a lot of money when you're talking about multiple outbreaks and large amounts of vaccine.

So this device here is a passive, which I mean it does not - it only requires that you freeze or refrigerate some of the blocks but you don't need any electricity. And one of the things unique about these systems is they can maintain that vaccine and transportation up to two to eight degrees for five days.

So if there's a delay at the airport and a lot of our vaccine is manufactured overseas so we can't really, you know, what - or Murphy's Law that could occur. So once this vaccine is packaged in these containers, they will arrive at two to eight degrees.

And the photo on the right actually identifies two devices that will require the manufacturer to place inside the vaccine. One is something that the NVS will utilize to actually crack that vaccine temperature when it arrives is a (hobo) device. And the other device is for the state, which is a simple device,

electronic device or it could be a passive device where they can actually determine what the temperature of that vaccine when it arrives.

And at the bottom actually shows a larger system, a GTS5420, which is a pallet shipment, which typically most of our vaccines will arrive in that larger device. And we'll work around manufacturers - this is one of our manufacturers in the U.K. that actually is showing - demonstrate how they package some their cards of the vaccine.

And typically a lot of these containers will maintain that temperature longer than what the manufacturer states of five days. And we actually validate one and we put it in different temperature settings and it would actually maintain that two to eight degrees, so.

Next slide I'll focus in on our other capability, emergency transportation contract. We do have a contract that covers 24 hours a day, 365 days a year. We've activated each year that I've been onboard her at APHIS. And recently we utilized the contract to fly a sample to Ames, Iowa. So this kind of cuts down on - it's reliable service cuts down on the diagnostics time for actually getting a diagnosis of a sample.

Slide 17, 3D commercial partners. They invest contracts with multiple all hazard response companies that can quickly provide larges numbers of trained personnel with equipment to support states that do not have enough of their own personnel. And we refer to them or term this as 3D contract based on the services that they can assist the states driving territories with depopulation, disposal and decontamination.

And one thing unique about these teams they're all hazard responders. They typically do this for a living. You know, they respond as far as meeting that

24-hour requirement. They're on call 24/7 days a week with their other business functions.

But one thing unique about these teams, they can staff up to 600 personnel in three days, 1000 within seven days or more if required. And most of the natural disasters and outbreaks or anything, they do maintain that because typically when things happen we kind of alert them and let them know what's going on and they pretty much know what's going on during - prior to us calling them.

And also they do, like I said, they do arrive within 24 hours. We currently have four of these all hazard response companies and we're looking at adding an additional one down in a Southern area of the country.

And one of the things NVS has done, you know, we talk about ESF and we actually assist, utilize these contractors as far as ESF 11 activity. And we also utilized them during the floods in Iowa where they were actually used to provide water when there was the floods in Iowa. So they're a very valuable asset and they are always very reliable.

Slide 18 gives you a - shows you a turkey depopulation, disposal demonstration in Virginia in 2009. And it shows our Kifco unit on the right and then it shows after affects of the foam unit that was used in this demonstration.

Slide 19 is a photo of one of our three contractors Clean Harbors using oil spill booms and posts to recover ground swine in June of 2008. So they can adapt to a lot of situations, utilize their equipment that they have for the typical daily functions and apply it to the agriculture.

And one of the things we also do is use agriculture experts to actually go to the sites and assist them with training and so forth. They're utilized with oil spills but then we kind of train them on how to handle cattle, poultry and other agricultural commodities.

Slide 20 focuses on outreach and exercise support. The NVS has a full time state federal liaison that some of you probably - most of you probably know him that interfaces with the federal state including the strategic national stockpile and other stakeholders, Dr. Lee Myers.

And if you have any questions or you can feel free to email Dr. Lee Myers and you can utilize our NVS generic email address. You can reach us any time. And the email address is [nvs@aphis.usda.gov](mailto:nvs@aphis.usda.gov). And she can tell in one of her main functions is continuous work with states, tribes and territories in the development of NVS state preparedness plans.

And typically she's the face to the states initially for the NVS. She goes out, she conducts seminars that focus on the whether or not states want to partner with NVS and conduct exercises or logistics training, which we provide. Next slide.

The next slide focuses on some of the - as I mentioned the exercise program. NVS has an annual exercise program where we partner with states. In April most of you probably saw in APHIS news to the states or a newsletter is that we recently conducted an exercise with the Navajo Nation in the Navajo capital of Window Rock, Arizona back in April.

Prior to that we conducted logistics training that focused on these actions state need to plan for such as request NVS countermeasure receive, store and manage inventories. And a lot of the states they realize how valuable it is to

understand not only these areas but also what is in our National Veterinary Stockpile push pack. So it gives them an idea of what's in the push pack so they know or are aware of some of the supplies we have.

And speaking of push pack, some of our suppliers were also folks working on a catalog that will provide all the inventory and items within the NVS inventory. We should have a draft copy by August 1 for some of you that are - what to know what our inventory is. And we'll be posting it on our Web site on the restricted site for state planners. So that's something I need to capture before I move on. Next slide.

This just gives you an idea on Slide 22 - an idea of some of our exercise history, some of the states we've partnered with, conducted exercises from July of 2006 with North Carolina. I talked about our April 2011 exercise with the Navajo National that was conducted in April.

And that even represented the first APHIS sponsored full-scale exercise on tribal lands. The Undersecretary was there, the Navajo Nation President was there and a lot of the local press was there. So it was a precedent exercise and it was very successful.

And 2012 will consist of another vaccine shipment tabletop exercise which will validate another one of our vaccine SOPs with one of our manufacturers and hopefully Canada and New Mexico can participate and lead into a full scale exercise with Colorado.

We've already start discussions with Colorado working on the NVS state preparedness plan and we'll have a workshop next month with Colorado just detailing all the activity for leading up to the full scale exercise in 2012.

Some of the challenges for the National Veterinary Stockpile; I focused on one earlier as far as a lot of our personal protective equipment such as our gloves have a two year shelf life. Some of our suits have manufacture only looks at them as having a shelf life of five years. We're recently awarded a contract with a third party logistics provider to assist us with the quality assurance and quality control of some of our items in our stockpile.

And actually it's been - it's good that he's able to actually reach out to some of our vendors and will assist us in rotating some of our inventory that we have. And we were successful last year with our (vercon).

We got a vendor that actually is - came out, looked at our (vercon) and started rotating some of the (vercon) we had in our warehouse, provided us a shelf life standard operating procedure and will assist us so that we never have to as long as the life of that contract have to procure (vercon) or the test strips which is - we see as successful on our part.

And then the other challenge is making sure that we have the trained staff that can respond and serve as a link between the state and APHIS in the event of an outbreak. So we want to make sure we have a trained corps of personnel. We focus on training.

We recently looked at our satellite phones. We went through internally is looking at making sure that all of our staff was trained on warehouse operations and assisting the states on how to perform inventory management if they don't have an automated system. We've got certain things that we can talk about as far as manual system that they could actually implement in the event that they don't have an automated system.

And one of the other things is vaccine. You know, we work towards the list - APHIS' list of 17 but, you know, vaccines become available, we will look at them. And I mentioned prior Rift Valley Fever has the potential that Pfizer as a company is working on a Rift Valley Fever vaccine. So and that's part of our Steering Committee's looking at vaccines in the pipeline so that we can incorporate them and increase our inventory stockpile on vaccines.

Dr. Don Hoenig: Mr. White.

Rodney White: Yes.

Dr. Don Hoenig: This is Don Hoenig. I just wanted to tell you that we're running a little short on time here as far as your presentation. Is it almost done?

Rodney White: Yes. I have two slides.

Dr. Don Hoenig: Okay. I wanted...

Rodney White: I have two slides.

Dr. Don Hoenig: Okay. I..

Rodney White: And the last slide pretty much is a summary slide that pretty much talks about everything but kind of summarizes what I've talked about from why the NVS is here with pretty much. We focus exclusively on logistics of disease response.

We manage or maintain large inventories so states have what they need to respond. And folks on Homeland Security Presidential 9 is 24-hour response time. And our second goal of helping states plan, train and exercise a rapid

delivery of counter measures so that responders have what they need and are trained on response.

And the last slide pretty much - if you have any questions or that we can't cover after this presentation, here's our generic. It shows our generic email address. You can email it and it'll reach one of our staff members. It's capital - it's [nvw@aphis.usda.gov](mailto:nvw@aphis.usda.gov). And we also have a Web site that we're working hard to update to provide updated information and useful tools for state planners.

And the number is - the emergency hot line number is actually showing 1-800-940-6524 and that's - and it's available if there's something that you need that's an emergency or critical. And that number you can call and reach anybody within the National Center for Animal Health Emergency Management.

And that's all I have. Any questions?

Dr. Don Hoenig: Thank you very much. Are there any questions on National Veterinary Stockpile?

Man: I have a question.

Rodney White: Go ahead.

Man: Rodney, this is a nice job and I believe emergency planners are comforted by knowing that the vendor - a stockpile is in place. In discussing this with some stakeholders, it was mentioned that it would be nice to have the catalog and inventory numbers and you mentioned that was in development. I think that's important.

What's related to that is how you would prioritize multiple simultaneous demands on the stockpile and that emergency planners be aware of that as well.

Rodney White: Could you - are you talking in reference to vaccines or are you talking about if there's multiple requests for the NVS equipment?

Man: Yes. Well both. Just if there was - if there was multiple challenges how you would prioritize who gets the supplies and the vaccine.

Rodney White: Well that wouldn't be my decision. That'd probably be a decision of the Deputy Administrator and talking with Dr. Jose Diaz who's the Associated Deputy Administrator. And they would pretty much have a conference.

And based on the details, the number of cattle or the risks involved, they would probably myself as the Director of the National Veterinary Stockpile and I'd inform them on what quantities we have available, what vaccines we have available and pretty much initiate our - I know the number - the question of quantities comes up and that's why we have a definitely delivery and definite quantity contracts.

And pretty much that will be discussed so that they can - so I would advise them on what we have available and they'd probably direct to me what would be the priority.

Man: Thank you.

Dr. Don Hoenig: Any other questions?

(Dr. Philip Spayer): Yes. This is (Phil Stare) with (Samson Farm). I had a question about the North Alabama tornado response. How did you all play out on that and how much could you all do centrally and how much as individual industry involved with.

Rodney White: Well just to clarify, we were contacted but we didn't activate or deploy any of our systems. There was a (Jim Howard) from North Carolina. He deployed a team and I was - and was informed that they used the North Carolina unit, which typically is similar to the units that we have. And I was just, you know, focusing that on the equipment utilized was not our Kifco or not the Kifco unit. And it was the North Carolina unit.

And I think the industry played a part in that also where they had Kifco units but they could not use them because some of the houses were collapsed and they relied on the North Carolina portable foam unit.

(Dr. Philip Spayer): Right. And I guess having gone through Katrina, you know, six years ago, there's nobody could help us that quick and so much disaster. It is a good thing for I think was brought up a spot problem but not a large area like North Alabama or when Mississippi got wiped out by Katrina. I just don't think we could stockpile enough stuff.

Rodney White: Right. And I - well, I think pretty much you're right. But as far as just responding to it, I'm pretty sure we can respond fast. But you're right, you know, based on the number and the disaster, you'd have to probably - it'd involved probably the National Veterinary Stockpile, state assets and also industry if they have them, so.

(Dr. Philip Spayer): And don't get me wrong, we very much like we being the poultry industry having a national reserve somewhere to keep all these materials on hand, you

brought it up, would be cost prohibitive for any one of us even large companies to maintain. So we do count on you all having that behind us.

Rodney White: And right, as far as - you know, that's why it's valuable or a benefit to have these surge contracts where, you know, you don't have to pay for all this but, you know, you want to make sure that you have the necessary items on hand to respond. But then like I said earlier, you know, you just don't know the massive, you know, amount of supplies needed and that's the value in these indefinite delivery, indefinite quantity contracts that we have.

Dr. Don Hoenig: Okay. Any other questions? Well thank you very much for that presentation. So do we have John Picanso or...

RJ Cabrera: Well Don, this is RJ. Given the time, you know, the hour, I'm wondering if we should go forward with another presentation or reserve...

Dr. Don Hoenig: Well I guess we were originally scheduled for 12:00 to 5:00 right?

Man: Right. I'd really like to hear from John if he's there.

John Picanso: Yes I'm here.

Dr. Don Hoenig: Yes. I'd say let's...

RJ Cabrera: Okay. Let's go. Let's go.

Dr. Don Hoenig: ...go for it.

John Picanso: I'll try to keep you on track. Hello everyone. I apologize. I was on. I don't think I made it into the speaker's room and by the time I got in Dr. Clifford's office, Rodney had already started. So my apologies.

Like to give you a quick summary of our modernization efforts around the generic disease database specific to surveillance and information collection around surveillance. I hope most of you or all of you got a two-page attachment that describes our efforts. Is that right? Maybe some of you got two pages.

RJ Cabrera: Yes. That was sent out to the committee John.

John Picanso: Okay. Great. Thanks RJ.

RJ Cabrera: It's also on the Web site for those of you that are listening in.

John Picanso: Great. So what I'd like to do is start with the project update slide. And if you don't have it, I'll try to be as descriptive as I can and keep out a lot of the technical jargon that sometimes I slip in. And of course at any time, please ask clarifying questions if you have one.

As some of you know, we started a contract of February 1 of 2011. It is to run until January 31 of 2012. It's a 12-month contractual project. It is utilizing the (Core 1) software. The makers is Trace First Limited. It is a non-U.S. company. They're headquartered in Northern Ireland. And we have since re-branded it internally within Veterinary Services as our Service Collaboration Services.

So if you see the acronym SCS within Veterinary Services documents, that's - that'll stand for Surveillance Collaboration Services and it describes the

fundamental of the (Core 1) software and things that we're doing around that project.

If you were familiar with the contract, it called for 30 installations - generic installations at our enterprise data center in Kansas City, Kansas and it also called for ten separate site installs if states chose to host this product themselves. And there was some hardware costs if a state did elect to - a site, if you will, if they elected to host this themselves.

There is no cost with this contract if you choose to use our enterprise data center. Along with our enterprise data center, it is considered a mission critical infrastructure for the USDA. Therefore Dr. Parr was kind enough to remind me last year when the federal shutdown was looming and with current budget talks the way they are it was not deemed a site that would be turned off during a federal shutdown.

So we get 24/7 support and service on all our hardware, all our patching, all our systems' work. And we've got personnel there around the clock. That contract is paid for by the USDA.

So to tell you about those 40 installations, we have completed all 30 installations in Kansas City and we have an additional installation included in that 30th. It is a federal repository of generic disease database that would be populated from a state installation.

We have completed three state migrations of generic disease database and those states are Virginia, Delaware and Maine. And I can tell you we are ahead of schedule to begin data migrations. But as some of you might know, when we get into some larger implementations, it will get slowed down as we get into having more volume of data.

But the good news is we're ahead of the schedule on all accounts against our project timeline that was written before February to be sure that we could meet all the needs of this contract.

We are currently if you look at the map - the colorized map, we've got all the states there. And this is a communications map. This isn't a marketing map. It is not an adoption map. What it is is it's helping us be aware of who has talked to what state and/or federal office, whether it was a VS person or a contractual personnel from Trace First.

And so you can see out of all the states there's a very high majority, I don't know, 90% plus where we've contacted the state. We've done some outreach. And they have viewed the production demo that we had made for this contract.

Then you also see some other color specifically green and orange and I'd like to talk about those. Collectively the green and orange states are states that have agreed to participate with us in this project. And as I already indicated, which is not updated on this map, we do have three states that we've completed the migration on.

We cannot turn any of these installations on until we complete our security work in - on the Federal Government side it's called a certification and accreditation. It's a several month project but that ensures both our cooperators and us that the software is safe, the systems are safe, the way data is delivered from system - the system is safe.

So even though it's burden and it's an expensive burden, it is something that we must do. It's federally mandated and for further protection for our

cooperators it ensures that we've got a good solid secure connection and we can protect the information that much more effectively for both sides.

So as of today we have about - I think it's 15 states that have agreed to adopt the SCS project with USDA. We've completed three. And one thing I'd like to highlight we are in negotiations with the Navajo Nation to perform a SCS installation in Kansas City on behalf of the Navajo Nation tribe, which is a big milestone. We - this will be the first piece of VS software that will reside within a tribal nation here in the U.S. So we thought that was very good.

Some other positive things about the project other than the software itself, we've been able to work with many, many IT offices around the country both federal and state. And when you're an IT delivery shop, it's very difficult to get the time and make it a priority to reach out and partner with other technology folks across the U.S.

And this was one of the requirements that I personally had with our CIO team here in Veterinary Services to reach out and really assist these folks whether it's a state installation or they're interested in coming to (Nitsi) to participate with the project. I think we've done a good job in that outreach.

You will see there's a few states that have hash marks and those are states that currently use USA Herds. There are more states that use USA Herds but these hash states they've agreed that they will continue to use USA Herds. And of course that's fine with us. We've been very clear that this project is not to displace any competing product that's out there.

And you might have heard me or others in various presentations across the U.S. indicate that our goal is to - for the performance period of this contract through January of 2012 is to adopt as many generic disease database

installations as we can. And then after that point we finish up to those 40 and we begin other market vendor solution integration projects.

And that won't really be done with the Trace First Company. That will be more my staff and your staff if you're a state shop with more technical discussions on moving USA Herds data into an installation of (Core 1) at the enterprise data center.

I'd like to also add that we are in technical discussions with all products out there around animal health management, USA Herds included and a couple other companies as well.

And we work with them on a weekly basis to ensure that if you're tracking some animal IDs with our portable devices, our MIM devices that - and some states have some disease management that they're undergoing right now. And they are collecting in some examples RFID on these devices.

That data does get sent to USA Herds and we're working with USA Herds in how to integrate that information into their product and then also how to get that information into a (Core 1) instance in Kansas City.

So we've got a few states that have agreed to host the software within their state. And as we get more milestones met with the agreements of adoption, we'll continue to put those out through emails, SharePoint site and industry and employ in NASAHO, National Association of State Animal Health Official calls.

And we've - one additional thing we've done some systems training for some VS personnel and we're going to offer according to the project plan about the 1st of October some end user training. And I know a few of you have had

personnel come out to Colorado. We did have a couple state people come out. And they got to see the product.

You may have heard that some people considered the functionality of the product a little short and we are working with the company to strengthen those shortages. But the goal is not to address 100% of everyone's requirement in every state because we've done that in the past and that takes a lot of money and a lot of time and to date we've not been that successful kind of with that flexibility.

And as we all know with reduced budgets, reduced staffs, we have to go to market much more quickly, much more cost effectively and we think we're doing it with this project. And it's one in a portfolio of about three where we're going to continue to modernize and get some of our IT systems more highly integrated.

A goal of this system is to be able to talk with our EMRS and have this system work with (the known) labs, which the company has been involved with and you might have seen them. It's a recent regional USAHA meetings doing some presentations.

And so one of the cornerstones of the project that once we get our security work done, we will make active all of these installations rather if they're in a state or they're one of the 30 installations in our enterprise data center and begin to use it for animal health management information and leverage the software as hard as we can.

It will be kind of standardized, if you will. And I know that was one of the things that we worked hard since I got introduced back into Veterinary

Services as the CIO. People really wanted to see more done around data standards.

We are working with other companies to do more standardization around the information that's collected. So when we do more integration in the out years we'll be able to be more effective with moving that data more quickly, more efficiently and ultimately responding to state and local and national reporting needs that folks will have.

So I guess I'd make it a quick presentation. I think I've touched on kind of a real current status of where we're at, where we've been, where we're going and I'd gladly open it for questions Dr. Hoenig.

Dr. Don Hoenig: Thanks a lot John. Any questions for John?

Dr. Boyd Parr: John, are you going to have - what are the - you know, as we look at putting state data in there and what we share, what are the FOIA and confidentiality, you know, private information on this part or are there any?

John Picanso: Well, what we would like to develop Dr. Parr is a - some kind of agreement with this project where you can see what's required around the security collection especially if they're state hosted installations because of course receiving information from like a non-audited IT shop as we all know could be risky but we've got some trust with our partners today.

So what we're trying to do is develop an MOU fairly generic that will get to those points. Thus far it has not been (foiable) any of our information systems to date. And we're working hard to try to keep it that way.

Dr. Boyd Parr: Thanks.

Dr. Don Hoenig: Other questions for John?

((Crosstalk))

Dr. Don Hoenig: Hello. Did somebody say...

Man: (Unintelligible).

Dr. Don Hoenig: Go ahead. Did somebody have a question?

Man: No.

John Picanso: Sorry. That was me making a comment that we didn't really get any questions.

Dr. Don Hoenig: Oh, okay. All right. Well, I think we've reached the end of our agenda here. I thank you John for hanging in there with us.

John Picanso: You're quite welcome. Thank you all.

Dr. Don Hoenig: And - yes. I guess before we sign off here I just need to touch on something that may have been covered when I couldn't get on as far as the in person meeting. RJ was - somebody had made the suggestion on email that we send out a doodle poll or something like that with respect to the date for the meeting. Is that going to be done or how did you decide to work that or hasn't that been discussed?

RJ Cabrera: That's pretty much where we ended up. We started talking about different dates and probably do about three weeks span somewhere in October and early November.

Dr. Don Hoenig: Okay.

RJ Cabrera: Send out a survey to do it.

Dr. Don Hoenig: All right. Well that would be great. And I think what I'd really like to focus on between now and the next meeting is some of the proposals for recommendations that we talked about. And I'll be relying on a couple people to try to draft some of those up. People who I think - people who brought up some of the topics.

And perhaps I'll - (Judith) and I can put out an email just maybe drafting just some of the bullet points that we talk about for recommendations and maybe even drafting something.

But I think the committee really needs to think about some action items. And we also would ask - I would ask that if the Secretary has any further issues that he would like the committee to weigh in on that, you know, that he pass those along to us. I certainly think we have some work to do here.

And I know the conference calls are long and hard - kind of hard to conduct business on. So at least I find them that way. But I think it's good that we have them.

And with respect to the agenda for September, we'll be putting out some requests for those and - as well as some action items based on what we did today.

So is there anything else that we need to discuss? All right. Well anything you (Michael) or RJ or (Jan), you feel that we - you'd like to say.

RJ Cabrera: I think we're good Don. I would say to the committee to stay tuned for some follow up emails on what we've discussed and probably you, (Judith), (Michael) and I will get together on a call or two...

Dr. Don Hoenig: Yes. Good.

RJ Cabrera: ...over the next few weeks. Okay.

Dr. Don Hoenig: Okay. So thank you for everyone who hung in there. And have a good weekend and stay cool.

Man: Okay. You too.

Woman: Thank you.

Dr. Don Hoenig: All right. So long.

Man: Thank you.

Dr. Don Hoenig: Thanks.

Woman: Bye bye.

END